

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
June 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 June 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-\_\_\_\_\_



Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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**Teva's AZILECT<sup>®</sup> 1 mg Tablets Meet End Points in ADAGIO Phase III Trial**

**AZILECT<sup>®</sup> Market Potential Dramatically Increases, as the Drug Could Become the First Disease Modifying Treatment for Parkinson's Disease**

**Jerusalem, Israel, June 16, 2008** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today the successful completion of ADAGIO, the phase III study designed to demonstrate that AZILECT<sup>®</sup> 1 mg tablets can slow down the progression of Parkinson's disease. In the trial, the currently marketed AZILECT<sup>®</sup> 1 mg tablets met all three primary end points, as well as the secondary and additional end points, all with statistical significance. The study also confirmed the safety and tolerability of AZILECT<sup>®</sup>.

Teva intends to submit these results to the regulatory authorities in the U.S. and Europe. Based on these results, AZILECT<sup>®</sup> could become the first Parkinson's disease treatment to receive a label for disease modification.

**Teva's Chief R&D Officer, Dr. Ben-Zion Weiner**, stated: "This scientific breakthrough addresses one of the most critical unmet needs in the treatment of patients with Parkinson's disease."

**Shlomo Yanai, President and Chief Executive Officer of Teva**, added, "This achievement demonstrates the strength of Teva's innovative R&D capabilities and highlights our continued commitment to the development of treatments for the more challenging areas of neurological diseases. These positive results could dramatically increase the market potential for AZILECT<sup>®</sup>, allowing AZILECT<sup>®</sup> to join COPAXONE<sup>®</sup> as another major Teva drug for neurological disorders."

The study protocol was based on the recommendations and guidance of the U.S. Food and Drug Administration. The 18-month study, the first of its kind, is one of the largest conducted in Parkinson's disease, involving 1,176 patients with early Parkinson's disease in 14 countries and 129 medical centers.

In addition, the 2 mg dose in the study met two of the three primary end points as well as the secondary end point. The 2 mg dose was also found to be safe and well tolerated.

More detailed data analysis will take place over the coming weeks and will be presented to the medical community at a later date.

### **About the Study**

ADAGIO is a randomized, multi-center, double-blind, placebo-controlled, parallel-group study prospectively examining rasagiline's potential disease-modifying effects in 1,176 patients with early, untreated Parkinson's disease. Patients from 129 centers in 14 countries were randomized to early-start treatment (72 weeks rasagiline 1 or 2 mg once daily) or delayed-start treatment (36 weeks placebo followed by 36 weeks rasagiline 1 or 2 mg once daily [active treatment phase]). The primary analyses of the trial were based on change in total UPDRS (Unified Parkinson's Disease Rating Scale) and included slope superiority of rasagiline over placebo in the placebo-controlled phase, change from baseline to week 72, and non-inferiority of early-start vs. delayed-start slopes during weeks 48-72 of the active phase. UPDRS is the most commonly used rating scale to assess disease status.

### **About AZILECT<sup>®</sup>**

AZILECT<sup>®</sup> 1 mg tablets (rasagiline tablets) are indicated for the treatment of the signs and symptoms of Parkinson's disease both as initial therapy alone and to be added to levodopa later in the disease. AZILECT<sup>®</sup> 1 mg tablets are currently available in 30 countries, including the US, Canada, Israel, Mexico, and most of the EU countries.

### **About Parkinson's Disease**

Parkinson's disease is an age-related degenerative disorder of the brain. Symptoms can include: tremor, stiffness, slowness of movement, and impaired balance. An estimated four million people worldwide suffer from the disease, which usually affects people over the age of 60.

### **About Teva**

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the world's 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 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. 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, including statements relating to the results of the ADAGIO phase III trial and the potential efficacy or future market or marketability of AZILECT<sup>®</sup>. Following further analysis, Teva's interpretation of the results could differ materially depending on a number of factors, and we caution investors not to place undue reliance on the forward-looking statements contained in this press release as there can be no guarantee that the results from the phase III trial discussed in this press release will be confirmed upon full analysis of the results of the trial and additional information relating to the safety, efficacy or tolerability of AZILECT<sup>®</sup> may be discovered upon further analysis of data from the phase III trial. Even if the results described in this release are confirmed upon full analysis of the ADAGIO study, we cannot guarantee that AZILECT<sup>®</sup> will be approved for marketing in a timely manner, if at all, by regulatory authorities in the EU or in the U.S. Additional risks relating to Teva and its business 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 or revise any forward-looking statement, whether as a result of new information, future events or otherwise.



Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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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/ Dan Suesskind

Name: Dan Suesskind  
Title: Chief Financial Officer

Date: June 16, 2008



