

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
February 09, 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 February 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):           

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):

Website: [www.tevapharm.com](http://www.tevapharm.com)

**TEVA ANNOUNCES RESULTS FROM A PHASE III STUDY FOR QNAZE(TM) NASAL AEROSOL IN PERENNIAL ALLERGIC RHINITIS**

***-- Results Support the Safety and Efficacy Profile for QNAZE(TM) and Teva's Current and Future Respiratory Growth Strategy -***

**Jerusalem, Israel, February 9, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced results from a Phase III study of QNAZE(TM) (beclomethasone dipropionate [BDP]) HFA, its nasal aerosol corticosteroid in development for the treatment of perennial allergic rhinitis (PAR) and seasonal allergic rhinitis (SAR). Results of the study evaluating patients with PAR showed the once-daily, non-aqueous formulation achieved all primary and secondary efficacy endpoints, demonstrating significantly greater relief of nasal symptoms, including runny nose, nasal congestion, nasal itching and sneezing, compared with placebo. Consistent with previous studies, the product demonstrated safety similar to placebo.

Teva recently reported successful results from a Phase III SAR study of its intranasal corticosteroid (INS), QNAZE(TM) (320 mcg/day), at the American College of Allergy, Asthma and Immunology (ACAAI) Annual Meeting in 2010. In this study, Teva's INS demonstrated significant improvements in nasal symptoms compared with placebo. Additionally, Teva is evaluating the long-term safety and effect of its INS on the hypothalamic pituitary-adrenal (HPA) axis in studies that are currently underway. The successful study results serve to further support the long-term respiratory strategy that Teva unveiled in a November 2010 analyst review, by including entry into the allergic rhinitis space.

**Study Design and Results**

This Phase III, randomized, double-blind, placebo-controlled, parallel-group clinical study assessed the efficacy and safety of Teva's INS in the treatment of PAR in subjects 12 years of age and older. At 35 U.S. investigational sites, 470 PAR patients were randomized to receive QNAZE(TM) (320 mcg, once-daily) or placebo as a nasal aerosol over a six-week period.

For the primary endpoint, the results showed a significant ( $p < 0.001$ ) change from baseline in the average morning and evening subject-reported reflective Total Nasal Symptom Score (rTNSS), a standard instrument for measuring nasal allergy symptoms. Similarly, the change in instantaneous TNSS (iTNSS), a secondary endpoint, was significantly greater versus placebo. Additionally, for both of these measures, all four individual nasal symptom scores of runny nose, nasal congestion, nasal itching and sneezing demonstrated significant improvement versus placebo.

Teva's INS was also well tolerated and the safety profile was similar to that of placebo. The most common treatment-emergent adverse events were nasal discomfort and nosebleed that were similar with both treatments.

"We are excited by the promising results we've seen to date for QNAZE(TM) in the treatment of both seasonal and perennial allergic rhinitis," said Prof. Yitzhak Peterburg, Teva's Group Vice President, Global Branded Products. "As Teva continues to expand its presence in the respiratory category, we remain committed to addressing the unmet needs among the 60 million patients in the U.S. who suffer with allergic rhinitis."

Currently, the only intranasal corticosteroids available for the treatment of PAR and SAR are products with an aqueous or "wet" spray. Aerosol spray formulations became unavailable in the U.S. following the U.S. Food and Drug Administration's (FDA) decision to phase out all metered dose inhalers (MDIs) that used ozone-depleting chlorofluorocarbon (CFC) propellants. Teva's INS is delivered as a non-aqueous aerosol formulation propelled by hydrofluoroalkane (HFA), which is environmentally friendly.

"We are encouraged by the positive efficacy and safety results from the Phase III perennial allergic rhinitis trial," said Tushar Shah, MD, Senior Vice President, Teva Global Respiratory Research and Development. "The aerosol delivery system offered by QNAZE<sup>TM</sup> may meet the needs of physicians and patients who are looking for an alternative treatment to currently available wet sprays."

## **About Allergic Rhinitis**

Allergic rhinitis (AR) is a chronic inflammatory disease characterized by symptoms such as sneezing, nasal itch, rhinorrhea, and nasal congestion. For many AR patients, nasal congestion or a stuffy nose may be the most frequent and bothersome symptom. According to a recent survey, patients suffer considerable discomfort during allergy attacks, such that nearly two out of five (38%) said their discomfort was not tolerable without relief. Based on the available evidence, intranasal corticosteroids are the most effective treatment options for patients with AR. Morbidity associated with AR can be significant. Effective treatment of AR may improve asthma control when both diseases coexist.

In the U.S., the prevalence of AR has increased during the past three decades; it is recently estimated at 20% in the general adult population and closer to 40% in children. Of the estimated 60 million Americans affected with AR, approximately 20% have SAR, 40% have PAR, and 40% have a combination of the two (i.e., PAR with seasonal exacerbation) depending on the allergen sensitivity. Because of its prevalence and health effect, AR is associated with

considerable direct and indirect costs. An estimate of \$11.2 billion in healthcare costs, 12 million physician office visits, 2 million days of school absences and 3.5 million lost work days per year are attributed to AR. In addition, the presence of co-morbidities such as asthma and sinusitis further increase AR-related treatment costs.

## **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 1,250 molecules and a direct presence in over 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health therapeutic areas as well as biologics. Teva's leading innovative product, Copaxone® is the number one prescribed treatment for multiple sclerosis. Teva employs approximately 40,000 people around the world and reached \$16.1 billion in net sales in 2010.

## **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®, Lotrel®, Protonix® and Gemzar®, 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 ratiopharm), 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 this report and in our other filings with the U.S. Securities and Exchange Commission.

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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 9, 2011

