TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
November 15, 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 November 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): _____

Website: **www.tevapharm.com**

TEVA HIGHLIGHTS QNAZE(TM) HFA PHASE III DATA AT THE 2010 ANNUAL MEETING OF THE AMERICAN COLLEGE OF ALLERGY, ASTHMA & IMMUNOLOGY

-- Results Demonstrate Teva`s Investigational Nasal Aerosol is Efficacious and Safe Among Patients with Seasonal Allergic Rhinitis -

Jerusalem, Israel, November 15, 2010 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced results from a Phase III study of QNAZE(TM) (beclomethasone dipropionate [BDP]) HFA, a nasal aerosol corticosteroid in development for the treatment of seasonal allergic rhinitis (SAR), that demonstrated significantly greater symptom relief compared with placebo. The results, presented at the 2010 Annual Meeting of the American College of Allergy, Asthma & Immunology (ACAAI) in Phoenix, Ariz., showed that the non-aqueous formulation met all primary and secondary efficacy endpoints, and that the product demonstrated safety similar to placebo.

In addition to the Phase III SAR trial, Teva is also evaluating the safety and efficacy of QNAZE(TM) in the treatment of perennial allergic rhinitis (PAR). The PAR studies are still underway at the time of this release.

"The results of this pivotal clinical trial suggest that QNAZE(TM) HFA may be efficacious and safe for individuals seeking relief from the nasal symptoms associated with their seasonal allergies," said Jay van Bavel, M.D., Allergy and Asthma Associates, Austin, Texas, and lead investigator for the study.

Intranasal corticosteroids are often used as first-line therapy for the treatment of allergic rhinitis. Currently, the only intranasal steroids (INS) available 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. QNAZE(TM) is delivered in an aerosol formulation propelled by hydrofluoroalkane (HFA). This formulation is "dry" and the propellant is environmentally friendly.

"We embarked on the QNAZE(TM) development program because we know there remain unmet needs amongst the 60 million Americans who suffer with allergic rhinitis that could be addressed by an aerosolized delivery of an intranasal steroid," said Prof. Yitzhak Peterburg, Teva`s Group Vice President, Global Branded Products.

About The Phase III Study

This Phase III, randomized, double-blind, placebo-controlled, parallel-group study assessed the efficacy and safety of QNAZE(TM) HFA in the treatment of SAR in subjects 12 years of age and older. At four U.S. investigational sites, 340 SAR patients were randomized to receive 320 mcg daily of QNAZE(TM) HFA or placebo as a nasal aerosol over a two-week period during the Mountain Cedar pollen season.

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. The symptom improvements were evident by day two and were maintained throughout the treatment period. 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 sneezing, runny nose, nasal itching and nasal congestion demonstrated significant improvement with QNAZE(TM) HFA versus placebo.

QNAZE(TM) HFA was also well tolerated and the safety profile was similar to that of placebo. The most common treatment-emergent adverse event was nasal discomfort that was similarly reported for both QNAZE(TM) HFA (n=11) and placebo (n=10).

Additional Data Presented At ACAAI

Additional results from a Phase I study that evaluated the pharmacokinetics, safety and tolerability of QNAZE(TM) HFA, showed that the systemic exposure following administration of the treatment (up to 320 mcg/day) was approximately 27 percent of orally inhaled BDP HFA, which is marketed by Teva as the asthma treatment QVAR&reg (beclomethasone dipropionate HFA) Inhalation Aerosol. All doses of QNAZE(TM) and QVAR&reg were well tolerated and no treatment-related adverse events were reported. Based on these results, the established QVAR&reg safety data may provide further supportive evidence for the development of this non-aqueous nasal formulation for the treatment of allergic rhinitis.

About Allergic Rhinitis

Allergic rhinitis (AR) is a chronic inflammatory disease characterized by sneezing, nasal itch, rhinorrhea, and nasal congestion as symptoms, in addition to allergic conjunctivitis in many subjects. For many AR patients, a stuffy nose may be the most irritating symptom; however, a recent survey reported almost half (46%) of parents of children with allergic rhinitis reported severe symptoms such as headache and ear and facial pain. 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 QVAR&reg

QVAR&reg is indicated in the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age or older. QVAR&reg is also indicated for asthma patients who require systemic corticosteroid administration, where adding QVAR&reg may reduce or eliminate the need for systemic corticosteroids.

Important Safety Information

QVAR&reg is not a bronchodilator and is not indicated for relief of acute bronchospasm. Common side effects associated with the use of QVAR&reg and placebo in clinical trials include, but are not limited to, headache (12% and 9%, respectively) and pharyngitis (8% and 4%, respectively). **Caution: Adrenal insufficiency may occur when transferring patients from systemic steroids (see WARNINGS, Prescribing Information)**. A reduction in growth velocity in growing children and teenagers may occur as a result of inadequate control of chronic diseases such as asthma or from use of corticosteroids for treatment.

For full prescribing information, please click here:

http://www.qvar.com/Document/PrescribingInformation.pdf.

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&reg, is the number one prescribed treatment for multiple sclerosis. Teva employs more than 40,000 people around the world and reached $13.9 billion in net sales in 2009.

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 Yaz&reg, 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&reg (including potential generic and oral competition for Copaxone&reg), 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 ("SEC")

Teva Pharmaceutical Industries Ltd. Web Site: 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 November 15, 2010