

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
August 08, 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 August 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):

**TEVA RECEIVES FDA ACCEPTANCE OF ITS NEW DRUG APPLICATION FOR  
BDP NASAL HFA FOR THE TREATMENT OF ALLERGIC RHINITIS**

*-- Novel Nasal Aerosol Corticosteroid Could Be the First Non-aqueous "Dry" Spray Available to Treat Seasonal and Perennial Allergic Rhinitis --*

**Jerusalem, August 8, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing Teva's New Drug Application (NDA) for beclomethasone dipropionate hydrofluoroalkane (BDP Nasal HFA), a nasal aerosol corticosteroid in development for the treatment of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR). Teva's NDA was submitted to the FDA on May 24, 2011.

The submission is based on a comprehensive clinical development program including results from two Phase III clinical trials assessing the safety and efficacy of BDP Nasal HFA in the treatment of SAR and PAR. In both trials, BDP Nasal HFA demonstrated significant improvement in nasal symptom scores of sneezing, runny nose, nasal itching and nasal congestion versus placebo. BDP Nasal HFA was generally well tolerated and the safety profile was similar to that of placebo.

"BDP Nasal HFA has demonstrated promising results in the treatment of both SAR and PAR, and we remain committed to addressing unmet needs and dissatisfaction with currently available treatments among the 60 million patients in the U.S. who suffer from allergic rhinitis," said Professor Yitzhak Peterburg, Teva's Group Vice President, Global Branded Products.

Currently, the only intranasal corticosteroids available for the treatment of SAR and PAR are products with an aqueous or "wet" spray. In contrast, BDP Nasal HFA is delivered as a pressurized, non-aqueous aerosol solution, or "dry" spray, propelled by HFA, which is environmentally friendly. Recent survey results have found that some nasal allergy patients who used an intranasal corticosteroid spray in the last year reported dripping in the throat as a

moderately or extremely bothersome side effect. Patients reported being less satisfied with current nasal sprays when they experienced discomfort from the spray or when they felt the medication drip down the back of their throats. Healthcare providers and specialists also reported patient dissatisfaction with current nasal sprays due to the bothersome side effects associated with these treatments.

"We are encouraged by the positive safety and efficacy results from both the Phase III trials evaluating BDP Nasal HFA in seasonal and perennial allergic rhinitis," said Eli O. Meltzer, M.D., Allergy & Asthma Medical Group & Research Center, San Diego, CA. "The new nasal aerosol delivery system which propels an odorless, non-aqueous spray also offers a built-in dose counter."

### **Seasonal Allergic Rhinitis (SAR) Study Design and Results**

The Phase III, randomized, double-blind, placebo-controlled, parallel-group study assessed the efficacy and safety of BDP Nasal 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 once-daily of BDP Nasal 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 BDP Nasal HFA versus placebo.

BDP Nasal HFA was also generally 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 BDP Nasal HFA (6.6%) and placebo (5.8%).

### **Perennial Allergic Rhinitis (PAR) Study Design and Results**

The Phase III, randomized, double-blind, placebo-controlled, parallel-group clinical study assessed the efficacy and safety of BDP Nasal HFA 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 BDP Nasal HFA (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). 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.

BDP Nasal HFA was also generally well tolerated and the safety profile was similar to that of placebo. The most common treatment-emergent adverse events were nasal discomfort (5.5% for BDP Nasal HFA vs. 4.2% for placebo) and nosebleed (3.8% for BDP Nasal HFA vs. 6.7% for placebo) that were similar with both treatments.

### **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 BDP Nasal HFA**

BDP Nasal HFA is an investigational intranasal corticosteroid in development for the treatment of allergic rhinitis. The product utilizes the same chemical formulation as QVAR<sup>®</sup> (beclomethasone dipropionate HFA) Inhalation Aerosol, an inhaled corticosteroid (ICS) approved by the U.S. Food and Drug Administration (FDA) for the maintenance treatment of asthma. BDP Nasal HFA is administered as a non-aqueous solution or "dry spray" delivered by hydrofluoroalkane (HFA), an environmentally friendly propellant.

### **About QVAR<sup>®</sup>**

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

## Important Safety Information

QVAR<sup>®</sup> is not a bronchodilator and is not indicated for relief of acute bronchospasm. Common side effects associated with the use of QVAR<sup>®</sup> 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 1,300 molecules and a direct presence in 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs approximately 42,000 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 version of Protonix<sup>®</sup>, 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<sup>®</sup> (including potential generic and oral competition for Copaxone<sup>®</sup>), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of Cephalon), 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: August 8, 2011



