TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
November 02, 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 October 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 Presents New Data on QNASL™ at the 2011 American College of Allergy, Asthma and Immunology Annual Meeting

-- Late-Stage Data Highlights Patient Satisfaction and Reinforces the Safety and Efficacy Profile of QNASL™ --

JERUSALEM--(BUSINESS WIRE)--October 31, 2011--Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced that data from four late-stage studies examining QNASL™ (beclomethasone dipropionate [BDP]) HFA, a nasal aerosol corticosteroid in development for the treatment of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) symptoms, will be presented at the 2011 Annual Meeting of the American College of Allergy, Asthma and Immunology (ACAAI) in Boston, Mass., November 3-8, 2011. Findings from one Phase III clinical study being presented demonstrate the degree of patient satisfaction with QNASL™, while the others support the safety and efficacy profile for the product.

On August 5, 2011, the United States (U.S.) Food and Drug Administration (FDA) accepted for review, the New Drug Application (NDA) filing for QNASL™. The submission was based on a comprehensive clinical development program including results from two Phase III clinical trials designed to evaluate the safety and efficacy of QNASL™ for the treatment of SAR and PAR symptoms. In both trials, QNASL™ demonstrated significant improvement in nasal symptom scores of sneezing, runny nose, nasal itching and nasal congestion versus placebo.

“We are pleased to have data accepted for presentation at the ACAAI Annual Meeting that highlight the favorable attributes associated with QNASL,” said Tushar Shah, MD, Senior Vice President, Teva Global Respiratory Research and Development. “These data provide insight into the level of patient satisfaction and ease of use of the device, which are important for patient acceptance and may impact adherence, and reinforce the safety and efficacy profile for QNASL demonstrating the product’s potential to provide relief for both nasal and ocular symptoms. We remain committed to the clinical development program for QNASL with the goal of addressing unmet needs amongst the 60 million people suffering from allergic rhinitis in the U.S.”

The following QNASL™ data will be presented:

Abstract Title & Poster Number

- **P361:** Patient Satisfaction and Ease-of-Use of BDP HFA Nasal Aerosol Device in Subjects With Perennial Allergic Rhinitis
- **P357:** BDP HFA Nasal Aerosol 320 µg Once Daily Effectively Improves Ocular Symptoms Associated With Seasonal Allergic Rhinitis
- **P358:** BDP HFA Nasal Aerosol 320 µg Once Daily Is Not Associated With HPA-Axis Suppression in Subjects With Perennial Allergic Rhinitis
- **P359:** BDP HFA Nasal Aerosol 320 µg Once Daily Is Safe and Effective in the Treatment of Nasal Symptoms Associated With Perennial Allergic Rhinitis
- **P362:** Long-Term Treatment With BDP HFA Nasal Aerosol 320 µg Once Daily Is Safe and Effective in Subjects With Perennial Allergic Rhinitis

“Despite currently available treatment options for allergic rhinitis, patients continue to be physically and emotionally affected by symptoms and are burdened by the side effects associated with aqueous, ‘wet’ sprays,” said Russell A. Settipane, MD, FACAAI, FAAAAI, FACCP, Allergy and Asthma Center and Asthma Nasal Disease & Allergy Research Center of New England, Providence, R.I. “We are encouraged by the data being presented by Teva at the ACAAI Annual Meeting this year and are looking forward to having a new option available to address the current dissatisfaction patients are experiencing with the ‘wet’ sprays, such as medicine dripping down the throat.”

Currently, the only intranasal corticosteroids available for the treatment of SAR and PAR are products with an aqueous or “wet” spray. In contrast, QNASL ™is delivered as a pressurized, odorless, non-aqueous aerosol solution, or “dry” spray, which is environmentally friendly. The new nasal aerosol delivery system also offers a built-in dose counter.

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.

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 QNASL™

QNASL™ is an investigational intranasal corticosteroid in development for the treatment of allergic rhinitis symptoms. The product utilizes the same chemical formulation as QVAR® (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. QNASL is administered as a non-aqueous solution or “dry spray” delivered by hydrofluoroalkane (HFA), an environmentally friendly propellant.

About QVAR®

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

Important Safety Information

QVAR® is not a bronchodilator and is not indicated for relief of acute bronchospasm. Common side effects associated with the use of QVAR® 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 about 60 countries. Teva's branded businesses focus on CNS, oncology, pain, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs approximately 45,000 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®, 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 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 our Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission.

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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/ Eyal Desheh
Name: Eyal Desheh
Title: Chief Financial Officer

Date: October 31, 2011