TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
September 13, 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 September 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 o

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Website: www.tevapharm.com

TEVA AND ALCOBRA ANNOUNCE PHASE II TRIAL OF NOVEL, NON-STIMULANT MG01CI FOR ADHD MEETS PRIMARY ENDPOINT

-- Product Demonstrated Favorable Safety and Tolerability Profile --

Jerusalem, Israel, September 7, 2011 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Alcobra Ltd. announced today top-line results from a six week, randomized, placebo-controlled, Phase II multi-center study designed to assess the safety and efficacy of MG01CI in adults with attention deficit hyperactivity disorder (ADHD). Results showed MG01CI met the primary efficacy outcome, demonstrating a significant improvement on the Conners' Adult ADHD Rating Scale-Investigator Rated Total ADHD Symptoms Score (CAARS-INV) compared to placebo ($p<0.03$).

In the study, 56 percent of subjects treated with MG01CI experienced an improvement in their CAARS-INV score of at least 25 percent, compared to 36 percent of patients in the placebo group ($p<0.03$). Additionally, 44 percent of the subjects treated with MG01CI demonstrated an improvement of more than 40 percent in their CAARS-INV score versus only 25 percent in the placebo group ($p<0.04$). MG01CI was well tolerated, with no drug-related serious adverse events reported and no clinically or statistically significant differences in adverse event profiles between the MG01CI and placebo treatment arms. Nausea and initial insomnia were more frequently reported in the MG01CI arm, yet the rate of patient discontinuation due to adverse events was similar in both groups (1.7%). Importantly, no increase in blood pressure or appetite suppression was recorded in the treatment group.

"ADHD is the most commonly studied and diagnosed chronic psychiatric disorder in children and adults, affecting about 3 to 5 percent of the population," said Iris Manor M.D., director of the ADHD Unit, Geha Mental Health Center in Petach Tikva, Israel. "I am very encouraged by the results of this trial, which warrants further clinical development of MG01CI, a novel non-stimulant drug that may benefit many people with ADHD."

In the trial, MGO1CI also demonstrated significant improvement on secondary endpoints, including the Adult ADHD Quality of Life Scale (AAQoL) and the Test of Variables of Attention (T.O.V.A.®) scores.

"We are very pleased with the Phase II data announced today," said Dr. Aharon Schwartz, Head of Teva's Innovative Ventures. "Our collaboration with Alcobra on the development of MG01CI for ADHD complements Teva's focus on developing a portfolio of products within our core specialty area of expertise – neurological disorders."

"These results confirm previous clinical experience indicating MG01CI may have a quick onset of activity with few side effects, distinguishing it from other non-stimulant ADHD treatments," said Dr. Yaron Daniely, CEO of Alcobra. "Based on the positive results of this Phase II trial and the high unmet need for novel ADHD treatments, we intend to commence Phase III studies in adults in 2012 and later on in children."

Following the successful completion of the Phase I study of MG01CI in 2010, Teva took an equity position in Alcobra, in addition to the right to acquire the company in stages up to full ownership upon regulatory approval of MG01CI.

Additional Phase II study results for MG01CI in ADHD are planned to be presented at international scientific meetings later this year.

About the Phase II Study

One hundred and twenty subjects in two Israeli centers (Geha MHC and Rambam), enrolled into the randomized, double-blind, placebo-controlled, parallel-group study in adult subjects with ADHD. Eligible subjects were randomly assigned in a 1:1 ratio to one of two treatment groups, 1400 mg MG01CI and Placebo. Patients enrolled in the study displayed similar demographic and ADHD symptoms characteristics as previously published studies, and randomization yielded comparable subject groups. The study consisted of three periods: a screening period of up to two weeks, a six-week double-blind treatment period, and a two-week safety follow-up period. Subjects were evaluated at baseline, and again following one, two, four and six weeks using validated, standard evaluation tools such

as the CAARS-INV scale, the AAQoL scale, the Clinical Global Impression (CGI) scale, and the T.O.V.A.® test. Safety evaluations included adverse events and concomitant medication recording, routine laboratory assessments, vital signs, physical and neurological exams, the Columbia-Suicide Severity Rating Scale (C-SSRS) and 12-lead electrocardiogram (ECG) measures.

About MG01CI

MG01CI is an extended release formulation of Metadoxine (pyridoxol L-2-pyrrolidone-5-carboxylate). Immediate-release Metadoxine has been used in the treatment of acute alcohol intoxication and treatment of alcohol withdrawal syndrome for more than 30 years. MG01CI allows the prolonging of the exposure to Metadoxine and improves its clinical performance. MG01CI was investigated in three pilot studies conducted in healthy adult volunteers at the Hadassah Medical Center Liver Unit (Jerusalem, Israel), and in a Phase IIa study in ADHD subjects at the Geha Mental Health Center ADHD unit (Petach Tikva, Israel).

About Attention Deficit Hyperactivity Disorder (ADHD)

ADHD is one of the most common chronic, lifetime neurobehavioral disorders. Business Insights estimated that there were approximately 23.3 million adults and 21.6 million children and adolescents with ADHD in 2009 in the world's seven major pharmaceutical markets (United States, France, Germany, Italy, Spain, United Kingdom and Japan), with an approximate market size of $5 billion. Current medications approved to treat ADHD include stimulants (i.e., amphetamines and methylphenidates, such as Adderall®, Concerta® and Vyvanse®) which are schedule II drugs, and the non-stimulants atomoxetine and guanfacine (Strattera® and Intuniv®, respectively). In addition to the specific burdens associated with scheduled drugs, all these medications have a variety of side effects, including insomnia, increased heart rate, blood pressure and loss of appetite and behavioral changes such as irritability.

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 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.

About Alcobra

Alcobra Ltd., founded by Dr. Dalia Megiddo and Udi Gilboa, is a privately held pharmaceutical company operating out of Israel focused on the research, development and commercialization of novel products for the treatment and control of CNS disorders. Alcobra's lead drug candidate, MG01CI, an extended-release formulation of Metadoxine, is developed for ADHD and other cognitive disorders.

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.

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: September 13, 2011