

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
June 29, 2009

**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 June 2009

Commission File Number 0-16174



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**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): \_\_\_\_\_

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes \_\_\_\_\_

No   X  

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):  
82-\_\_\_\_\_



Contact:

Teva:

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Antares:

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**Teva and Antares Announce FDA Approval of Needle-Free Injector Product for Administration of Tev-Tropin<sup>®</sup> (Human Growth Hormone)**

**--New patient-friendly option to be made available for Tev-Tropin--**

**Jerusalem, Israel, and Ewing, NJ, June 29, 2009, Teva Pharmaceutical Industries Ltd.** (Nasdaq: TEVA) **and its partner, Antares Pharma, Inc.** (NYSE Amex: AIS) today announced the approval of a Supplemental New Drug Application (sNDA), which added "needle-free injection" to its Tev-Tropin<sup>®</sup> [somatotropin (rDNA) for injection] brand human growth hormone (hGH) drug label. Teva will market the Antares needle-free device as the Tev-Tropin Tjet Injector system.

"We are pleased to add this new technology to our growing portfolio through our successful partnership with Antares, and to offer patients a less invasive delivery system," stated Larry Downey, head of Teva's North America Brand Pharmaceuticals division. "This significant achievement demonstrates our ability to leverage our leadership in the pharmaceutical industry, and our ongoing commitment to utilize our global strengths in innovative activities."

"This is the first product approval stemming from our portfolio of product collaborations with Teva and is a very exciting milestone for the Company" said Paul K. Wotton, President and Chief Executive Officer of Antares Pharma. "Importantly it is another example of delivering on our strong focus and commitment to patients, together with our partners, to provide new ways to administer drugs. We look forward to the launch of this product by Teva."

Human growth hormone is a protein given by injection that is commonly used to treat children with growth hormone deficiency. Pediatric patients benefit both from the avoidance of using needles as well as the rapid injection speed associated with giving needle-free injections. According to industry estimates, the market for human growth hormone in the United States is approximately \$1 billion which is the largest market segment globally. Antares currently markets its needle-free injection system for use in the treatment of growth hormone deficient children through its partners in Europe, Japan and Asia.

### **About Tev-Tropin®**

TEV-TROPIN<sup>®</sup> is indicated only for the treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone (GH).

### **Important Safety Information for Tev-Tropin®**

TEV-TROPIN<sup>®</sup> stimulates linear growth in children lacking endogenous GH. Treatment of growth hormone-deficient (GHD) children with TEV-TROPIN<sup>®</sup> produces growth rate and IGF-1 levels similar to those seen after treatment with hGH of pituitary origin.

Unless patients with Prader-Willi Syndrome (PWS) also have a diagnosis of GHD, TEV-TROPIN<sup>®</sup> is not indicated for treatment of pediatric patients who have growth failure due to genetically confirmed PWS. Because of reported fatalities, patients with PWS who are severely obese, have severe respiratory impairment, respiratory infections, or sleep apnea should interrupt use of GH.

Patients should be observed for evidence of glucose intolerance, hypopituitarism, malignant transformation of skin lesions, hypothyroidism, slipped capital femoral epiphysis, and intracranial hypertension. Fundoscopic examination of patients is recommended at the initiation and periodically during the course of GH treatment. TEV-TROPIN<sup>®</sup> should not be initiated in patients with acute critical illness as a complication of open heart surgery, abdominal surgery, multiple accidental trauma, or those with acute respiratory failure. TEV-TROPIN<sup>®</sup> should not be used in patients with evidence of an active malignancy, progressive or recurrent underlying intracranial tumor, active proliferative or severe nonproliferative diabetic retinopathy, or closed epiphysis.

When somatropin is administered subcutaneously at the same site over a long period of time, tissue atrophy may result. This can be avoided by rotating the injection site.

Because somatropin increases growth rate, patients with a history of scoliosis who are treated with somatropin should be monitored for progression of scoliosis.

Somatropin may alter the clearance of drugs metabolized by the CP450 enzyme system and careful monitoring is advisable.

Benzyl alcohol associated with toxicity in newborns is contained in the diluent supplied with TEV-TROPIN<sup>®</sup>. Treatment of patients with coexisting ACTH deficiency should have glucocorticoid replacement dose adjusted to avoid inhibition of growth.

In studies of growth hormone-deficient children, headaches occurred infrequently. Injection-site reactions (eg, pain, bruise) occurred in 8 of the 164 treated patients.

## **About Teva**

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the world's leading generic pharmaceutical company. The Company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80 percent of Teva's sales are in North America and Europe.

## **About Antares Pharma ([www.antareshpharma.com](http://www.antareshpharma.com))**

Antares Pharma is a product development company committed to improving pharmaceuticals through its patented drug delivery systems. Antares has multiple development partnerships with leading pharmaceutical companies. The Company's products are designed to improve safety and efficacy profiles by minimizing dosing and reducing side effects while enabling improved patient compliance. Antares has three validated drug delivery systems: the ATD<sup>™</sup> Advanced Transdermal Gel Delivery system; subcutaneous injection technology platforms, including Vibex<sup>™</sup> disposable pressure-assisted auto injectors, Valeo<sup>™</sup>/Vision<sup>®</sup> reusable needle-free injectors, and disposable multi-use pen injectors; and Easy Tec<sup>™</sup> oral disintegrating tablets (ODT). Two of the systems have generated FDA-approved products. Antares Pharma has corporate headquarters in Ewing, New Jersey, with subsidiaries performing research, development, manufacturing and product commercialization activities in Minneapolis, Minnesota and Basel, Switzerland.



**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<sup>®</sup>, Lotrel<sup>®</sup> and Protonix<sup>®</sup>, the current economic conditions, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the effects of competition on our innovative products, especially Copaxone<sup>®</sup> sales, dependence on the effectiveness of our patents and other protections for innovative products, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, 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, the uncertainty surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, including the integration of Barr Pharmaceuticals, Inc., the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent litigation settlements and the intensified scrutiny by the U.S. government, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, 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").*

**Antares' Safe Harbor Statement under the U.S. Private Securities Litigation Reform Act of 1995:**

*This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements related to the launch of the T-Jet device and the related potential device sales and royalties, the Company's future financial performance, and other statements which are other than statements of historical facts. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "continue," and other similar terminology or the negative of these terms, but their absence does not mean that a particular statement is not forward-looking. Such forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those anticipated by the forward-looking statements. These risks and uncertainties include, among others: that the Company may experience difficulties or delays in the initiation, progress, or completion of its clinical trials, including the phase 3 trial of Anturol, whether caused by competition, adverse events, investigative site initiation rates, patient enrollment rates, regulatory issues, or other factors; that clinical trials may not demonstrate that Anturol is both safe and effective for the treatment of patients with overactive bladder syndrome; that the safety and/or efficacy results of the phase 3 trial of Anturol may not support an application for marketing approval in the United States or any other country; that an application for marketing approval may not be accepted for priority review or at all by the FDA or any other regulatory authority; and that the Company may lack the financial resources and access to capital to fund future clinical trials. Additional information*

*concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2008, and in the Company's other periodic reports and filings with the Securities and Exchange Commission. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. All forward-looking statements are based on information currently available to the Company on the date hereof, and the Company undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this press release, except as required by law.*

Please see enclosed full prescribing information.

Tev-Tropin<sup>®</sup> is a registered trademark of Teva Pharmaceuticals USA, Inc.

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Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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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 :June 29, 2009

