

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
October 21, 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 October 2009

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

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

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**TEVA COMMENTS ON POSITIVE RESULTS OF PHASE III TRIAL IN  
MEDIWOUND'S DEBRASE<sup>&reg</sup>**

*-- Study Enrollment Completed Following Positive Interim Analysis  
Demonstrating Efficacy of Debrase<sup>&reg</sup> in Treating Burns --*

*-- Filing for Marketing Authorization in Europe Expected in 2010 --*

**Jerusalem, Israel, October 20, 2009** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today that MediWound Ltd., a company in which Teva holds an 11% interest, reported positive results from a pre planned interim analysis of a phase III trial for Debrase<sup>&reg</sup>, an enzymatic debriding agent for burns.

MediWound reported that the phase III study with Debrase<sup>&reg</sup> for the treatment of burns met the two primary endpoints of the study - reduction in the percentage of wound surgically excised and reduction in the percentage of wound autografted - with statistical significance. Based on these results, and in accordance with the approved clinical study protocol and past communications with the European Medicines Agency (EMA), MediWound announced that the study is deemed to have reached its objectives and that MediWound is permitted to stop recruitment at this time. Following the completion of a full analysis of the study, MediWound expects to submit an application for marketing authorization in Europe during 2010.

"We are delighted with the successful results of MediWound. We look forward to bringing this new treatment option to markets around the world", said Dr. Aharon Schwartz, Vice President, Teva Innovative Ventures. "MediWound is a prime example of how we broaden our innovative pipeline through licensing of promising products. Teva Innovative Ventures currently has about 20 portfolio companies. Our objective is to seek partnerships globally with companies and academic institutions with molecules in all stages of development to develop new specialty medicines and treatments."

Debrase<sup>&reg</sup> is an innovative product developed for the enzymatic removal of burn-injured tissue (eschar). Debrase<sup>&reg</sup> may present an alternative to surgery and/or the lengthy non-surgical procedures which are commonly practiced today. The selective activity of Debrase<sup>&reg</sup>, which removes only the eschar without harming vital tissue, also minimizes the need for additional skin grafts, allowing for potential spontaneous healing of the burn wound. If approved, Debrase<sup>&reg</sup> may change the standard of care for burns, offering patients, doctors, hospitals and

payors a superior and more cost effective treatment option.

Debrase<sup>&reg</sup> was granted orphan drug status in Europe and the United States, granting marketing exclusivity for 10 and 7 years, respectively.

Teva currently holds 11% of MediWound (on a fully diluted basis) and owns the marketing rights for Debrase<sup>&reg</sup> in certain territories. Teva has options to expand its marketing rights for Debrase<sup>&reg</sup> to Europe and North America, which become exercisable upon receipt of a marketing authorization from the EMEA and the FDA, respectively. If such options are exercised, Teva can and/or may be required to purchase up to 51% of MediWound.

### **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.

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

*This release contains forward-looking statements. 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 Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements, including statements relating to the interim results of the Debrase<sup>&reg</sup> phase III trial, the timing of a submission to the EMEA and the potential efficacy of, future market for, or marketability of Debrase<sup>&reg</sup>. We caution investors not to place undue reliance on the forward-looking statements contained in this press release, as there can be no assurance that the interim results from the phase III trial discussed in this press release will be confirmed upon full analysis of the results of the trial, and additional information relating to the safety or efficacy of Debrase<sup>&reg</sup> may be discovered upon further analysis of data from the phase III trial. Even if the results described in this release are confirmed upon full analysis of the Debrase<sup>&reg</sup> study, we cannot guarantee that any submission related to Debrase<sup>&reg</sup> will be approved in a timely manner, if at all, by regulatory authorities in the EU. Additional risks relating to Teva and its business are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.*

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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 October 21, 2009

