

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

November 08, 2002

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 November 2002

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 ☒

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 ☒

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

Teva Pharmaceutical Industries Ltd. Web Site www.tevapharm.com

Contact: Dan Suesskind

Chief Financial Officer
Teva Pharmaceutical Industries Ltd
(011) 972-2-589-2840
(917) 853-2592

Bill Fletcher
President and CEO
Teva North America.
(215) 591-8800
(215) 896-1110

FOR IMMEDIATE RELEASE

Dorit Meltzer
Director, Investor Relations
Teva Pharmaceutical Industries Ltd.
(011) 972-3-926-7554
(011) 972-55-227733

TEVA TO TERMINATE THE PROMISE TRIAL FOLLOWING UNFAVORABLE INTERIM ANALYSIS

Jerusalem, Israel, November 7, 2002 - Teva Pharmaceutical Industries Ltd. (Nasdaq: Teva) announced that an interim analysis of its clinical trial on primary progressive multiple sclerosis showed that it was improbable that the study at its current protocol, would reach statistical significance. The scheduled interim analysis by the study's data safety monitoring committee came two years into the three-year study. There have been no safety concerns about treatment with COPAXONE^(R) (glatiramer acetate for injection).

"Primary progressive MS is very different from relapsing-remitting MS, affecting less than 10% of MS patients worldwide, and there is much we still need to learn about what causes these patients to progress. Even though this trial will not yield a drug therapy, the amount of data accumulated, will bring us a step closer to future treatments to help people with primary progressive MS." said Jerry S. Wolinsky M.D., principal investigator of the study, and director of

FOR IMMEDIATE RELEASE

the MS Research Group at the University of Texas Health Science Center, Houston, Texas. "What we do know is that COPAXONE^(R) is an effective treatment for the relapsing form of the disease as was demonstrated in three placebo-controlled trials, and with data accumulated on long term efficacy of up to 8 years".

We are sorry that the results mean that patients with primary progressive MS will not benefit from COPAXONE^(R) as do over 60,000 relapsing-remitting patients worldwide. However, we knew when we launched the trial that no company has yet been able to find a therapy for this severely affected patient population," said Israel Makov, President and CEO of Teva. "Our company is committed to continued research in the field of MS both with COPAXONE^(R) and new molecules".

COPAXONE^(R) is the second most prescribed therapy for relapsing-remitting MS in the United States and is approved in 41 countries worldwide, including the U.S., Canada, Australia, Israel and all the European countries. In Europe, COPAXONE^(R) is marketed by Teva Pharmaceutical Industries Ltd., and Aventis Pharma. In North America, COPAXONE^(R) is marketed by Teva Neuroscience, a fully owned subsidiary of Teva Pharmaceutical Industries.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 35 pharmaceutical companies in the world. More than 80 percent of Teva's sales are in North America and Europe. The company develops, manufactures and markets generic

and branded human pharmaceuticals and active pharmaceutical ingredients. Teva's innovative R&D focuses on developing novel drugs for diseases of the central nervous system.

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 current 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. Important factors that could cause or contribute to such differences include Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competitive generic products, the impact of competition from brand-name companies that sell their own generic products or successfully extend the exclusivity period of their branded products, Teva's ability to rapidly integrate the operations of acquired businesses, the availability of product liability coverage in the current insurance market, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration ("FDA") and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, acceptance and demand for new pharmaceutical products and new therapies, uncertainties regarding market acceptance of innovative products newly launched, currently being sold or in development, the impact of restructuring of clients, reliance on strategic alliances, exposure to product liability claims, dependence on patent and other protections for innovative products, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission ("SEC"). Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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/ Dan Suesskind

Name: Dan Suesskind

Title: Chief Financial Officer

Date: November 7, 2002