

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
October 04, 2004

**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 2004

Commission File Number 0-16174



- 1 -

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

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Contact: Dan Suesskind

Chief Financial Officer

Teva Pharmaceutical Industries Ltd.

(011) 972-2-589-2840

Bill Fletcher

President and CEO

Teva North America

**FOR IMMEDIATE RELEASE** (215) 591-8800

Dorit Meltzer

Director, Investor Relations

Teva Pharmaceutical Industries Ltd.

(011) 972-3-926-7554

**TEVA ANNOUNCES APPROVAL OF MESALAMINE RECTAL SUSPENSION USP**

**Jerusalem, Israel, October 1, 2004** - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the U.S. Food and Drug Administration has granted final approval for the company's ANDA for Mesalamine Rectal Suspension, USP, 4 gm/60 mL. Shipment of this product is expected to begin immediately.

Teva's Mesalamine Rectal Suspension is the AB-rated generic equivalent of Solvay's Rowasa<sup>®</sup> Enema, and is indicated for treatment of mild to moderate ulcerative colitis, proctosigmoiditis and proctitis.

The brand product has annual sales of approximately \$58 million.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 25 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Close to 90% 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, 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, including its recent acquisition of Sicor Inc., 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 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. 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.*

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## **TEVA AND BIOVAIL ANNOUNCE RESOLUTION OF ARBITRATION**

### **PROCEEDINGS; EXPANSION OF RELATIONSHIP**

**Jerusalem, Israel, October 1, 2004** - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) and Biovail Corporation (NYSE:BVF) (TSX:BVF) announced today that the pending arbitration between the two companies relating to a dispute over their existing agreement has been amicably resolved in its entirety, with each side granting a full release to the other in respect of the subject matter of that arbitration. In addition, the companies have expanded their business relationship for controlled release generic products and active raw materials. Under agreements entered into by their respective subsidiaries, Biovail has granted Teva a four-year extension to the ten year product-by-product supply terms for each of the currently marketed products covered by the exclusive marketing and product development agreement that was originally established in 1997, granted Teva an option on one additional



bioequivalent product under development by Biovail, and transferred in their entirety Biovail's product development files and related intellectual property for two extended release generic products, which Teva will now continue to develop and ultimately manufacture on its own. In consideration for these agreements, Teva has agreed to make up-front and milestone based payments and has also agreed to an increase in the gross margin percentage shared with Biovail under the exclusive marketing agreement for the balance of its extended term. Teva and Biovail affiliates have also entered into a long-term API supply agreement under which Biovail will increase its purchases for raw material from Teva's API division. These transactions confer financial benefits to both parties. Additional details were not disclosed.

Mr. Eugene Melnyk, Chairman and CEO of Biovail commented: "Our arbitration has resulted in an expansion of our relationship with Teva on different fronts, providing mutual benefits to both parties. We look forward to continuing our productive relationship with Teva."

Mr. Israel Makov, CEO of Teva said: "These new agreements allow both parties to benefit from our mutual strengths and should provide Teva with the opportunity to further expand its portfolio of controlled release generic products."

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Biovail Corporation is an international full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture, sale and promotion of pharmaceutical products utilizing advanced drug-delivery technologies. For more information about Biovail, visit the company's Web site at [www.biovail.com](http://www.biovail.com)

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*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. 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: October 01, 2004

