

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
November 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 November 2004

Commission File Number 0-16174

- 1 -

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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-_____

Teva Pharmaceutical Industries Ltd.

Web Site: www.tevapharm.com

| | | | |
|----------|--|-------------------------------------|----------------|
| Contact: | Dan Suesskind , Chief Financial Officer, | Teva Pharmaceutical Industries Ltd. | 972-2-589-2840 |
| | Bill Fletcher , <i>President and CEO</i> , | Teva North America | (215) 591-3000 |
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FOR IMMEDIATE RELEASE

TEVA REPORTS RECORD Q3 SALES, NET INCOME, EPS AND CASH FLOW

Net Sales reach \$1.25 billion (+53%), Net Income \$252 million (+61%),

EPS \$0.38 (+46%).

Record third quarter in-market sales of Copaxone[®] totaled \$242 million, up 34%.

Cash flow from operations of \$391 million.

The Company increases guidance for 2004.

Jerusalem, Israel, November 4, 2004 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today reported **net sales** of \$1,247 million, up 53% compared to the third quarter of 2003 and **net income** of \$252 million, up 61% over the comparable quarter of 2003. **Fully diluted EPS** this quarter reached \$0.38, an increase of 46% over the third quarter of 2003 (adjusted for the 2:1 stock split in June 2004).

Comparative data for 2003 does not include the results of Sicor, which was acquired in January 2004.

The strengthening of various currencies relative to the US dollar accounted for 7% of the increase in global net sales, but had only a moderate effect on the bottom line. Less than half of the quarter over quarter net sales growth is attributable to the Sicor acquisition.

64% of net sales were in North America, 26% were in Europe, and 10% were in the rest of the world (of which more than half was in Israel).

Israel Makov, Teva's President and CEO, commented: "I am very pleased with our organization's disciplined performance, which again demonstrates our commitment and our ability to generate sustainable and profitable growth. In the third quarter, all of our major businesses contributed to our growth and we benefited from Gabapentin sales in both Europe and the API division. The combination of our global reach, API capabilities, generic pipeline and dedication to R&D differentiate us from our competitors and strengthen our leadership position in the generic industry. Furthermore, our position in the global Multiple Sclerosis market has never been stronger. This has resulted not only in record profits, but also in record cash flow from operations."

North American pharmaceutical sales totaled \$719 million compared to \$452 million in the third quarter of 2003, an increase of 59%. This increase was mainly attributable to the consolidation of Sicor and the sales of 24 new products that were not sold in the comparable quarter of 2003, the most significant being Oxycodone, Carboplatin and Medroxyprogesterone vials, as well as increased sales of Copaxone[®].

Teva's U.S. generic pipeline is currently comprised of 120 product applications (including 14 tentative approvals), with total annual brand sales exceeding \$75 billion. Of these product applications, 67 were submitted under Paragraph IV. Teva believes that in the case of 25 of these Paragraph IV filings, it may be "first to file", thereby potentially providing Teva with periods of exclusivity for products which, in the aggregate, have annual brand sales exceeding \$20 billion.

Pharmaceutical sales in Europe increased 53% in the quarter to \$275 million as compared to \$180 million in the comparable period of 2003. This increase was attributable to sales of new products in several European countries, mainly Gabapentin and Pravastatin, higher Copaxone[®] sales and strengthenings of European currencies in relation to the U.S. dollar.

Copaxone[®] - Global in-market sales of **Copaxone[®]** this quarter amounted to \$242 million, an increase of 34% over the comparable quarter of 2003. In U.S. dollar terms, Copaxone[®] was the fastest growing MS therapy worldwide. U.S. sales of \$163 million increased 32% over the comparable period in 2003 and sales outside the U.S., mainly in Europe, increased by 39% to \$79 million. In terms of total prescriptions in the U.S., Copaxone[®] reached its highest quarterly market share of 30.5%.

In October 2004, three important studies on Copaxone[®] were presented at the European Committee for Treatment and Research in MS (ECTRIMS) annual meeting, including a study which presented the latest Copaxone[®] long-term data that showed that 91% of Copaxone[®] patients continue to walk without assistance after 10 years of treatment. This prospective, long-term, open-label, organized study represents the longest continuous assessment of therapy in patients with MS. Teva has announced its commitment to extending the observation period of this trial to 15 years.

Agilect[®] - In October, Teva's clinical and regulatory staff met with their counterparts at both the U.S. Food and Drug Administration (FDA) and the European Medicines Association (EMA) to discuss Agilect[®] (rasagiline) in the US and **Azilect[®]** (rasagiline) in Europe. In these meetings, Teva responded to questions, and provided additional information and analysis. In the case of the FDA, the Company intends to submit a written response to the approvable letter in the next several days. The FDA has up to six months to review Teva's submission, while the EMA may respond even earlier.

API sales to third parties totaled \$146 million, an increase of 54% over the third quarter of 2003. API sales, including internal sales to Teva's pharmaceutical businesses, were \$263 million, an increase of 65% over the comparable quarter in 2003. This substantial growth is mainly attributed to sales of Gabapentin raw material, as well as the inclusion of Sikor's API sales and the increased demand for API products worldwide. The API division currently offers 188 products.

Teva's **gross profit margin** amounted to 47.3% for the third quarter of 2004, as compared with 46.4% in the third quarter of 2003. The higher gross margin that was recorded in this quarter is attributable to the inclusion of Sikor's results, new generic products and higher sales of Copaxone[®] and API.

Gross R&D spending for the quarter grew to \$95 million, an increase of 54% over the comparable quarter of 2003, reflecting substantially higher generic and innovative R&D efforts. **Net R&D** amounted to \$90 million, up 65%.

Selling, General and Administrative (SG&A) expenses reached 14.6% of sales as compared with 15.4% in the third quarter of 2003 and 14.6% for the first nine months of 2004. The 45% increase in absolute terms as compared with the third quarter of 2003 mainly reflects costs associated with the higher sales volume and is in line with recent quarterly levels, which have been in the range of between 14-15%.

Financial Income for the reported quarter amounted to \$9 million compared with financial expenses of \$1 million in third quarter of 2003, reflecting primarily favorable currency trends as well as higher yields on Teva's investment portfolio, resulting from higher interest rates.

The tax rate provided for the third quarter was 22.6%, higher than the 20.0% tax rate in the third quarter of 2003. This increase is primarily due to Sicor's higher tax rate.

Shareholders Equity at September 30, 2004 exceeded \$5 billion for the first time, up 55% from \$3.3 billion at December 31, 2003.

Cash flow generated from operating activities for the third quarter of 2004 amounted to \$391 million compared with \$138 million in the third quarter of 2003 and \$627 million generated in the full year 2003. The high cash flow generated this quarter reflects the increased net income and lower inventory levels.

Outlook for 2004 - Teva is updating its full year 2004 guidance for net sales to exceed \$4.7 billion. This compares to previously announced guidance of net sales in excess of \$4.5 billion. The company expects fully diluted earnings per share of \$1.43 - \$1.44, up from a previously announced range of \$1.35 to \$1.37. In both cases, the guidance excludes the effect of the new Financial Accounting Standard Board (FASB) accounting rules that relate to convertible bonds with a contingent conversion feature. These rules will become applicable in the fourth quarter of 2004 and their effect on Teva's EPS in 2004 is expected to be dilutive by 1 Cent in Q4 of 2004 and approximately 4 Cent for the full year.

Dividend

The Board of Directors, at its meeting on November 1, 2004, declared a cash dividend per ADR for the third quarter of 2004 of NIS 0.225 (approximately \$0.05 according to the rate of exchange on November 3, 2004). The record date will be November 10, 2004, and the payment date will be November 25, 2004. Tax will be withheld at a rate of 18.5%.

Conference Call Details

Teva will host a conference call to discuss the Company`s third quarter results on Thursday, November 4, 2004 at 09:00 a.m. EST. The call will be webcast and can be accessed through the Company`s website at www.tevapharm.com. Following the conclusion of the call, a replay will be available until November 11, 2004, midnight EST on the website or by calling 1-(800) 642-1687 in the U.S. or ++1-(706) 645-9291 outside the U.S. The pass code to access the replay is: 1629200.

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 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. 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 or license their own generic products (so called "authorized generics") or successfully extend the exclusivity period of their branded products, the effects of competition on Copaxone® sales, including potential competition from the expected launch of Antegren®, Teva's ability to rapidly integrate the operations of acquired businesses, including its acquisition of Sicor Inc., regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to completion of appellate litigation, including that relating to Neurontin, 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, European Medicines Association and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, Teva's ability to successfully identify, consummate and integrate acquisitions, exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations outside the United States that may be adversely affected by terrorism or major hostilities, 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.

Teva Pharmaceutical Industries Limited**Consolidated Statements of Income**(in millions, except earnings per ADR)

| | July - September 2004 U.S. Dollars | 2003 | January - September | |
|--|---|-------|---------------------|---------|
| | | | 2004 | 2003 |
| NET SALES | 1,247.3 | 812.6 | 3,476.1 | 2,334.4 |
| COST OF SALES | 657.7 | 435.4 | 1,852.8 | 1,248.5 |
| GROSS PROFIT | 589.6 | 377.2 | 1,623.3 | 1,085.9 |
| R&D EXPENSES | 95.0 | 61.6 | 258.4 | 166.2 |
| LESS PARTICIPATIONS & GRANTS | 4.6 | 6.8 | 12.7 | 16.5 |
| R&D EXPENSES - net | 90.4 | 54.8 | 245.7 | 149.7 |
| SG&A EXPENSES | 181.5 | 125.3 | 508.6 | 377.9 |
| | 317.7 | 197.1 | 869.0 | 558.3 |
| GSK LITIGATION SETTLEMENT INCOME | | | | 100.0 |
| RESTRUCTURING EXPENSES | | | | 7.4 |
| ACQUISITION OF R&D IN PROCESS | | | 596.6 | |
| IMPAIRMENT OF PRODUCT RIGHTS | | | 30.0 | |
| OPERATING INCOME | 317.7 | 197.1 | 242.4 | 650.9 |
| FINANCIAL INCOME (EXPENSES) - net | 8.8 | (1.2) | 9.3 | (14.1) |
| INCOME BEFORE TAXES | 326.5 | 195.9 | 251.7 | 636.8 |
| INCOME TAXES | 73.9 | 39.1 | 196.7 | 131.7 |
| | 252.6 | 156.8 | 55.0 | 505.1 |
| PROFIT (LOSS) ON EQUITY INVESTMENTS | | (0.2) | 0.4 | 0.6 |
| MINORITY INTERESTS | (0.9) | (0.6) | (2.4) | (1.0) |
| NET INCOME | 251.5 | 156.6 | 53.0 | 504.7 |
| EARNINGS PER ADR: | | | | |
| <i>Basic</i> (\$) | 0.41 | 0.29 | 0.09 | 0.95 |
| <i>Diluted</i> (\$) | 0.38 | 0.26 | 0.08 | 0.89 |
| NET INCOME BEFORE NON-RECURRING ITEMS: | | | | |
| NET INCOME | 251.5 | 156.6 | 685.8 | 431.5 |
| EARNINGS PER ADR: | | | | |

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| | | | | |
|----------------------------------|-------|-------|-------|-------|
| <i>Basic (\$)</i> | 0.41 | 0.29 | 1.13 | 0.82 |
| <i>Diluted (\$)</i> | 0.38 | 0.26 | 1.05 | 0.76 |
| WEIGHTED AVERAGE NUMBER OF ADRs: | | | | |
| <i>Basic</i> | 619.3 | 531.8 | 608.1 | 531.0 |
| <i>Diluted</i> | 663.9 | 611.8 | 626.1 | 582.4 |

- 7 -

***Teva Pharmaceutical Industries
Limited***

Balance Sheet Data

(in millions)

| | September 30 2004 U.S. Dollars | December 31 2003 |
|----------------------------|--------------------------------------|---------------------|
| ASSETS | | |
| CURRENT ASSETS | 4,155.8 | 3,716.4 |
| INVESTMENTS & OTHER ASSETS | 645.6 | 445.1 |
| FIXED ASSETS - net | 1,168.5 | 827.4 |
| INTANGIBLE ASSETS - net | 3,129.0 | 927.0 |
| TOTAL ASSETS | 9,098.9 | 5,915.9 |

LIABILITIES AND SHAREHOLDERS` EQUITY

| | | |
|--|---------|---------|
| CURRENT LIABILITIES | 1,967.1 | 1,694.9 |
| LONG-TERM LIABILITIES | 506.5 | 475.0 |
| MINORITY INTERESTS | 9.4 | 6.7 |
| CONVERTIBLE SENIOR DEBENTURES | 1,518.5 | 449.9 |
| SHAREHOLDERS` EQUITY | 5,097.4 | 3,289.4 |
| TOTAL LIABILITIES & SHAREHOLDERS` EQUITY | 9,098.9 | 5,915.9 |

- 8 -

Teva Pharmaceutical Industries Limited

Sales for the Quarter July - September 2004 (US \$ millions)

Sales by Geographical Areas

| Sales For the Period | 2004 | 2003 | % Change | % of Total |
|-----------------------------|----------------|--------------|-----------------|-------------------|
| North America | 804.3 | 507.7 | 58.4% | 64.5% |
| Europe | 322.5 | 207.7 | 55.3% | 25.9% |
| Rest of the World | 120.5 | 97.2 | 24.0% | 9.6% |
| Total | 1,247.3 | 812.6 | 53.5% | 100.0% |

Sales by Business Segments

| Sales For the Period | 2004 | 2003 | % Change | % of Total |
|-----------------------------|----------------|--------------|-----------------|-------------------|
| Pharmaceutical | 1,095.7 | 712.9 | 53.7% | 87.9% |
| A.P.I. | 146.2 | 94.8 | 54.2% | 11.7% |
| Veterinary and Other | 5.4 | 4.9 | 10.2% | 0.4% |
| Total | 1,247.3 | 812.6 | 53.5% | 100.0% |

Pharmaceutical Sales

| Sales For the Period | 2004 | 2003 | % Change | % of Total |
|-----------------------------|-------------|-------------|-----------------|-------------------|
|-----------------------------|-------------|-------------|-----------------|-------------------|

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| | | | | |
|-------------------|----------------|--------------|--------------|---------------|
| North America | 718.6 | 451.7 | 59.1% | 65.6% |
| Europe | 275.1 | 179.9 | 52.9% | 25.1% |
| Rest of the World | 102.0 | 81.3 | 25.5% | 9.3% |
| Total | 1,095.7 | 712.9 | 53.7% | 100.0% |

- 9 -

Teva Pharmaceutical Industries Limited

Sales for the Period January - September 2004 (US \$ millions)

Sales by Geographical Areas

| Sales For the Period | 2004 | 2003 | % Change | % of Total |
|----------------------|----------------|----------------|--------------|---------------|
| North America | 2,221.9 | 1,447.6 | 53.5% | 63.9% |
| Europe | 899.6 | 622.6 | 44.5% | 25.9% |
| Rest of the World | 354.6 | 264.2 | 34.2% | 10.2% |
| Total | 3,476.1 | 2,334.4 | 48.9% | 100.0% |

Sales by Business Segments

| Sales For the Period | 2004 | 2003 | % Change | % of Total |
|----------------------|----------------|----------------|--------------|---------------|
| Pharmaceutical | 3,073.0 | 2,044.3 | 50.3% | 88.4% |
| A.P.I. | 387.0 | 276.0 | 40.2% | 11.1% |
| Veterinary and Other | 16.1 | 14.1 | 14.2% | 0.5% |
| Total | 3,476.1 | 2,334.4 | 48.9% | 100.0% |

Pharmaceutical Sales

| Sales For the Period | 2004 | 2003 | % Change | % of Total |
|----------------------|---------|---------|----------|------------|
| North America | 1,989.0 | 1,283.1 | 55.0% | 64.7% |
| Europe | 780.1 | 535.8 | 45.6% | 25.4% |

Balance Sheet Data

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| | | | | |
|-------------------|----------------|----------------|--------------|---------------|
| Rest of the World | 303.9 | 225.4 | 34.8% | 9.9% |
| Total | 3,073.0 | 2,044.3 | 50.3% | 100.0% |

- 10 -

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 04, 2004

