TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K May 04, 2010
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 May, 2010
Commission File Number <u>0-16174</u>
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 office)
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):
-1-

### **Teva Reports First Quarter 2010 Results**

#### Strong Operational Results on a GAAP and non-GAAP Basis

JERUSALEM--(BUSINESS WIRE)--May 4, 2010--Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today reported results for the quarter ended March 31, 2010.

#### First Quarter Highlights:

- Quarterly net sales of \$3.7 billion, up 16%, compared to the comparable period in 2009.
- Quarterly non-GAAP net income and non-GAAP EPS of \$830 million and \$0.91, up 31% and 28%, respectively, compared with the first quarter of 2009. Quarterly GAAP net income and EPS totaled \$713 million and \$0.79, up 58% and 55%, respectively, compared with the first quarter of 2009.
- Quarterly non-GAAP operating income of \$1.0 billion, up 21% compared with the first quarter of 2009. Quarterly GAAP operating income totaled \$834 million, up 55% compared with the first quarter of 2009.
- Record quarterly global in-market sales of Copaxone® of \$796 million, up 28% over the first quarter of 2009. Copaxone® continues to be the leading MS therapy in the U.S. and globally.
- Quarterly cash flow from operations of \$886 million, up 21% compared with the first quarter of 2009.
- Entered into a definitive agreement to acquire ratiopharm for an enterprise value of €3.625 billion; the transaction is expected to close by year-end 2010.

"2010 is off to a great start for Teva, with strong operational results and cash flow," said **Shlomo Yanai, Teva's President and Chief Executive Officer.** "We continued our strong growth momentum in the first quarter, driven by contributions from across our many businesses and geographies, and we are looking forward to another year of continuous growth."

Mr. Yanai continued, "One of the most exciting events of this quarter, of course, was our agreement to acquire ratiopharm, an important milestone in executing our long-term strategy, and one that will make Teva -- the global generics leader -- the leader in Europe as well."

Net sales for the first quarter increased 16% to \$3,653 million, compared to \$3,147 million in the first quarter of 2009.

**Exchange rate** differences between this quarter and the comparable quarter in 2009 contributed approximately \$98 million to sales this quarter, while having a negligible effect on operating income. The impact on sales resulted primarily from the decline in the value of the U.S. dollar relative to certain other currencies (primarily the Euro, the Canadian dollar, the Hungarian forint, the Russian ruble, the Polish zloty and British pound) in the first quarter of 2010 compared with the first quarter in 2009.

Non-GAAP **net income** for the first quarter of 2010 totaled \$830 million, an increase of 31%, while non-GAAP diluted **earnings per share** were \$0.91, an increase of 28% compared to the first quarter of 2009. On a U.S. GAAP basis, net income for the first quarter totaled \$713 million, up 58% compared to the first quarter of 2009, while diluted earnings per share were \$0.79, up 55% compared to the first quarter of 2009.

Non-GAAP net income and non-GAAP EPS for the first quarter of 2010 are adjusted to exclude the following items:

- Amortization of purchased intangible assets of \$130 million;
- Legal settlements of \$17 million;
- Acquisition expenses (primarily related to the ratiopharm acquisition) and restructuring expenses of \$17 million;
- Purchase of R&D in-process of \$4 million; and
- Related tax benefits of \$51 million.

Teva believes that excluding these items facilitates investors' understanding of the trends in the Company's underlying business. In the first quarter of 2009, non-GAAP net income and non-GAAP EPS excluded inventory step up, amortization of purchased intangible assets, restructuring expenses, impairment of assets and related tax effects. See the attached table for a reconciliation of U.S. GAAP reported results to the adjusted non-GAAP figures.

Quarterly non-GAAP **operating income** (which excludes amortization of purchased intangible assets, legal settlements, acquisition and restructuring expenses, and purchase of R&D in-process, as detailed above) reached \$1,002 million, an increase of 21% compared with the first quarter of 2009. On a U.S. GAAP basis, operating income for the first quarter of 2010 totaled \$834 million, up 55% compared to the first quarter of 2009.

**Sales in North America** for the first quarter reached \$2,309 million, accounting for 63% of total sales and representing an increase of 20% compared with the first quarter of 2009. The increase in quarterly sales resulted from the launch of a generic version of Mirapex® (pramipexole) in the quarter, as well as the continued strong sales of generic versions of Adderall XR® (mixed amphetamine salts), Pulmicort Respules® (budesonide), Accutane® (isotretinoin), and Eloxatin® (oxaliplatin) launched in previous quarters. The quarter's sales also reflected continued strong sales of Copaxone®.

As of April 26, 2010, Teva had 210 product applications awaiting final FDA approval, including 44 tentative approvals. Collectively, the brand products covered by these applications had annual U.S. sales of over \$113 billion. Of these applications, 133 were "Paragraph IV" applications challenging patents of branded products. Teva believes it is the first to file on 83 of the applications, relating to products with annual U.S. branded sales exceeding \$50 billion.

**Sales in Europe** in the first quarter of 2010 totaled \$812 million, accounting for 22% of total sales and representing an increase of 10% compared with the first quarter of last year. The increase in sales was mostly attributable to increased sales of Copaxone® and Azilect®, as well as strong generic sales in Italy, Poland and Portugal. In local currency terms, sales in Europe grew 1% compared with the first quarter of 2009.

Since the beginning of 2010, Teva has received 206 generic approvals in Europe relating to 64 compounds in 135 formulations, including three EMA (European Medicines Agency) approvals valid in all EU member states. In addition, as of March 31, 2010, Teva had approximately 3,207 marketing authorization applications pending approval in 30 European countries, relating to 242 compounds in 474 formulations, including six applications pending with the EMA.

**International sales** in the first quarter of 2010 totaled \$532 million, accounting for 15% of total sales and representing an increase of 10% compared to the first quarter of 2009. The increase in sales was driven primarily by increased sales in Russia and Israel. In local currency terms, international sales grew 7% compared with the first quarter of 2009.

**Copaxone®** remains the number one MS therapy in the U.S. and globally. Global in-market sales reached a record \$796 million in the first quarter of 2010, an increase of 28% over the first quarter of 2009. In the U.S., quarterly in-market sales increased 19% to \$513 million compared to the first quarter of 2009. In-market sales outside the U.S. totaled \$283 million, up 48% compared to the first quarter of 2009, with significant growth in certain international markets where sales are not evenly distributed throughout the year. In local currency terms, in-market sales of Copaxone® outside the U.S. grew 36% in the first quarter of 2010.

Global in-market sales of **Azilect**® reached a record \$77 million in the quarter, a 40% increase over the comparable period in 2009. Growth in sales outside the U.S. (primarily in Spain, Italy, Turkey and France) and in the U.S. contributed to the increase in in-market sales in the first quarter of 2010. In local currency terms, global in-market sales of Azilect® grew 35% in the first quarter of 2010.

Teva's global **respiratory** product sales totaled \$193 million in the quarter, up 4% compared to \$185 million in the first quarter of 2009. The increase is attributable to continued growth in Qvar® and ProAir sales in the U.S. Teva's respiratory product sales in the U.S. totaled \$124 million in the first quarter. As of March 31, 2010, Teva maintained its leadership position with a 51% market share in the SABA (short acting beta agonist) market in the U.S., with Qvar® solidifying its number two position in the inhaled corticosteroid category (ICS) market.

Teva's **women's health** business sales declined to \$79 million in the quarter, compared to \$97 million in the comparable quarter in 2009. Results were impacted primarily by weak sales of Plan B<sup>®</sup> One-Step in the current quarter compared to Plan B<sup>®</sup> sales in the comparable quarter last year, partially offset by strong sales of Seasonique<sup>®</sup> and ParaGard<sup>®</sup>.

**API sales** to third parties totaled \$139 million in the first quarter, compared to \$158 million in the comparable quarter in 2009.

Non-GAAP gross profit margin reached 58.4% in the first quarter of 2010, similar to the non-GAAP gross profit margin recorded in the comparable quarter of 2009. Non-GAAP gross profit margins continued to benefit from the contribution to sales of new and recently launched generic products in the U.S., improved gross margins of the U.S. generics base business as well as the contribution to sales of innovative and branded products (including Copaxone®, ProAir,™Azilect® and women's health products). GAAP gross profit margin reached 55.1% in the first quarter of 2010 compared with GAAP gross profit of 49.9% in the comparable quarter of 2009, resulting primarily from inventory step up expenses recorded in the first quarter of 2009 in connection with the Barr acquisition, partially offset by higher amortization of purchased intangible assets recorded in the first quarter of 2010.

**Net Research & Development** (R&D) expenditures in the first quarter totaled \$207 million, or 5.7% of sales, compared to \$219 million recorded in the first quarter of 2009, or 7.0% of sales. Gross R&D in the first quarter of 2010, before reimbursement from third parties for certain R&D expenses, totaled \$217 million, or 5.9% of sales. For the full year, Teva continues to expect net R&D expenses to be between 6% and 6.5% of net sales.

Selling and Marketing (S&M) expenditures (excluding amortization of purchased intangible assets) totaled \$744 million, or 20.4% of sales, for the first quarter, compared to \$596 million, or 18.9% of sales, in the comparable quarter of 2009. The increase in S&M expenses is attributable primarily to higher royalty payments in connection with new and recently launched generic products sold in the U.S. and higher payments to sanofi-aventis resulting from higher Copaxone® sales. Commencing April 1, 2010, Teva will no longer make these payments to sanofi-aventis in connection with our North American Copaxone® sales. With the termination of this obligation, selling and marketing expenses after April 1, 2010 will decrease accordingly.

**General and Administrative (G&A)** expenditures totaled \$182 million, or 5.0% of sales, for the first quarter, compared with \$196 million, or 6.2% of sales, in the comparable quarter of 2009.

The **tax rate** provided for the first quarter was 14% of pre-tax non-GAAP income and represents Teva's current estimate of the annual rate of tax for 2010 compared to a rate of 16% of pre-tax non-GAAP income for all of 2009. On a GAAP basis, the annual tax rate for 2010 is estimated to be approximately 11%.

**Cash flow** generated from operating activities during the first quarter of 2010 was \$886 million, compared to \$733 million in the comparable quarter in 2009. Free cash flow – excluding net capital expenditures (of \$164 million) and dividends (of \$165 million) – reached \$557 million. Cash and marketable securities as of March 31, 2010 were \$3.0 billion, up approximately \$550 million from December 31, 2009.

**Total equity** as of March 31, 2010 amounted to \$19.7 billion, an increase of \$424 million compared to \$19.3 billion as of December 31, 2009. The increase in total equity is attributable primarily to net income recorded in the first quarter, partially offset by the negative impact on equity resulting from the weakening of major non-U.S. currencies compared to the U.S. dollar (mainly the Euro) as well as dividends paid to shareholders.

For the first quarter of 2010, the weighted average **share count** for the fully diluted earnings per share calculation was 921 million shares on both a GAAP and non-GAAP basis. As of March 31, 2010, Teva's share count going forward for the fully diluted share calculation is estimated at 923 million shares, while the share count for calculating Teva's market capitalization is approximately 894 million shares.

#### **Dividend**

The Board of Directors, at its meeting on May 3, 2010, declared a cash dividend for the first quarter of 2010 of NIS 0.70 (approximately 18.8 cents according to the rate of exchange on May 3, 2010) per share.

The record date will be May 12, 2010, and the payment date will be May 27, 2010. Tax will be withheld at a rate of 9%.

#### **Conference Call**

Teva will host a conference call to discuss the Company's first quarter 2010 results, on Tuesday, May 4, 2010 at 9:00 a.m. ET. The call will be webcast and can be accessed through the Company's website at <a href="www.tevapharm.com">www.tevapharm.com</a>. Following the conclusion of the call, a replay of the webcast will be available within 24 hours at the Company's website. A replay of the call will also be available until May 11, 2010, at 11:59 p.m. ET, by calling 201-612-7415 outside the United States or 877-660-6853 in the United States. The pass code to access the replay is: Account # 3055 and Conference ID# 349279.

#### **About Teva**

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 15 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Western Europe.

#### 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 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>, current economic conditions, the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on our innovative products, especially Copaxone® sales, dependence on the effectiveness of our patents and other protections for innovative products, especially Copaxone<sup>®</sup>, 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 though 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, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, the effects of reforms in healthcare regulation, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, potential tax liabilities that may arise should our agreements (including intercompany arrangements), be challenged successfully by tax authorities, our ability to successfully identify, consummate and integrate acquisitions and other business combinations (including our pending acquisition of ratiopharm), the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, as well as to

credit risk, 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 increased government scrutiny of our agreements with brand companies in both the U.S. and Europe, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks, and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2009, in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

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# **Consolidated Statements of Income**

(Unaudited, U.S. Dollars in millions, except share and per share data)

		Three Months Ended	
		March 31,	
		2010	2009
Net sales		3,653	3,147
Cost of sales (a)		1,640	1,576
Gross profit		2,013	1,571
Research and development expenses		207	219
Selling and marketing expenses (b)		752	604
General and administrative expenses		182	196
Legal settlements, acquisition and restructuring expenses and impairment		34	14
Purchase of research and development in process		4	-
Operating income		834	538
Financial expenses– net		27	63
Income before income taxes		807	475
Provision for income taxes (c)		85	25
		722	450
Share in profits (losses) of associated companies – net		(8)	1
Net income		714	451
Net income attributable to non-controlling interests		1	*
Net income attributable to Teva		713	451
Earnings per share attributable to Teva:	Basic (\$)	0.80	0.53
	Diluted (\$)	0.79	0.51
Weighted average number of shares (in millions):	Basic	892	857
	Diluted	921	894
Non-GAAP net income attributable to Teva:***		830	634
Non-GAAP earnings per share attributable to Teva:	Basic (\$)	0.93	0.74
	Diluted (\$)	0.91	0.71
Weighted average number of shares (in millions):	Basic	892	857
	Diluted	921	910

### \*\*\* See reconciliation attached.

- (a) Cost of sales includes \$122 million and \$46 million of amortization of purchased intangible assets in the three months ended March 31, 2010 and 2009, respectively, and \$220 million of inventory step-up in the three months ended March 31, 2009.
- (b) Selling and marketing expenses includes \$8 million of amortization of purchased intangible assets in the three months ended March 31, 2010 and 2009.
- (c) Provision for income taxes includes \$(51) million and \$(105) million of related tax effect of non-GAAP charges in the three months ended March 31, 2010 and 2009, respectively.
- \* Represents an amount of less than \$0.5 million.

# **Condensed Balance Sheets**

# (Unaudited, U.S. Dollars in millions)

	March 31,	December 31,
A GOZZING	2010	2009
ASSETS		
Current assets:	2.256	1.007
Cash and cash equivalents	2,356	1,995
Short-term investments	337	253
Accounts receivable	5,136	5,019
Inventories	3,244	3,332
Deferred taxes and other current assets	1,538	1,542
Total current assets	12,611	12,141
Long-term investments and receivables	665	534
Deferred taxes, deferred charges and other assets	603	642
Property, plant and equipment, net	3,737	3,766
Identifiable intangible assets, net	3,872	4,053
Goodwill	12,563	12,674
Total assets	34,051	33,810
LIABILITIES AND EQUITY		
Current liabilities:		
Short-term debt and current maturities of long term liabilities	1,974	1,301
Sales reserves and allowances	3,006	2,942
Accounts payable and accruals	2,671	2,680
Other current liabilities	692	679
Total current liabilities	8,343	7,602
Long-term liabilities:		
Deferred income taxes	1,713	1,741
Other taxes and long term payables	675	727
Employee related obligations	174	170
Senior notes and loans	3,416	3,494
Convertible senior debentures	47	817
Total long-term liabilities	6,025	6,949
Equity:		
Teva shareholders' equity	19,650	19,222
Non-controlling interests	33	37
Total equity	19,683	19,259

Total liabilities and equity

34,051

33,810

## Reconciliation between Reported and Non-GAAP Net Income

(Unaudited, U.S. Dollars in millions, except share and per share data)

		Three Months Ended	
		March 31,	
		2010	2009
Reported net income attributable to Teva		713	451
Inventory step-up		-	220
Purchase of research and development in process		4	-
Amortization of purchased intangible assets - under cost of sales		122	46
Amortization of purchased intangible assets - under selling and marketing		8	8
Legal settlements		17	-
Impairment of assets		-	2
Acquisition and restructuring expenses		17	12
Related tax effect		(51)	(105)
Non-GAAP net income attributable to Teva		830	634
Diluted comings non characteributable to Toyar	Donanted (\$)	0.70	0.51
Diluted earnings per share attributable to Teva:	Reported (\$) Non-GAAP	0.79	0.51
	Non-GAAP (\$)	0.91	0.71
	(Ψ)	0.51	0.71
Add back for diluted earnings per share calculation:			
Interest expense on convertible senior debentures, and issuance costs, net			
Interest expense on convertible senior debentures, and issuance costs, net of tax benefits	_	11	1
	Non-GAAP		
	(\$)	11	11
Diluted weighted average number of shares (in millions):	Reported	921	894
	Non-GAAP	921	910

# Reconciliation between Reported and Non-GAAP Operating Income

(Unaudited, U.S. Dollars in millions)

	Three Months Ended March 31,	
	2010	2009
Reported operating income	834	538
Inventory step-up	-	220
Purchase of research and development in process	4	-
Amortization of purchased intangible assets - under cost of sales	122	46
Amortization of purchased intangible assets - under selling and marketing	8	8
Legal settlements	17	-
Impairment of assets	-	2
Acquisition and restructuring expenses	17	12
Non-GAAP operating income	1,002	826

Teva Pharmaceutical Industries Limited

# **Condensed Cash Flow**

(Unaudited, U.S. Dollars in millions)

	Three Months Ended March 31,	
	2010	2009
Operating activities:		
Net income	714	451
Purchase of research and development in process	4	-
Other adjustments to reconcile net income to net cash provided from operations	168	282
Net cash provided by operating activities	886	733
Net cash used in investing activities	(328)	(142)
Net cash used in financing activities	(175)	(24)
Translation adjustment on cash and cash equivalents	(22)	(71)
Net increase in cash and cash equivalents	361	496
Balance of cash and cash equivalents at beginning of period	1,995	1,854
Balance of cash and cash equivalents at end of period	2,356	2,350

### Teva Pharmaceutical Industries Limited

		Months			
	Ended				
	March 31,		March 31, % of Total	% of Total	
	2010	2009	2010	2009	% Change
	(Unaudited, U.S Dollars in millions)				
Sales by Geographical Areas					
North America	2,309	1,925	63%	61%	20%
Europe*	812	739	22%	24%	10%
International	532	483	15%	15%	10%
Total	3,653	3,147	100%	100%	16%

<sup>\*</sup> Includes EU member states, Switzerland & Norway.

### CONTACT:

Teva Pharmaceutical Industries Ltd.

Elana Holzman, 972 (3) 926-7554

or

Teva North America

**Kevin Mannix,** 215-591-8912

### **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: May 4, 2010