

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

November 02, 2010

[Table of Contents](#)

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 6-K

**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 2010**

**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)

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

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):

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****INDEX**

<u>Consolidated Statements of Income</u>	<b>Page</b> 2
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Cash Flow</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
<u>Operating and Financial Review and Prospects</u>	20
<u>Risk Factors</u>	36
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	36
<u>Legal Proceedings</u>	36

**Exhibits**

As listed below, attached as Exhibit 101 to this Report on Form 6-K is certain information contained in this Report on Form 6-K of Teva Pharmaceutical Industries Limited relating to the three and nine months ended September 30, 2010, formatted in XBRL (Extensible Business Reporting Language). Users of this data are advised, in accordance with Rule 406T of Regulation S-T promulgated by the Securities and Exchange Commission, that this Interactive Data File is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

<b>Exhibit No.</b>	<b>Description</b>
EX-101.INS	XBRL Taxonomy Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Presentation Linkbase Document

**INTRODUCTION AND USE OF CERTAIN TERMS**

Unless otherwise indicated or the context otherwise requires, all references to the Company, we, our and Teva refer to Teva Pharmaceutical Industries Limited and its subsidiaries. References to U.S. dollars, U.S.\$ and \$ are to the lawful currency of the United States of America, and references to NIS are to new Israeli shekels. Market share data is based on information provided by IMS Health Inc., a leading provider of market research to the pharmaceutical industry ( IMS ), unless otherwise stated.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONSOLIDATED STATEMENTS OF INCOME**

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

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Net sales	\$ 4,250	\$ 3,550	\$ 11,703	\$ 10,097
Cost of sales	1,783	1,622	5,102	4,829
Gross profit	2,467	1,928	6,601	5,268
Research and development expenses	239	195	663	583
Selling and marketing expenses	751	671	2,147	1,924
General and administrative expenses	236	212	607	605
Legal settlements, acquisition and restructuring expenses and impairment	53	97	78	163
Purchase of research and development in process			9	
Operating income	1,188	753	3,097	1,993
Financial expenses net	3	52	178	176
Income before income taxes	1,185	701	2,919	1,817
Provision for income taxes	133	49	336	172
	1,052	652	2,583	1,645
Share in losses of associated companies net	*	2	17	21
Net income	1,052	650	2,566	1,624
Net income attributable to non-controlling interests	2	1	6	3
Net income attributable to Teva	\$ 1,050	\$ 649	\$ 2,560	\$ 1,621
Earnings per share attributable to Teva:				
Basic	\$ 1.17	\$ 0.73	\$ 2.86	\$ 1.87
Diluted	\$ 1.15	\$ 0.72	\$ 2.82	\$ 1.81
Weighted average number of shares (in millions):				
Basic	899	884	895	867
Diluted	921	915	921	896

\* Represents an amount of less than \$0.5 million.

**The accompanying notes are an integral part of the condensed financial statements.**

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONSOLIDATED BALANCE SHEETS**

(U.S. dollars in millions)

	September 30, 2010 Unaudited	December 31, 2009 Audited
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 935	\$ 1,995
Short-term investments	21	253
Accounts receivable	5,228	5,019
Inventories	3,862	3,332
Deferred taxes and other current assets	1,813	1,542
<b>Total current assets</b>	<b>11,859</b>	<b>12,141</b>
<b>Long-term investments and receivables</b>	<b>680</b>	<b>534</b>
<b>Deferred taxes, deferred charges and other assets</b>	<b>819</b>	<b>642</b>
<b>Property, plant and equipment, net</b>	<b>4,228</b>	<b>3,766</b>
<b>Identifiable intangible assets, net</b>	<b>5,881</b>	<b>4,053</b>
<b>Goodwill</b>	<b>15,569</b>	<b>12,674</b>
<b>Total assets</b>	<b>\$ 39,036</b>	<b>\$ 33,810</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities:</b>		
Short-term debt and current maturities of long term liabilities	\$ 1,076	\$ 659
Convertible senior debentures short term	1,332	642
Sales reserves and allowances	3,348	2,942
Accounts payable and accruals	2,514	2,680
Other current liabilities	1,053	679
<b>Total current liabilities</b>	<b>9,323</b>	<b>7,602</b>
<b>Long-term liabilities:</b>		
Deferred income taxes	2,330	1,741
Other taxes and long term payables	738	727
Employee related obligations	199	170
Senior notes and loans	4,726	3,494
Convertible senior debentures long term	14	817
<b>Total long term liabilities</b>	<b>8,007</b>	<b>6,949</b>
<b>Contingencies</b> , see note 14		
<b>Total liabilities</b>	<b>17,330</b>	<b>14,551</b>
<b>Equity:</b>		
<b>Teva shareholders equity:</b>		
Ordinary shares as of September 30, 2010 and December 31, 2009: authorized 2,500 million shares and 1,500 million shares, respectively; issued and outstanding 936 million shares and 923 million shares, respectively	49	49

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Additional paid-in capital	13,178	12,880
Retained earnings	8,726	6,662
Accumulated other comprehensive income	639	555
Treasury shares as of September 30, 2010 and December 31, 2009 38 million ordinary shares	(924)	(924)
	21,668	19,222
<b>Non-controlling interests</b>	38	37
<b>Total equity</b>	21,706	19,259
<b>Total liabilities and equity</b>	\$ 39,036	\$ 33,810

The accompanying notes are an integral part of the condensed financial statements.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONSOLIDATED STATEMENTS OF CASH FLOW**

(U.S. dollars in millions)

(Unaudited)

	<b>Nine months ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>Operating activities:</b>		
Net income	\$ 2,566	\$ 1,624
Adjustments to reconcile net income to net cash provided by operations:		
Depreciation and amortization	727	668
Decrease (increase) in working capital items	(274)	175
Deferred income taxes net and uncertain tax positions	(79)	(131)
Purchase of research and development in process	9	
Stock-based compensation	59	41
Impairment of assets	30	39
Other items net	(4)	
<b>Net cash provided by operating activities</b>	<b>3,034</b>	<b>2,416</b>
<b>Investing activities:</b>		
Acquisitions, net of cash acquired of \$218 million	(4,962)	
Purchase of property, plant and equipment	(476)	(507)
Proceeds from realization of investments	598	148
Purchase of investments and other assets	(415)	(274)
Other items net	16	(20)
<b>Net cash used in investing activities</b>	<b>(5,239)</b>	<b>(653)</b>
<b>Financing activities:</b>		
Proceeds from senior notes, net of issuance costs of \$6 million	2,492	
Repayment of short term loans in connection with the acquisition of Barr		(1,750)
Net increase (decrease) in other short-term credit	971	(150)
Dividends paid	(496)	(387)
Proceeds from exercise of options by employees	137	123
Proceeds from long-term loans and other long-term liabilities received	44	305
Conversion of convertible debentures	(45)	
Repayment of long-term loans and other long-term liabilities	(1,968)	(206)
Excess tax benefit on options exercised	11	13
<b>Net cash provided by (used in) financing activities</b>	<b>1,146</b>	<b>(2,052)</b>
<b>Translation adjustment on cash and cash equivalents</b>	<b>(1)</b>	<b>33</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(1,060)</b>	<b>(256)</b>
<b>Balance of cash and cash equivalents at beginning of period</b>	<b>1,995</b>	<b>1,854</b>



<b>Balance of cash and cash equivalents at end of period</b>	\$ 935	\$ 1,598
--	--------	----------

**Supplemental disclosure of non-cash financing activities:**

During the nine months ended September 30, 2010, \$90 million principal amount of convertible senior debentures was converted into approximately 2.8 million Teva shares.

**The accompanying notes are an integral part of the condensed financial statements.**

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements****(Unaudited)****NOTE 1 Basis of presentation:**

The accompanying unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the financial position and results of operations of Teva Pharmaceutical Industries Limited ( "Teva" or the "Company" ). These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements included in its Annual Report on Form 20-F for the year ended December 31, 2009, as filed with the Securities and Exchange Commission. The results of operations for the nine months ended September 30, 2010 are not necessarily indicative of results that could be expected for the entire fiscal year.

**NOTE 2 Certain transactions:*****a. Ratiopharm acquisition***

On August 10, 2010, Teva acquired the total shareholdings and control of Merckle ratiopharm Group ( "ratiopharm" ), a global pharmaceutical company that operates in more than 20 countries, for a total cash consideration of \$5.2 billion. This transaction was accounted for as a business combination. Ratiopharm's results of operations were included in Teva's consolidated financial statements commencing August 2010.

The cash consideration was financed through Teva's internal resources, the issuance of senior notes (see note 3) and credit lines, including credit agreements for an aggregate amount of \$1.5 billion, of which \$500 million had been repaid through September 30, 2010.

With the closing of the acquisition, Teva is now the leading generic company in Europe, with the number two position in Germany and leading market positions in other key European markets. The goodwill arising from the acquisition consists primarily of vertical integration between Teva's API activities and ratiopharm's finished dose manufacturing, synergies and economies of scale.

The table below summarizes the preliminary estimates of the fair value of assets acquired and liabilities assumed and resulting goodwill. These preliminary estimates are subject to revision, which may result in significant adjustments to the preliminary values presented below, when the appraisals are finalized. However, such adjustments are not expected to significantly change the pro-forma information included below.

The primary areas of the preliminary purchase price allocation that are not yet finalized relate to the fair values of intangible assets acquired and liabilities assumed, income taxes and resulting goodwill. We expect to obtain information to assist us in determining the fair value of the net assets acquired at the acquisition date during the measurement period.

	U.S. \$ in millions
Current assets	\$ 1,242
Investment and non-current assets	68
Property, plant and equipment	369
Identifiable intangible assets:	
Existing product rights	1,544
Existing trade name	168
Research and development in-process	458
Goodwill	2,804
<b>Total assets acquired</b>	<b>6,653</b>

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Current liabilities	863
Long-term liabilities, including deferred taxes	610
Total liabilities assumed	1,473
Net assets acquired	\$ 5,180
Cost of investment paid	\$ 5,180

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

Below are certain pro forma combined statement of income data for the nine months ended September 30, 2010 and 2009, as if the acquisition of ratiopharm had occurred on January 1, 2010 and 2009, respectively, after giving effect to: (a) purchase accounting adjustments, including amortization of identifiable intangible assets; (b) estimated additional interest expense due to: (i) borrowings under the one year credit facilities from banks in connection with the acquisition; (ii) the issuance of senior notes in connection with the acquisition; (iii) add-back of interest income on Teva's cash and cash equivalents and marketable securities used as cash consideration in the acquisition; and (iv) add-back of financial expenses of \$102 million resulting from the hedging of the euro denominated purchase price for the acquisition; and (c) elimination of intercompany sales.

This pro forma financial information is not necessarily indicative of the combined results that would have been attained had the acquisition taken place at the beginning of 2010 and 2009, respectively, nor is it necessarily indicative of future results.

	<b>Nine months ended September 30, 2010                      2009 (U.S. \$ in millions, except earnings per share) (Unaudited)</b>	
Net sales	\$ 12,978	\$ 11,714
Net income attributable to Teva	\$ 2,636	\$ 1,554
<b>Earnings per share:</b>		
Basic	\$ 2.94	\$ 1.79
Diluted	\$ 2.90	\$ 1.74

***b. Termination of agreement***

Under agreements entered into by Teva and Sanofi-Aventis, the sale and distribution, in North America, Europe and certain other countries, of Copaxone®, an innovative product of the Company for the treatment of multiple sclerosis, had been carried out by Sanofi-Aventis.

On April 1, 2008, Teva took over the U.S. and Canadian distribution of Copaxone®. Under the terms of the agreements, Sanofi-Aventis was entitled to payment by Teva of previously agreed-upon termination consideration of 25% of the in-market sales of Copaxone® in the U.S. and Canada for an additional two-year period, which ended on April 1, 2010.

***c. Subsequent event Acquisition of Laboratoire Théramex***

On October 28, 2010, we entered into a definitive agreement to acquire Laboratoire Théramex from Merck Serono, for approximately 265 million in cash (approximately \$367 million) and certain performance-based milestone payments.

Théramex offers a wide variety of women's health products and had revenues of approximately 94 million in 2009, more than two-thirds of which were derived from sales in France and Italy. The planned acquisition is expected to expand our women's health business into important growth markets in Europe and the rest of the world.

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Subject to regulatory approval, the transaction is expected to close towards the end of this year or in early 2011.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)****NOTE 3 Issuance of senior notes:**

In June 2010, subsidiaries of the Company issued an aggregate of \$2.5 billion principal amount of senior notes as described in the table below. All such notes are guaranteed by Teva.

Issuer	Annual interest rate	Principal amount issued (U.S. \$ in millions)	Due
Teva Pharmaceutical Finance III, LLC	LIBOR plus 0.40	\$ 500	December 2011
Teva Pharmaceutical Finance III, LLC *	1.5	\$ 1,000	June 2012
Teva Pharmaceutical Finance II, B.V. *	3	\$ 1,000	June 2015

\* In June 2010, the Company entered into two interest rate swap agreements with respect to its \$1 billion principal amount of 1.50% senior notes due 2012 and to its \$1 billion principal amount of 3.00% senior notes due 2015 (see note 11).

**NOTE 4 Inventories:**

Inventories consisted of the following:

	September 30, 2010 Unaudited	December 31, 2009 Audited
	U.S. \$ in millions	
Raw and packaging materials	\$ 1,199	\$ 1,072
Products in process	591	522
Finished products	1,983	1,658
	3,773	3,252
Materials in transit and payments on account	89	80
	\$ 3,862	\$ 3,332

**NOTE 5 Convertible senior debentures:**

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

During the nine months ended September 30, 2010, convertible senior debentures were converted as follows:

	<b>Nine months ended September 30, 2010</b>	
	<b>Principal amount converted (U.S. \$ in millions)</b>	<b>Number of shares converted into (In millions)</b>
0.5% convertible senior debentures due 2024	\$ 34	0.9
0.25% convertible senior debentures due 2024	56	1.7
0.25% convertible senior debentures due 2026	45	0.2
	\$ 135	2.8

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

The balances under convertible senior debentures classified as short-term and long-term were as follows:

	Balance under convertible senior debentures long term		Balance under convertible senior debentures short term	
	September 30, 2010	December 31, 2009	September 30, 2010	December 31, 2009
	U.S. \$ in millions		U.S. \$ in millions	
	Unaudited	Audited	Unaudited	Audited
0.5% convertible senior debentures due 2024	\$ 3	\$ 37	\$	\$
0.25% convertible senior debentures due 2024	11			67
0.25% convertible senior debentures due 2026			530	575
1.75% convertible senior debentures due 2026		780	802	
	\$ 14	\$ 817	\$ 1,332	\$ 642

**NOTE 6 Earnings per share:**

Basic earnings per share is computed by dividing net income attributable to Teva by the weighted average number of ordinary shares outstanding during the period, net of treasury shares.

In computing diluted earnings per share for the three months and nine months ended September 30, 2010 and 2009, respectively, basic earnings per share was adjusted to take into account the potential dilution that could occur upon: (i) the exercise of options and non-vested restricted stock units ( RSUs ) granted under employee stock compensation plans and one series of convertible senior debentures, using the treasury stock method; and (ii) the conversion of the remaining convertible senior debentures using the if-converted method, by adding to net income interest expense on the debentures and amortization of issuance costs, net of tax benefits, and by adding the weighted average number of shares issuable upon assumed conversion of the debentures.

In computing diluted earnings per share for the nine months ended September 30, 2009, no account was taken of the potential dilution of the convertible senior debentures, amounting to 16 million weighted average shares, since they had an anti-dilutive effect on earnings per share.



**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

The net income and the weighted average number of shares used in the computation of basic and diluted earnings per share for the three and nine months ended September 30, 2010 and 2009 are as follows:

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>	<b>2009</b>	<b>September 30,</b>	<b>2009</b>
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
	<b>(in millions)</b>			
Net income attributable to Teva	\$ 1,050	\$ 649	\$ 2,560	\$ 1,621
Interest expense on convertible senior debentures, and issuance costs, net of tax benefits	11	10	33	1
<b>Net income used for the computation of diluted earnings per share</b>	<b>\$ 1,061</b>	<b>\$ 659</b>	<b>\$ 2,593</b>	<b>\$ 1,622</b>
Weighted average number of shares used in the computation of basic earnings per share	899	884	895	867
<b>Add:</b>				
Additional shares from the assumed exercise of employee stock options and unvested RSUs	4	8	6	8
<b>Weighted average number of additional shares issued upon the assumed conversion of convertible senior debentures</b>	<b>18</b>	<b>23</b>	<b>20</b>	<b>21</b>
Weighted average number of shares used in the computation of diluted earnings per share	921	915	921	896

**NOTE 7 Revenue recognition:**

Revenue is recognized when title to, and risk and reward for, a given product are transferred to the customer, with provisions for estimated chargebacks, returns, rebates, discounts and shelf stock adjustments established concurrently with the recognition of revenue, and deducted from sales.

Provisions for chargebacks, returns, rebates and other promotional items are included in Sales reserves and allowances under Current liabilities. Provisions for doubtful debts and prompt payment discounts are netted against Accounts receivable.

The provision calculations are based on historical experience and specific terms in individual agreements. Chargebacks are the single largest component of sales reserves and allowances. Provisions for estimating chargebacks are determined using historical chargeback experience, or expected chargeback levels and wholesaler sales information for new products, which are compared to externally obtained distribution channel reports for reasonableness. Shelf-stock adjustments are granted to customers based on existing inventory of a customer following actual or anticipated decreases in the invoice or contract price of the related product. Where there is historical experience of customer returns, Teva records a reserve for estimated sales returns by applying that experience to the amounts invoiced, taking into account the amount of returned products to be destroyed compared to product that can be placed back in inventory for resale.



**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)****NOTE 8 Comprehensive income:**

Comprehensive income is as follows:

	Three months ended September 30,		Nine months ended September 30,	
	U.S. \$ in millions			
	2010	2009	2010	2009
Net income	\$ 1,052	\$ 650	\$ 2,566	\$ 1,624
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) from available-for-sale securities, net of tax	(3)	4	26	(3)
Unrealized loss on derivative financial instruments	(85)		(78)	
Realization and reclassification adjustment on available for sales securities, net of tax	2	(3)	(24)	(10)
Currency translation adjustment, net of tax	1,500	689	156	603
<b>Total comprehensive income</b>	<b>2,466</b>	<b>1,340</b>	<b>2,646</b>	<b>2,214</b>
Comprehensive loss (income) attributable to the non-controlling interests	2	(4)	(2)	(6)
<b>Comprehensive income attributable to Teva</b>	<b>\$ 2,468</b>	<b>\$ 1,336</b>	<b>\$ 2,644</b>	<b>\$ 2,208</b>

**NOTE 9 Entity-wide disclosures:**

Net sales by geographic area were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	U.S. \$ in millions			
	2010	2009	2010	2009
North America	\$ 2,724	\$ 2,228	\$ 7,500	\$ 6,261
Europe	1,001	830	2,624	2,346
International markets	525	492	1,579	1,490
	\$ 4,250	\$ 3,550	\$ 11,703	\$ 10,097

**NOTE 10 Fair value measurement:**

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

Financial items carried at fair value as of September 30, 2010 and December 31, 2009 are classified in the tables below in one of the three categories described above:

	September 30, 2010			Total
	U.S. \$ in millions			
	Level 1	Level 2	Level 3	
Cash and cash equivalents:				
Money markets	\$ 166	\$	\$	\$ 166
Cash deposits and other	769			769
Marketable securities*:				
Auction rate securities			68	68
Collateral debt obligations	11		1	12
Equity securities	103			103
Structured investment vehicles		83		83
Other	10			10
Derivatives **::				
Liability derivatives mainly options and forward contracts		(13)		(13)
Interest rate and cross-currency swaps (liabilities)		(143)		(143)
Interest rate swaps (assets)		62		62
Asset derivatives mainly options and forward contracts		81		81
<b>Total</b>	<b>\$ 1,059</b>	<b>\$ 70</b>	<b>\$ 69</b>	<b>\$ 1,198</b>

	December 31, 2009			Total
	U.S. \$ in millions			
	Level 1	Level 2	Level 3	
Cash and cash equivalents:				
Money markets	\$ 512	\$	\$	\$ 512
Cash deposits and other	1,483			1,483
Marketable securities*:				
Auction rate securities			75	75
Collateral debt obligations	13		1	14
Equity securities	104			104
Structured investment vehicles		37		37
Other mainly debt securities	240			240
Derivatives net**		(11)		(11)
<b>Total</b>	<b>\$ 2,352</b>	<b>\$ 26</b>	<b>\$ 76</b>	<b>\$ 2,454</b>

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

- \* Marketable securities consist mainly of debt securities classified as available-for-sale and are recorded at fair value. The fair value of quoted securities is based on current market value (Level 1 input) or observable prices (Level 2 input). When securities do not have an active market or observable prices, fair value is determined using a valuation model (Level 3 input). This model is based on reference to other instruments with similar characteristics, or a discounted cash flow analysis, or other pricing models making use of market inputs and relying as little as possible on entity-specific inputs.
- \*\* Derivatives primarily represent foreign currency and option contracts and interest rate swaps which are valued primarily based on observable inputs including interest rate curves and both forward and spot prices for currencies.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

The following table summarizes the activity for those financial assets where fair value measurements are estimated utilizing Level 3 inputs.

	<b>2010</b>	<b>2009</b>
	<b>U.S. \$ in millions</b>	
Carrying value as of January 1	\$ 76	\$ 98
Amount realized		(8)
Net change to fair value:		
Loss included in other comprehensive income (loss)	(7)	(25)
Carrying value as of September 30,	\$ 69	\$ 65

Teva's financial instruments consist mainly of cash and cash equivalents, marketable securities, current and non-current receivables, short-term credit, accounts payable and accruals, long-term loans and other long-term senior notes and loans, convertible senior debentures and derivatives.

The fair value of the financial instruments included in working capital and non-current receivables is usually identical or close to their carrying value. The fair value of long-term bank loans and senior notes also approximates their carrying value, since they bear interest at rates close to the prevailing market rates. The fair value of the senior notes, convertible senior debentures and interest rate swap agreements included under long-term liabilities amounted to \$4,496 million and \$2,150 million at September 30, 2010, and December 31, 2009, respectively, based on quoted market values and prevailing market rates. The fair value of interest rate swap agreements included under long term investments and receivables amounted to \$62 million and \$10 million at September 30, 2010 and December 31, 2009, respectively.

The fair values and the carrying amounts of derivatives and convertible senior debentures with an earliest date of redemption within 12 months are assets of \$81 million and \$20 million (derivatives) and liabilities of \$1,297 million and \$771 million (convertible senior debentures and derivatives) at September 30, 2010, and December 31, 2009, respectively. The fair value of derivatives generally reflects the estimated amounts that Teva would receive or pay to terminate the contracts at the reporting dates.

Changes in fair value of available for sale securities, net of taxes, are reflected in other comprehensive income. Unrealized losses considered to be temporary are reflected in other comprehensive income; unrealized losses that are considered to be other-than-temporary are charged to income as an impairment charge. On April 1, 2009, the Company adopted an accounting pronouncement that changes the method for determining whether another-than-temporary impairment exists for debt securities and the amount of the impairment to be recorded in earnings. At December 31, 2009, as well as at September 30, 2010, the credit loss was \$293 million.

In January 2010, the FASB updated its guidance regarding fair value measurements disclosures. More specifically, this update requires (a) an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers; and (b) information about purchases, sales, issuances and settlements to be presented separately (i.e. the activity is to be presented on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This update clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value, and requires disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. As applicable to Teva, this guidance is effective as of January 1, 2010, except for the gross presentation of the Level 3 roll forward information, which is required beginning January 1, 2011. As applicable to Teva, the adoption of the new guidance did not have a material impact on its consolidated financial statements.

**NOTE 11 Derivative instruments and hedging activities:**

*a. Interest rate and cross-currency swaps*

During the second quarter of 2010, the Company entered into swap agreements with respect to its \$1 billion principal amount of 1.50% senior notes due 2012 and its \$1 billion principal amount of 3.00% senior notes due 2015.

The purpose of the interest rate swap agreement with respect to the 2012 senior notes was to change the interest rate from fixed to floating rate. As a result of this agreement, Teva is currently paying an effective interest rate of three months LIBOR plus an average 0.41% on the \$1 billion principal amount, as compared to the stated 1.50% fixed rate.



**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes To Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

The purpose of the interest rate and cross-currency swap agreement with respect to the 2015 senior notes was to convert the notes' denomination from dollars to euros. As a result of this agreement, Teva pays a fixed rate of 2.36% on the euro principal amount, as compared to the stated 3.00% fixed rate on the dollar principal amount.

The above transactions qualify for hedge accounting.

***b. Derivative instrument disclosure***

The fair value of derivative instruments consists of:

1. Asset derivatives, comprising interest rate and cross-currency swap agreements, designated as hedging instruments. These are reported under long-term investments and receivables, and the fair value amounted to \$62 million and \$10 million at September 30, 2010 and December 31, 2009, respectively.
2. Asset derivatives, comprising primarily foreign exchange contracts, not designated as hedging instruments for accounting purposes. These are reported under deferred taxes and other current assets, and the fair value amounted to \$81 million and \$20 million at September 30, 2010 and December 31, 2009, respectively.
3. Liability derivatives, comprising interest rate swap agreements, designated as hedging instruments. These are reported under senior notes and loans, and the fair value amounted to \$143 million and \$10 million at September 30, 2010 and December 31, 2009, respectively.
4. Liability derivatives, comprising foreign exchange contracts, not designated as hedging instruments for accounting purposes. These are reported under accounts payable, and the fair value amounted to \$13 million and \$31 million at September 30, 2010 and December 31, 2009, respectively.

Derivatives on foreign exchange contracts hedge Teva's balance sheet items from currency exposure but are not designated as hedging instruments for accounting purposes. With respect to such derivatives, losses of \$14 million and \$27 million were recognized under financial expenses-net for the nine months ended September 30, 2010 and 2009, respectively, and a gain of \$104 million and a gain of \$43 million were recognized under financial expenses-net for the three months ended September 30, 2010 and 2009, respectively. Such losses offset the revaluation of the balance sheet items also booked under financial expenses-net.

With respect to the interest rate and cross-currency swap agreements, gains of \$14 million and \$6 million were recognized under financial expenses-net for the nine months and three months ended September 30, 2010, respectively. Such gains mainly reflect the differences between the fixed interest rate and the floating interest rate.

***c. Derivative instruments in connection with the ratiopharm acquisition***

In anticipation of the closing of the ratiopharm acquisition, the Company entered into derivative transactions, which include forward and option contracts, in the amount of 1.5 billion, in order to partially hedge the euro-denominated acquisition commitment of 3.6 billion. As these

transactions did not qualify for hedge accounting, the change in fair value of these transactions was recognized under finance expenses net, resulting in a loss of \$102 million and a gain of \$45 million for the nine months and the three months ended September 30, 2010, respectively.

**NOTE 12 Recently adopted and issued accounting pronouncements:**

***a. Recently adopted accounting pronouncements:***

In June 2009, the FASB updated accounting guidance relating to variable interest entities. As applicable to Teva, this guidance was effective commencing January 1, 2010. The adoption of the new guidance did not have a material impact on the consolidated financial statements.

***b. Recently issued accounting pronouncements:***

In October 2009, the FASB issued amendments to the accounting and disclosure for revenue recognition. These amendments, effective for fiscal years beginning on or after June 15, 2010 (early adoption is permitted), modify the criteria for recognizing revenue in multiple element arrangements and require companies to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. Additionally, the amendments eliminate the residual

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

method for allocating arrangement considerations. Teva believes that the adoption will not have a material impact on its consolidated financial statements.

In April 2010, the FASB issued an amendment to the accounting and disclosure for revenue recognition milestone method. This amendment, effective for fiscal years beginning on or after June 15, 2010 (early adoption is permitted), provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. Teva believes that the adoption will not have a material impact on its consolidated financial statements.

**NOTE 13 Legal settlements, acquisition and restructuring expenses and impairment:**

Legal settlements, acquisition and restructuring expenses and impairment consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
	U.S. \$ in millions			
Legal settlements	\$ (1)	\$ 13	\$ (7)	\$ 55
Acquisition expenses	6		21	
Restructuring expenses	21	47	34	69
Impairment of long-lived assets	27	37	30	39
<b>Total</b>	<b>\$ 53</b>	<b>\$ 97</b>	<b>\$ 78</b>	<b>\$ 163</b>

**NOTE 14 Contingencies:****General**

From time to time, Teva and its subsidiaries are subject to legal claims for damages and/or equitable relief arising in the ordinary course of business. In addition, as described below, in large part as a result of the nature of its business, Teva is frequently subject to patent litigation. Teva believes it has meritorious defenses to the actions to which it is a party and vigorously pursues the defense of each such action, including those described below. Based upon the status of these cases, management's assessment of the likelihood of damages, the potential exposure involved relative to insurance coverage, and the advice of counsel, no provision has been made in Teva's financial statements for any of such actions except as otherwise noted below. Furthermore, based on currently available information, Teva believes that none of the proceedings described below is likely to have a material adverse effect on its financial condition; however, if one or more of such proceedings were to result in judgments against Teva, such judgments could be material to its results of operations in a given period.

From time to time, Teva seeks to develop generic products for sale prior to patent expiration in various territories. In the United States, to obtain approval for most generic products prior to the expiration of the originator's patent(s), Teva must challenge the patent(s) under the procedures set forth in the Hatch-Waxman Act of 1984, as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003. To the extent that it seeks to utilize such patent challenge procedures, Teva is and expects to be involved in patent litigation regarding the validity, enforceability or infringement of the originator's patent(s). Teva may also be involved in patent litigation involving the extent to which alternate manufacturing process techniques may infringe originator or third-party process patents.

Additionally, depending upon a complex analysis of a variety of legal and commercial factors, Teva may, in certain circumstances, elect to market a generic product even though litigation is still pending. This could be before any court decision is rendered or while an appeal of a lower

court decision is pending. To the extent Teva elects to proceed in this manner, it could face substantial liability for patent infringement if the final court decision is adverse to Teva. Although Teva currently has insurance coverage for certain types of damages for patent infringement, a claim for coverage may be subject to a deductible, involve a co-insurance participation, exceed policy limits or be ultimately found to relate to damages that are not covered by Teva's policy. Except as described below, Teva does not have a reasonable basis to estimate the loss, or range of loss, that is reasonably possible with respect to such patent infringement cases. However, if Teva were to be required to pay damages in any such case, courts would generally calculate the amount of any such damages based on a reasonable royalty or lost profits of the patentee. If damages were based on a reasonable royalty, the amount would be related to a percentage of the sales of Teva's generic product. If damages were determined based on lost profits, the amount would be related to the sales of the branded product. In addition, the launch of an authorized generic and other generic competition may be relevant to the damages estimation. Although the legislation concerning

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes To Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

generic pharmaceuticals, as well as the patent law, is different in countries other than the United States where Teva does business, from time to time Teva is also involved in litigation regarding corresponding patents in those countries.

Teva's business inherently exposes it to potential product liability claims. As Teva's portfolio of available products continues to expand, the number of product liability claims asserted against Teva has increased. Teva believes that it maintains product liability insurance coverage in amounts and with terms that are reasonable and prudent in light of its business and related risks. However, Teva sells, and will continue to sell, pharmaceutical products that are not covered by insurance and accordingly may be subject to claims that are not covered by insurance as well as claims that exceed its policy limits. Product liability coverage for pharmaceutical companies is becoming more expensive and increasingly difficult to obtain. As a result, Teva may not be able to obtain the type and amount of coverage it desires.

In connection with third-party agreements, Teva may under certain circumstances be required to indemnify, and may be indemnified by, in unspecified amounts, the parties to such agreements against third-party claims.

***Intellectual Property Matters***

In 1992, Teva Canada Limited (Teva Canada, which was then known as Novopharm Limited) commenced sales of zidovudine or azidothymidine (AZT), which is a generic version of Retrovir. Teva Canada ceased sales of AZT in December 2002, when the Supreme Court of Canada upheld the patent as valid and infringed. Although the patent subsequently expired in March 2006, Teva Canada has not resumed sales of AZT. A provision for this matter has been included in the financial statements. The trial to quantify damages is currently scheduled to begin on May 30, 2011.

In October 2004, Alpharma and Teva launched their 100 mg, 300 mg and 400 mg gabapentin capsule products and, in December 2004, Alpharma and Teva launched their 600 mg and 800 mg gabapentin tablet products. Gabapentin capsules and tablets are the AB-rated generic versions of Pfizer's anticonvulsant Neurontin capsules and tablets, which had annual sales of approximately \$2.7 billion for the twelve months ended September 2004, based on IMS data. Teva's subsidiary IVAX Pharmaceuticals, Inc. (IVAX) also launched its non-AB rated tablets in August 2004 and its AB-rated capsules and tablets in March and April 2005, respectively. In August 2005, the United States District Court for the District of New Jersey granted summary judgment in favor of Teva, Alpharma and IVAX. On September 21, 2007, the Court of Appeals for the Federal Circuit (the Federal Circuit) reversed the summary judgment decision and remanded the case for further proceedings. A trial has not been scheduled. The patent at issue expires in 2017. Were Pfizer ultimately to be successful in its allegation of patent infringement, Teva could be required to pay damages relating to sales of its gabapentin products and be enjoined from selling its gabapentin products until patent expiry. Pursuant to the terms of the agreement with Alpharma, were Pfizer to be successful in its allegation of patent infringement against Alpharma, Teva may also be required to indemnify Alpharma against damages related to a portion of the sales of Alpharma's gabapentin products.

In May 2007, Teva commenced sales of its 300 mg cefdinir capsule product and 125 mg/5 ml and 250 mg/5 ml cefdinir powder for oral suspension products. Cefdinir capsules and cefdinir for oral suspension are the AB-rated generic versions of Abbott's antibiotic Omnicel, which had annual sales of approximately \$860 million for the twelve months ended December 2006, based on IMS data. Teva is in litigation with Abbott in the United States District Court for the Northern District of Illinois with respect to a polymorph patent that expires in 2011. In May 2007, the District Court denied Abbott's motion for a preliminary injunction, finding that Abbott was not likely to prevail on the merits as to Teva's noninfringement defense, based on the record before the Court. In May 2009, the Federal Circuit affirmed the District Court's denial of the preliminary injunction. On January 11, 2010, the United States Supreme Court denied Abbott's petition for certiorari. The case was remanded to the District Court, and has now been settled under terms that are confidential.

In May 2007, Teva commenced sales of its 2.5mg/10mg, 5mg/10mg, 5mg/20mg, and 10mg/20mg amlodipine besylate/benazepril capsules. Amlodipine besylate/benazepril capsules are the AB-rated generic versions of Novartis' Lotrel, which had annual sales of approximately \$1.4 billion for the twelve months ended March 2007, based on IMS data. In June 2007, the United States District Court for the District of New Jersey denied Novartis' motion for a preliminary injunction, finding that Novartis was not likely to succeed on its allegations of infringement. The patent at issue expires in 2017. A trial date has not been scheduled. Were Novartis ultimately to be successful in its allegation of patent infringement, Teva could be required to pay damages related to sales of its amlodipine besylate/benazepril capsules and be enjoined from selling

those products until patent expiry.

In June 2007, Teva Canada commenced sales of its 2.5 mg, 5 mg, 7.5 mg, 10 mg and 15 mg olanzapine tablets, which are the generic versions of Eli Lilly's Zyprexa®. Zyprexa® had annual sales in Canada of approximately \$180 million for the twelve months ended May 2007, based on IMS data. In June 2007, the Federal Court of Canada denied Lilly's request to prohibit the Minister of Health from issuing Teva Canada's final regulatory approval. Shortly after the launch by Teva Canada, Lilly filed an action for patent infringement. In October 2009, the patent at issue, which was otherwise set to expire on April 24, 2011, was held to be invalid. On July 21, 2010, the Court of Appeal set aside the judgment of the Federal Court, with two grounds of invalidity being sent back to the

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes To Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

Federal Court for reconsideration in accordance with the Court of Appeal's instructions. Were Lilly ultimately to be successful with regard to these invalidity issues, Teva Canada could be required to pay damages related to its sales of olanzapine tablets and be enjoined from selling those products until patent expiry.

In December 2007, Teva commenced sales of its 20 mg and 40 mg pantoprazole sodium tablets. Pantoprazole sodium tablets are the AB-rated generic versions of Wyeth's Protonix®, which had annual sales of approximately \$2.5 billion for the twelve months ended September 2007, based on IMS data. In September 2007, the United States District Court for the District of New Jersey denied Wyeth/Altana's motion for a preliminary injunction, finding that Wyeth/Altana was not likely to prevail on the merits as to Teva's invalidity defense on the compound patent, based on the record before the Court. In May 2009, the Federal Circuit affirmed the District Court's denial of the preliminary injunction. The patent at issue expired on July 19, 2010, and the innovator has been granted pediatric exclusivity, which expires on January 19, 2011. On April 23, 2010, the jury returned a verdict finding that the patent is not invalid. On July 16, 2010, the Court denied Teva's motion to overturn the verdict. Based on the fact that Teva has defenses remaining at the trial level, including patent misuse, the Court also denied Wyeth/Altana's request that Teva's final approval date be reset to January 2011. A ruling for Teva on the patent misuse claim may render the patent unenforceable. The parties are in discovery on the remaining patent and damages issues. In addition, Teva believes that it has substantial grounds for appeal of the Court's decision on invalidity and intends to pursue its appeals vigorously. Teva does not believe that an award of damages in this matter is probable. In addition, in light of the rulings prior to Teva's launch denying a preliminary injunction to Wyeth/Altana, Teva believes that the likelihood of treble damages is remote. Were Wyeth/Altana ultimately to be successful in its allegation of patent infringement, Teva could be required to pay damages relating to the sale of its pantoprazole sodium tablets and be enjoined from further selling those products until patent expiry.

In May 2010, Teva commenced sales of its drospirenone and ethinyl estradiol tablets under the name Gianvi™. Gianvi™ tablets are the generic version of Bayer's Yasmin® tablets, which had sales of approximately \$782 million for the twelve months ended December 31, 2009, based on IMS data. On June 1, 2010, Teva filed suit against Bayer in the Southern District of New York, seeking declaratory judgment of invalidity and non-infringement of three Orange Book patents that expire on June 30, 2014. On June 7, 2010, Bayer filed suit against Teva in the United States District Court for the District of Nevada alleging infringement of the same three patents. Teva has filed a motion to transfer the Nevada action to New York, where its declaratory judgment action is pending. Were Bayer ultimately to be successful in its allegation of patent infringement, Teva could be required to pay damages relating to the sale of its Gianvi™ tablets and be enjoined from further selling those products until patent expiry. A provision for this matter has been included in the financial statements.

In July 2008, Teva learned that Sandoz Inc., the U.S. generic drug division of Novartis AG, in conjunction with Momenta Pharmaceuticals, Inc., had filed an ANDA with the FDA for a generic version of Copaxone® (glatiramer acetate) containing Paragraph IV certifications to each of the patents that Teva has listed in the FDA's Orange Book for the product. On August 28, 2008, Teva filed a complaint against Sandoz, Inc., Sandoz International GmbH, Novartis AG and Momenta Pharmaceuticals, Inc. in the United States District Court for the Southern District of New York, alleging infringement of four Orange Book patents. The patents, which expire on May 24, 2014, cover the chemical composition of Copaxone®, pharmaceutical compositions containing it and methods of using it. The lawsuit triggered a stay of any FDA approval of the Sandoz ANDA until the earlier of the expiration of a period of 30 months or a district court decision in Sandoz's favor. Sandoz, Inc. and Momenta Pharmaceuticals Inc. filed their answers to Teva's complaint in November 2008, asserting several affirmative defenses to Teva's patent infringement claims, including non-infringement, invalidity and unenforceability of the asserted Orange Book patents. The answers also seek declaratory judgments of non-infringement, invalidity and unenforceability with respect to three unasserted Orange Book patents and two non-Orange Book patents. In December 2008, Sandoz International GmbH and Novartis AG brought a motion to dismiss Teva's patent claims on personal jurisdiction grounds, which is still pending. In December 2009, Sandoz filed a motion for summary judgment of invalidity based on indefiniteness, which was denied on September 7, 2010. A claim construction hearing was held on January 20, 2010. A trial date has not been scheduled. On December 10, 2009, Teva filed a separate complaint against Sandoz and Momenta alleging infringement of four marker non-Orange Book patents, the last of which expires in February 2020. On January 7, 2010, Sandoz moved to dismiss these claims, arguing that their alleged infringing acts were protected under statute and/or not ripe at the current time.

On October 16, 2009, after learning that Mylan Laboratories, Inc. had filed an ANDA containing Paragraph IV certifications with the FDA for a generic version of Copaxone®, Teva filed a complaint against Mylan and Natco Pharma Limited in the United States District Court for the Southern District of New York, alleging infringement of each of the seven Orange Book patents. Mylan and Natco's answers to the complaint also included declaratory judgment claims with respect to two non-Orange Book patents. No trial date has been scheduled. On September 21,

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

2010, Teva filed a separate complaint against Mylan and Natco alleging infringement of the four marker patents. The Sandoz/Momenta and Mylan cases have been consolidated for trial.

As described above, Copaxone<sup>®</sup>, Teva's leading innovative product, from which it derives substantial revenues and which contributes disproportionately to its profits, faces intense patent challenges. Although Teva believes that Copaxone<sup>®</sup> has strong patent



---

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes To Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

protection, should its patents be successfully challenged or should there be a launch at risk, Teva may face intense generic competition for Copaxone<sup>®</sup>, which would adversely affect its results of operations.

***Product Liability Matters***

Barr and Duramed have been named as defendants in approximately 6,000 personal injury product liability cases brought against them and other manufacturers by plaintiffs claiming injuries from the use of certain estrogen and progestin products. The cases primarily involve medroxyprogesterone acetate (a progestin that has been prescribed to women receiving estrogen-containing hormone therapy), and a much smaller number involve Cenestin<sup>®</sup> (an estrogen-containing product sometimes prescribed to treat symptoms associated with menopause). A high percentage of the plaintiffs were unable to demonstrate actual use of a Barr or Duramed product. As a result, approximately 5,500 cases have been dismissed, leaving approximately 510 pending. To date, Barr and Duramed products have been identified in 490 of those cases. Additional dismissals are expected. The vast majority of the claims are covered by insurance.

Teva and its subsidiary Pliva, Inc. have been named as defendants in over 400 product liability lawsuits brought against them and other manufacturers by plaintiffs claiming injuries from the use of metoclopramide (the generic form of Reglan<sup>®</sup>). Those claims include allegations of neurological disorders, including tardive dyskinesia, as a result of ingesting the product. For over twenty years, the FDA-approved label for metoclopramide has contained warning language about the risk of tardive dyskinesia, and that the risk of developing this syndrome increased with duration of treatment and total cumulative dose. In February 2009, the FDA announced that manufacturers of metoclopramide would be required to revise the label, including the addition of a black box warning about the risk of tardive dyskinesia from long-term exposure to metoclopramide. The vast majority of the cases are in the very early stages, and it has not yet been determined how many plaintiffs actually used a Teva or Pliva product. Teva and Pliva expect to be dismissed from at least some of these cases where plaintiffs cannot demonstrate that they used either a Teva or Pliva product. Certain of these claims are currently covered by insurance.

Teva Parenteral Medicines, Inc. has been named as a defendant in almost 250 lawsuits in state court in Las Vegas, Nevada relating to its propofol product. The plaintiffs in these lawsuits claim that they were infected with the hepatitis C virus as a result of the re-use, by medical practitioners at a series of commonly owned endoscopy centers, of single-patient vials of propofol on more than one patient. Teva's propofol product states in its label that it is for single-patient use only and that aseptic techniques must be followed at all times when using the product. Teva is also named as a defendant in almost 100 other cases brought by plaintiffs who were also patients at these endoscopy centers, but who have not contracted the virus. These plaintiffs allege a cause of action based on the fear of contracting an infectious disease. The first trial began on April 12, 2010, and on May 5, 2010, the jury returned a verdict in favor of plaintiffs for \$5.1 million in compensatory damages. On May 7, 2010, the jury awarded \$356 million in punitive damages against Teva and \$144 million in punitive damages against Baxter, the distributor of the product. Baxter is seeking indemnification from Teva for the damages awarded by the jury, but Teva believes that the indemnification agreement at issue does not extend to punitive damages. The Court ordered Teva to post a bond of approximately \$580 million (covering both Teva and Baxter's damages together with estimated post-judgment interest for three years) to stay execution of the judgment pending appeal, and Teva did so on August 18, 2010. Teva filed several post-trial motions, all of which were denied, and final judgment was entered on September 28, 2010. Teva believes that it has numerous grounds for reversal of the jury verdicts, which have been appealed to the Nevada Supreme Court. Teva does not believe that an award of damages in this matter is probable. Jury selection in another trial is scheduled to begin on November 8, 2010.

***Competition Matters***

In April 2006, Teva and its subsidiary Barr Laboratories were sued, along with Cephalon, Inc., Mylan Laboratories, Inc., Ranbaxy Laboratories Ltd. and Ranbaxy Pharmaceuticals, Inc., in a class action lawsuit filed in the United States District Court for the Eastern District of Pennsylvania. The case alleges generally that the settlement agreements entered into between the different generic pharmaceutical companies and Cephalon, in their respective patent infringement cases involving finished modafinil products (the generic version of Provigil<sup>®</sup>), were unlawful because the settlement agreements resulted in the exclusion of generic competition. The case seeks unspecified monetary damages, attorneys' fees and costs. The case was brought by King Drug Company of Florence, Inc. on behalf of itself and as a proposed class action on behalf of any other person or entity that purchased Provigil<sup>®</sup> directly from Cephalon from January 2006 until the alleged unlawful conduct

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

ceases. Similar allegations have been made in a number of additional complaints, including those filed on behalf of proposed classes of direct and indirect purchasers of the product, by an individual indirect purchaser of the product, certain retail chain pharmacies that purchased the product and by Apotex, Inc. The cases seek various forms of injunctive and monetary relief, including treble damages and attorneys' fees and costs. In February 2008, following an investigation of these matters, the Federal Trade Commission (FTC) sued Cephalon, alleging that Cephalon violated Section 5 of the Federal Trade Commission Act, which prohibits unfair or deceptive acts or practices in the marketplace, by unlawfully maintaining a monopoly in the sale of Provigil® and improperly excluding generic competition. The FTC's complaint does not name Teva or Barr as a defendant. On March 29, 2010, the Court denied defendants' motions to dismiss the federal antitrust claims and some of the related state law claims. In November 2009, another class action lawsuit with essentially the same allegations was

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes To Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

initiated by an independent pharmacy in Tennessee. In May 2010, another independent pharmacy also filed suit in Ohio with the same allegations. Both of these cases have been transferred to the Eastern District of Pennsylvania.

Teva Pharmaceuticals USA, Inc. (Teva USA) was named as a defendant, along with Biovail Corp. and Elan Corporation, plc, in several civil actions currently pending in the United States District Court for the District of Columbia. The cases allege generally that arrangements between Biovail and Elan relating to sales of nifedipine cc extended release tablets, in connection with which Teva USA acted as a distributor for Biovail, were unlawful under the federal antitrust laws. The challenged arrangements were previously the subject of a consent decree entered into by the FTC with Biovail and Elan, to which Teva USA was not a party. The complaints seek unspecified monetary damages, attorneys' fees and costs. Four of the cases were brought on behalf of alleged classes of persons who allegedly purchased nifedipine cc extended release tablets made by Elan or Biovail in the United States directly from Teva USA. Two cases that were brought individually by alleged direct purchasers were dismissed as to Teva USA pursuant to a settlement agreement between those purchasers and Teva USA. Teva has entered into a settlement agreement with the class plaintiffs for \$10 million, which was preliminarily approved by the court on July 7, 2010.

Barr has been named as a co-defendant with Bayer Corporation, The Rugby Group, Inc. and others in approximately 38 class action complaints filed in state and federal courts by direct and indirect purchasers of ciprofloxacin (Cipro<sup>®</sup>) from 1997 to the present. The complaints allege that a 1997 Bayer-Barr patent litigation settlement agreement was anti-competitive and violated federal antitrust laws and/or state antitrust and consumer protection laws. A prior investigation of this agreement by the Texas Attorney General's office on behalf of a group of state attorneys general was closed without further action in December 2001. In March 2005, the court in the federal multi-district litigation granted summary judgment in Barr's favor and dismissed all of the federal actions before it. In November 2007, the Second Circuit transferred the appeal involving the indirect purchaser plaintiffs to the Court of Appeals for the Federal Circuit, while retaining jurisdiction over the appeals of the direct purchaser plaintiffs. In October 2008, the Federal Circuit affirmed the grant of summary judgment in the defendants' favor on all claims by the indirect purchaser plaintiffs. The plaintiffs' petition for a panel rehearing and rehearing *en banc* was denied in December 2008. The plaintiffs filed a petition for certiorari to the United States Supreme Court, which was denied in June 2009. On April 29, 2010, the Second Circuit also affirmed the grant of summary judgment in the defendants' favor on all claims by the direct purchaser plaintiffs. On May 19, 2010, plaintiffs filed their petition for a rehearing *en banc*, which was denied on September 7, 2010. Plaintiffs' time to petition for *certiorari* to the United States Supreme Court has not yet expired. All but three of the state cases have been dismissed. Following an earlier stay of the California case, the California court granted defendants' summary judgment motions on August 21, 2009, and directed the entry of final judgment on September 24, 2009. Plaintiffs have appealed this decision. The Kansas action is stayed, and the Florida action is in the very early stages, with no hearings or schedule set to date.

Teva believes that the agreements at issue in the foregoing matters are valid settlements to patent lawsuits and cannot form the basis of an antitrust claim.

***Government Reimbursement Investigations and Drug Pricing Litigation***

Together with many other pharmaceutical manufacturers, Teva and/or its subsidiaries in the United States, including Teva USA, Sicom Inc. (Sicom), IVAX, and Barr (collectively, the Teva parties), are defendants in a number of cases pending in state and federal courts throughout the country that relate generally to drug price reporting by manufacturers. Such price reporting is alleged to have caused governments and others to pay inflated reimbursements for covered drugs. These drug pricing cases, which seek unspecified amounts in money damages, civil penalties, treble damages, punitive damages, attorneys' fees, and/or administrative, injunctive, equitable or other relief, are at various stages of litigation.

In May 2008, the United States District Court for the District of Massachusetts unsealed a drug pricing action against several generic pharmaceutical companies, including various Teva parties. The action was filed by a private party pursuant to the federal False Claims Act, and it alleges, on behalf of the federal government, drug pricing claims arising from the federal government's contributions to the various state Medicaid programs. According to the complaint, the federal government declined to intervene in the litigation. In December 2009, the Teva parties reached an agreement in principle to settle this matter and the Florida and Texas matters mentioned below, as well as another previously unserved action in California (which Teva understands was dismissed without prejudice), and provision for the settlement was included in the financial statements for the fourth quarter of 2009. In July 2010, the Teva parties executed a settlement agreement with the plaintiffs, pursuant to

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

which the pending actions were dismissed.

Additionally, a number of state attorneys general, approximately 47 counties in New York and the City of New York have also filed various actions relating to drug price reporting. The Teva parties (either collectively or individually) have been named in one or more actions in numerous states relating to reimbursements under Medicaid or other programs, including Alaska, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Mississippi, Missouri, New York, Oklahoma, South Carolina, Texas, Utah and Wisconsin. In addition to the actions relating to their Medicaid programs, the states of Mississippi and South Carolina have brought actions in their state courts on behalf of their state health plans. The Teva parties reached a settlement in principle with counsel for the New York

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes To Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

litigants and the state of Iowa, and entered into settlement agreements with the states of Hawaii, Alaska, Idaho and Kentucky. A provision for the cases, including the settlements, was included in the financial statements for the fourth quarter of 2009.

Class actions and other cases have been filed against over two dozen pharmaceutical manufacturers, including Sicom, regarding allegedly inflated reimbursements or payments under Medicare or certain insurance plans. These cases were consolidated under the federal multi-district litigation procedures and are currently pending in the United States District Court for the District of Massachusetts (the MDL ). In March 2008, the Track 2 defendants in the MDL, including Sicom, entered into a settlement agreement to resolve the MDL. The court granted preliminary approval of the amended MDL settlement in July 2008, and a hearing for final approval has been postponed for procedural reasons. A provision for these matters, including Sicom's share of the MDL settlement payment, was included in the financial statements.

In December 2009, the United States District Court for the District of Massachusetts unsealed a complaint alleging that numerous drug manufacturers, including Teva USA and other subsidiaries, violated the federal False Claims Act in connection with Medicaid reimbursement for certain vitamins, dietary supplements and DESI products that were allegedly ineligible for reimbursement. The Department of Justice declined to join in the matter.

***Environmental Matters***

Teva's subsidiaries, including those in the United States and its territories, are parties to a number of proceedings, including some brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as the Superfund law, or other national, federal, provincial or similar state and local laws imposing liability for compliance or regulatory matters or the investigation and remediation of releases of hazardous substances and for natural resource damages. Many of these proceedings seek to require the generators of hazardous wastes disposed of at a third-party owned site, or the party responsible for a release of hazardous substances into the environment that impacted a site, to investigate and clean up the sites or to pay for such activities and any related damages to natural resources. Teva has been made a party to these proceedings, along with other potentially responsible parties, as an alleged generator of wastes that were disposed of or treated at third-party waste disposal sites, or as a result of an alleged release from one of Teva's (or its predecessors') facilities or former facilities that may have adversely impacted a site.

In many of these cases, the government or private litigants allege that the responsible parties are jointly and severally liable for the investigation and cleanup costs. Although the liability among the responsible parties may be joint and several, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties reflects the relative contributions of the parties to the site conditions and takes into account other pertinent factors. Teva's potential liability varies greatly at each of the sites in the proceedings; for some sites the costs of the investigation, cleanup and natural resource damages have not yet been determined, and for others Teva's allocable share of liability has not been determined. At other sites, Teva has been paying a share of the costs, but the amounts have not been, and are not expected to be, material. Teva has taken an active role in identifying those costs, to the extent they are estimable, which do not include reductions for potential recoveries of cleanup costs from insurers, former site owners or operators. In addition, civil proceedings relating to alleged federal and state regulatory violations at some of Teva's facilities may result in the imposition of significant civil penalties, in amounts not currently determinable, and require that corrective action measures be implemented.

**Table of Contents**

**OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

*The following discussion and analysis 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>, Protonix<sup>®</sup> and Yaz<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<sup>®</sup> 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 legislation affecting the pharmaceutical industry, including the recent U.S. healthcare reforms, our ability to achieve expected results through 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 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 ).*

*Forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update any forward-looking statements or other information contained in this report, whether as a result of new information, future events or otherwise. You are advised, however, to consult any additional disclosures we make in our reports to the SEC on Form 6-K. Also note that we provide a cautionary discussion of risks and uncertainties under Risk Factors in our Annual Report on Form 20-F for the year ended December 31, 2009. These are factors that we believe could cause our actual results to differ materially from expected results. Other factors besides those listed could also adversely affect us. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.*

## **Table of Contents**

### **Results of Operations**

#### *Comparison of Three Months Ended September 30, 2010 to Three Months Ended September 30, 2009*

##### *Highlights*

Among the highlights of the third quarter of 2010 were:

Closing of the ratiopharm acquisition and consolidation of its results in Teva's financial statements commencing in August 2010;

Net sales reached a record \$4,250 million, an increase of 20% (\$700 million) over the third quarter of 2009, primarily as a result of increased sales of generics in the U.S. and the consolidation of ratiopharm's sales;

Net income attributable to Teva reached a record \$1,050 million, an increase of 62%, while operating income reached a record \$1,188 million, an increase of 58%, or \$435 million, compared to the third quarter of 2009. Earnings per fully-diluted share reached a record \$1.15, an increase of 60% compared to \$0.72 in the third quarter of 2009;

Sales grew in each of our principal geographic markets: in North America by \$496 million, in Europe by \$171 million (exceeding \$1 billion for the first time), and in our International markets by \$33 million, with growth in local currency terms in our European and International regions of 33% and 13%, respectively;

In the U.S., we launched a generic version of Effexor XR® (venlafaxine HCl ER) pursuant to a settlement agreement with Wyeth Pharmaceuticals;

Global in-market sales of Copaxone® reached a record \$808 million, an increase of 4% over the comparable quarter of 2009, driven mainly by price increases in the U.S. Net of exchange rate effects, global in-market sales of Copaxone® grew by 6%;

Global in-market sales of Azilect® reached \$81 million, an increase of 28% compared to the third quarter of 2009, primarily attributable to volume growth in Europe and in the U.S.;

Cash flow from operating activities reached a record \$1,194 million, compared to \$1,025 million in the third quarter of 2009, an increase of 16%;

Net financial expenses amounted to \$3 million, compared to \$52 million in the third quarter of 2009, primarily attributable to gains resulting from hedging activities of the euro-denominated purchase price for the ratiopharm acquisition; and

Exchange rate differences between the third quarter of 2010 and the comparable quarter of 2009 had a negative impact on sales of approximately \$122 million and a negligible negative impact on operating income.

### **Acquisitions**

***Ratiopharm***

On August 10, 2010, Teva acquired the total shareholdings and control of Merckle ratiopharm Group ( ratiopharm ), a global pharmaceutical company that operates in more than 20 countries, for a total cash consideration of \$5.2 billion. This transaction was accounted for as a business combination and was financed through Teva's internal resources, the issuance of \$2.5 billion in senior notes and bank borrowings of \$1.5 billion, of which \$500 million has been repaid through September 30, 2010. Ratiopharm's results of operations were included in Teva's consolidated financial statements commencing August 2010. With the closing of the acquisition, Teva is now the leading generic company in Europe, with the number two position in Germany and leading market positions in other key European markets.

***Laboratoire Théramex***

On October 28, 2010, Teva entered into a definitive agreement to acquire Laboratoire Théramex from Merck-Serono. Under the terms of the agreement, Teva will make a payment of 265 million at closing (approximately \$367 million at current exchange rates) and certain performance-based milestone payments. Théramex offers a wide variety of women's health products and had in-market sales of approximately 100 million in 2009, approximately 70% of which were derived from sales in France and Italy. The planned acquisition is expected to expand Teva's women's health business into important growth markets in Europe and the rest of the world. Subject to regulatory approval, the transaction is expected to close later this year or in early 2011.



**Table of Contents****Financial Data**

The following table presents certain financial data as a percentage of net sales for the periods indicated and the percentage change for each item as compared to the third quarter of last year.

	Percentage of net sales Three months ended September 30,		Percent change 2010 from 2009 %
	2010 %	2009 %	
Net sales	100.0	100.0	20
Gross profit	58.0	54.3	28
Research and development expenses	5.6	5.5	23
Selling and marketing expenses	17.7	18.9	12
General and administrative expenses	5.5	6.0	11
Legal settlements, acquisition and restructuring expenses and impairment	1.2	2.7	(45)
Operating income	28.0	21.2	58
Financial expenses net	0.1	1.5	(94)
Income before income taxes	27.9	19.7	69
Provision for income taxes	3.1	1.3	171
Share in losses of associated companies net	*	0.1	(100)
Net income attributable to non-controlling interests	0.1		100
Net income attributable to Teva	24.7	18.3	62

\* Less than 0.05%.

**Sales****General**

Net sales for the three months ended September 30, 2010 reached \$4,250 million, an increase of 20% over the comparable quarter of 2009. The growth in sales was attributable mainly to higher sales of generics in the U.S., the inclusion, beginning in August 2010, of ratiopharm's results, which increased our sales in Europe and Canada, higher Copaxone® sales in the U.S. and higher Azilect® sales, as well as higher sales of API to third parties. The increase in sales was partially offset by the effect of exchange rate differences and lower sales of specialty respiratory products (mainly lower sales of ProAir® in the U.S.).

The following table presents net sales by geographic area for the three months ended September 30, 2010 and 2009.

**Sales by Geographic Area**

	Three months ended September 30,		% of 2010	% of 2009	Percent change 2010 from 2009
	2010 U.S. dollars in millions	2009			
North America	\$ 2,724	\$ 2,228	64%	63%	22%
Europe*	1,001	830	24%	23%	21%
International markets	525	492	12%	14%	7%

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Total	\$ 4,250	\$ 3,550	100%	100%	20%
-------	----------	----------	------	------	-----

\* All members of the European Union as well as Switzerland and Norway.

### **Sales by Geographic Area**

#### *North America*

Sales in North America for the three months ended September 30, 2010 reached \$2,724 million, an increase of 22%, or \$496 million, over the comparable quarter of 2009. The growth in sales was mainly attributable to higher sales of generic pharmaceuticals in both the U.S. and, primarily as a result of the ratiopharm acquisition, in Canada and an increase in sales of Copaxone<sup>®</sup>. These increases were offset in part by the loss of sales of injectable products produced in our Irvine, California facility and lower sales of ProAir<sup>™</sup> and Plan B<sup>®</sup>.

The growth in sales of generics in the U.S. was the result of, among other things, the following:

The launch of Teva's generic version of Effexor XR<sup>®</sup> (venlafaxine HCl ER) pursuant to a settlement agreement with Wyeth Pharmaceuticals; and

Sales of products not sold in the comparable quarter in the prior year, primarily the generic versions of Pulmicort<sup>®</sup> (budesonide inhalation), which was re-launched in December 2009 pursuant to a settlement agreement with AstraZeneca, Mirapex<sup>®</sup> (pramipexole dihydrochloride), which was launched in the first quarter of 2010 pursuant to an agreement with Boehringer Ingelheim, Yaz<sup>®</sup> (drospirenone and ethinyl estradiol, which we market as Gianvi), Cozaar<sup>®</sup> (losartan potassium) and Hyzaar<sup>®</sup> (losartan potassium hydrochlorothiazide).

**Table of Contents**

The increase in sales of generic products in the U.S. was offset in part by decreased sales of certain products due to loss of exclusivity and/or increased competition, primarily our generic versions of Lotrel® (amlodipine benazapril), Protonix® (pantoprazole) and Yasmin® (drospirenone, which we market as Ocella ), due to a decrease in the overall market for this product. In addition, there were no sales of our generic versions of Ortho Tri-Cyclen Lo® (norgestimate and ethinyl estradiol, which we marketed as Tri-Lo Sprintec ) which we launched in the third quarter of 2009 and, under a settlement agreement, agreed to exit the market, and Eloxatin® (oxaliplatin injection), which was also launched in the third quarter of 2009 and was sold through the second quarter of 2010 pursuant to a settlement with Sanofi-Aventis.

Other factors affecting the change in sales in North America include:

Continued growth in sales of Copaxone® in the U.S., which reached \$588 million this quarter, an increase of \$47 million, or 9%, over the third quarter of 2009, primarily due to price increases;

A 24% decrease from the comparable quarter in 2009 in sales of specialty respiratory products in the U.S., which were \$126 million this quarter, primarily reflecting lower sales of ProAir™ due to strong competition in the short-acting beta agonist market this quarter and increased demand last year due to the severe early flu season; and

Growth in sales of women's health products to \$116 million, a 13% increase from \$103 million in the comparable quarter in 2009. Among the most significant generic products we sold in U.S. in the third quarter of 2010 were generic versions of Effexor XR® (venlafaxine HCl ER), Pulmicort® (budesonide inhalation), Adderall XR® (mixed amphetamine salts ER), Cozaar® (losartan potassium), Mirapex® (pramipexole dihydrochloride), Yasmin® (drospirenone, which we market as Ocella ), Accutan® (isotretinoin, which we market as Claravis ), Lotrel® (amlodipine/benazapril), Hyzaar® (losartan potassium hydrochlorothiazide) and Ya2® (drospirenone and ethinyl estradiol, which we market as Gianvi ).

In the third quarter of 2010, we maintained our U.S.-leading market share of pharmaceutical prescriptions, with total prescriptions increasing by over 12 million to reach 639 million in the twelve months ended September 30, 2010, or 16.5% of total U.S. prescriptions for such period. In the same twelve-month period, our generic prescriptions increased by over 13 million to reach 610 million, or 21.4% of total U.S. generic prescriptions.

During the third quarter of 2010, we launched five new products in the U.S.: generic versions of Effexor XR® (venlafaxine ER capsules), Amerge® (naratriptan), Catapres-TTS® (clonidine), Prozac® Weekly™ (fluoxetine) and Diastat® AcuDial™ (diazepam).

In addition, generic versions of the following fourteen branded products were sold during the third quarter of 2010 in the U.S. that were not sold in the comparable quarter of 2009 (listed in order of launch date): Allegra-D® 12 Hour (fexofenadine HCl and pseudoephedrine HCl ER), Prevacid® Delayed Release (lansoprazole DR), Pulmicort® (budesonide inhalation), Mirapex® (pramipexole dihydrochloride), Trusopt® (dorzolamide hydrochloride ophthalmic solution), Cozaar® (losartan), Hyzaar® (losartan and hydrochlorothiazide), Flomax® (tamsulosin hydrochloride), Activella® (estradiol and norethindrone acetate), Valtrex® (valacyclovir), Subutex® (buprenorphine sublingual), Yaz® (drospirenone and ethinyl estradiol), Differin® (adapalene gel) and Arimidex® (anastrozole).

Below are the abbreviated new drug application ( ANDA ) approvals that we received from the FDA during the third quarter of 2010:

Product	Form	Approval Date	Brand Name	Annual Brand Sales \$ millions (IMS)*
Naratriptan	tablets	July 7, 2010	Amerge®	58
Norethindrone & ethinyl estradiol w/FE	chewable tablets	August 5, 2010	Femcon FE®*	56
Donepezil HCl (ZG)	tablets	August 11, 2010**	Aricept®	2,493
Clonidine	transdermal system	August 20, 2010	Catapres-TTS®	298
Paricalcitol	capsules	August 23, 2010**	Zemplar®	111

Gemcitabine

injection

August 31, 2010\*\*\*

Gemzar®

801

\* For the 12 months ended September 30, 2010.

\*\* Tentative approval.

\*\*\* Originally final; converted to tentative approval.

## **Table of Contents**

We expect that our sales in North America will continue to be fueled by our strong U.S. generic pipeline, which, as of October 26, 2010, included 203 product registrations awaiting final FDA approval (including some products through strategic partnerships), 45 of which have received tentative approvals. Collectively, the branded products covered by these applications had U.S. sales of over \$118 billion in the twelve months ended September 30, 2010. Of these applications, 134 were Paragraph IV applications challenging patents of the branded products. We believe we are the first to file with respect to 83 of these applications, covering branded products that had U.S. sales of more than \$55 billion in the twelve months ended September 30, 2010. IMS reported branded product sales are one of the many indicators of the potential future value of a launch, but equally important are the mix and timing of competition, as well as cost-effectiveness. The potential advantages of being the first filer with respect to some of these products may be subject to forfeiture. We take into consideration a variety of legal and commercial factors in determining when to launch an approved product, which may affect the specific launch date.

In Canada, sales increased by 46% in U.S. dollar terms, and by 39% in local currency terms, over the comparable quarter of 2009. The growth in sales was primarily attributed to the inclusion of ratiopharm's Canadian sales and royalties related to rosuvastatin. Also as a result of the ratiopharm acquisition, Teva Canada became the leading generic pharmaceutical company in Canada in terms of U.S. dollar sales.

On July 31, 2009, we entered into a consent decree with the FDA with respect to the operations of Teva Animal Health. As a result of the consent decree, the FDA mandated that all Teva Animal Health products be recalled and all finished goods inventory be destroyed. At September 30, 2010, we had approximately \$68 million of intangible assets and approximately \$63 million of fixed assets and API inventory relating to animal health products. Due to uncertainties regarding the ability of Teva Animal Health to produce and sell our products in the future, the above assets are monitored periodically for impairment.

In December 2009, the FDA issued a warning letter relating to our Irvine, California injectable products manufacturing facility. We voluntarily ceased production at the facility during the second quarter of 2010, and are executing a remediation plan required by the FDA. We expect that manufacturing activity will be able to be resumed in late 2010 or early 2011. During the third quarter, we incurred approximately \$51 million in additional expenses due to uncapitalized production costs, write-offs of inventory and assets, for a total of approximately \$103 million as of September 30, 2010. If we are unable to resume the production and sale of injectable products within the timeframe currently expected, or if we change our plans as to the scale of operations or products at the Irvine facility, additional expenses are likely to be incurred and there may be further impairment of tangible and intangible assets. At September 30, 2010, we had approximately \$137 million of intangible assets and approximately \$267 million of fixed assets and inventory relating to products produced at the Irvine facility.

### ***Europe***

Sales in Europe amounted to \$1,001 million, an increase of 21% over the third quarter of 2009. The growth in sales was attributed to the inclusion, commencing August 2010, of sales of ratiopharm, mainly in Germany, France, Spain and Italy, higher sales of generic pharmaceuticals, higher sales of Azilect® and higher sales of API, which were partially offset by lower Copaxone® sales to Sanofi-Aventis. In local currency terms, sales grew by 33%.

Highlights for the third quarter of 2010 in our European region include the following:

Beginning August 2010, the inclusion of sales of ratiopharm (mainly in Germany, France, Italy, Spain, Portugal, Finland and Austria).

In large part as a result of the ratiopharm acquisition, we increased or maintained our market share in key European markets, including Germany, France, Spain and Poland. In local currency terms, our retail sales experienced above-market growth in certain European countries, including Germany, France, Italy, Spain and Poland.

Healthcare reforms were enacted in Germany, effective August 1, 2010, which increased mandatory rebates from 6% to 16% for innovative brands and froze prices at August 1, 2009 levels. Furthermore, effective September 1, 2010, we faced an adjustment of maximum reimbursement prices for the off-patent pharmaceutical market.

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

During the third quarter of 2010, we received 442 generic drug approvals in Europe relating to 92 compounds in 177 formulations, including one European Medicines Agency (EMA) approval valid in all EU member states. As of September 30, 2010, we had 3,706 marketing authorization applications pending approval in 30 European countries relating to 287 compounds in 583 formulations, including nine applications (three of which are duplicates due to the ratiopharm acquisition) pending with the EMA.

### *International Markets*

Our International markets include all countries other than the U.S., Canada, EU member states, Switzerland and Norway. Our sales in these countries reached an aggregate of \$525 million in the third quarter of 2010, an increase of 7% over the third quarter of 2009. The growth in sales was attributable to the higher sales of generic pharmaceuticals in Russia, overall sales in Israel and Latin America, as well as higher API sales to third parties. Sales also benefited from the first time consolidation of ratiopharm's results. The increase was partially offset by a decrease in Copaxone® sales in Russia and the effect of changes in foreign exchange rates. In local currency terms, sales grew by 13%.

**Table of Contents**

Approximately 35% of our sales in International markets were generated in Latin America, 27% in Israel, 25% in Russia and other Eastern European markets, and 13% in all other markets.

Sales in our International markets in the third quarter of 2010, in comparison to the third quarter of 2009, primarily reflect the following factors:

A 20% increase in the Latin American region, in local currency terms;

A 13% increase in sales in Israel, primarily driven by sales of products for which we act as distributor and sales of medical products; and

A 2% increase in Eastern Europe pharmaceutical sales, primarily attributed to the inclusion, commencing August 2010, of ratiopharm's sales, partly offset by a decrease in Copaxone® sales in Russia, which was related to the timing of tenders.

**Sales by Product Line**

The following table presents the breakdown of net sales by product line for the three months ended September 30, 2010 and 2009.

**Sales by Product Line**

	Three months ended September 30, 2010      2009		% of 2010	% of 2009	Percent change 2010 from 2009
	U.S. dollars in millions				
Generics and other*	\$ 2,968	\$ 2,305	70%	65%	29%
Innovative products	770	747	18%	21%	3%
Specialty respiratory products	207	243	5%	7%	(15%)
Active pharmaceutical ingredients	159	136	3%	4%	17%
Women's health	116	103	3%	3%	13%
Biosimilars	30	16	1%	**	88%
<b>Total</b>	<b>\$ 4,250</b>	<b>\$ 3,550</b>	<b>100%</b>	<b>100%</b>	<b>20%</b>

\* Other includes nonpromoted branded products, medical devices, over-the-counter products, distributed products and animal health products.

\*\* Less than 0.5%.

**Generics and Other**

Sales of generics and other products grew by \$663 million, or 29%, in the third quarter of 2010 over the comparable period in 2009. Our largest market for generics is the U.S., accounting for approximately 55% of total sales of generics and other products in the third quarter of 2010, or \$1,627 million, and growing by approximately \$413 million, or 34%, over the comparable quarter in 2009. U.S. sales benefited from approximately \$773 million of products sold in the third quarter of 2010 that were not sold in the comparable quarter of 2009, as discussed above under Sales by Geographic Area - North America. Sales of new products were partially offset by declines in sales of previously-launched products, primarily those where we had exclusive or semi-exclusive rights in the third quarter of 2009, such as Lotrel® (amlodipine benazapril), Protonix® (pantoprazole) and Yasmin® (drospirenone, marketed as Ocella®), as well as the absence of sales of certain injectable products

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

manufactured in our Irvine, California facility. In addition, we had no sales of our generic versions of Ortho Tri-Cyclen Lo<sup>®</sup> (norgestimate and ethinyl estradiol, marketed as Tri-Lo Sprintec ) which we launched in the third quarter of 2009 and, under a settlement agreement, agreed to exit the market, and Eloxatin<sup>®</sup> (oxaliplatin injection), which was also launched in the third quarter of 2009 and was sold through the second quarter of 2010 pursuant to a settlement with Sanofi-Aventis.

Generics and other products from non-U.S. markets grew by \$250 million, or 23%, in the third quarter of 2010 over the comparable period in 2009 primarily due to the inclusion of ratiopharm's sales. This growth was partially offset by an exchange rate impact of approximately \$107 million. In local currency terms, sales grew by 33%.



---

## **Table of Contents**

### ***Innovative Products***

Teva's sales of Copaxone® and Azilect® amounted to \$770 million this quarter, an increase of 3% over the third quarter of 2009. Total global in-market sales of Copaxone® and Azilect® in the quarter were \$890 million, an increase of 6% over the comparable quarter of 2009.

**Copaxone®.** In the third quarter of 2010, Copaxone® (glatiramer acetate) continued to be the leading multiple sclerosis therapy in the U.S. and globally. During the third quarter of 2010, global in-market sales of Copaxone® reached a record \$808 million, an increase of 4% over the comparable quarter of 2009. U.S. sales increased 9% to \$588 million as a result of price increases in 2010. In-market sales of Copaxone® outside the U.S. totaled \$220 million, a decrease of \$16 million compared to the third quarter of 2009, largely due to the timing of tenders in Russia, the effect of exchange rates and cost-containment measures by governments. Net of exchange rate effects, global in-market sales of Copaxone® grew by 6%. In local currency terms, in-market sales outside the U.S. were the same as in the third quarter of 2009. Unit growth occurred in several European and Latin American markets, including Germany, the U.K., Spain, Italy, Argentina, Mexico and Turkey.

To date, Copaxone® has been approved for marketing in 54 countries worldwide, including the U.S., Russia, Canada, Israel, and all EU countries. Copaxone® reached a global market share among multiple sclerosis treatments of approximately 30% (in U.S. dollar terms). According to September 2010 IMS data, Copaxone® reached a record market share in the U.S. in terms of total prescriptions of 40.3%. In new prescription terms, market share was 39.1%.

**Azilect®.** Our once-daily treatment for Parkinson's disease, Azilect® (rasagiline tablets), continued to establish itself in the U.S. and Europe. Global in-market sales in the quarter reached \$81 million compared to \$64 million in the third quarter of 2009, an increase of 28%, primarily attributable to volume growth in Europe (mainly France, Spain, Italy and Germany) and in the U.S. In local currency terms, in-market sales of Azilect® grew 35%. Azilect® is now approved for marketing in 44 countries worldwide. According to September 2010 IMS data for the U.S. market, Azilect® reached a market share of 4.5% for both new and total prescriptions.

### ***Specialty Respiratory Products***

Our global respiratory products had sales of \$207 million in the third quarter of 2010, a decrease of 15% compared to \$243 million in the third quarter of 2009. These figures do not include revenues attributable to respiratory products that are sold in the U.S. as generic drugs (e.g., budesonide). Sales in the U.S. declined to \$126 million, a 24% decrease from the comparable quarter in the prior year, reflecting both increased competition in the short-acting beta agonist market and increased demand last year due to the severe early flu season. ProAir® nevertheless maintained its leadership in the SABA market in the U.S., with an average market share of 48.7% during the quarter. Sales of Qvar®, demand for which was also affected by last year's flu season, reached an average share of 19.3% of all inhaled corticosteroids during this quarter, continuing its second-place position in terms of new and total prescriptions.

### ***Active Pharmaceutical Ingredients (API)***

API sales to third parties amounted to \$159 million this quarter, an increase of 17% from the third quarter of 2009. This growth was primarily the result of growth in sales to customers located in our International and European markets.

### ***Women's Health Products***

Our women's health business in the U.S. recorded sales of \$116 million, an increase of 13% from \$103 million in the comparable quarter in 2009. These figures do not include revenues attributable to women's health products that are sold in the U.S. as generic drugs (e.g., drospirenone and ethinyl estradiol, which we market as Gianvi®). The increase was primarily due to increased sales of Seasonique® and ParaGard®. Plan B One-Step®, which was introduced in the third quarter of 2009, was negatively affected by the launch of a generic version of our two-pill version of Plan B®, which we ceased marketing in mid-2009.

### ***Biosimilars***

During the third quarter of 2010, sales of biosimilar pharmaceuticals reached \$30 million, as compared with \$16 million in the comparable quarter of 2009. Most of our sales of biosimilars (which, beginning August 2010, also included in-market sales of ratiopharm's products) were generated in our European and International markets. We currently sell human growth hormone in the U.S. and granulocyte colony stimulating factor (GCSF) in certain countries in Europe. In addition, in the third quarter of 2010 we launched TevaGrastim® in Israel.

**Other Income Statement Line Items**

***Gross Profit***

In the third quarter of 2010, gross profit amounted to \$2,467 million, an increase of 28%, or \$539 million, compared to the third quarter of 2009. The net increase in gross profit was a result of higher sales in the quarter, partially offset by inventory step-up charges recorded this quarter in connection with the ratiopharm acquisition. Amortization of ratiopharm intangibles will commence in the first quarter of 2011.

---

## **Table of Contents**

The increase in gross margin from 54.3% to 58.0% primarily reflects the product mix in the U.S., which included a number of high-margin products such as generic versions of Effexor XR<sup>®</sup> (venlafaxine HCl ER capsules), Pulmicort<sup>®</sup> (budesonide inhalation), Cozaar<sup>®</sup> (losartan potassium) and Hyzaar<sup>®</sup> (losartan potassium hydrochlorothiazide).

Exchange rate differences between the third quarter of 2010 and the comparable quarter of 2009, which had a negative impact on sales and a smaller negative impact on gross profit, resulted in an increase in gross margin.

### ***Research and Development (R&D) Expenses***

Net R&D spending for the quarter totaled \$239 million, an increase of 23% over the comparable quarter in 2009. As a percentage of sales, R&D spending was 5.6% in the third quarter of 2010, compared to 5.5% in the third quarter of 2009. This increase was driven by growth in both generic and branded (mainly respiratory and biologic products) R&D expenditures, as well as by the inclusion of ratiopharm's R&D expenditures in the quarter. For the full year, net R&D expenses are expected to be approximately 6% of net sales. Approximately 53% of our R&D expenditures were for generic R&D, and the remainder was for our innovative products, respiratory products, women's health products and biosimilar products.

A portion of our R&D activities is conducted through joint ventures, primarily the Teva-Lonza and the Teva-Kowa joint ventures. Our share in R&D expenses of these joint ventures is reflected in the income statement under share in losses of associated companies net.

### ***Selling and Marketing Expenses***

Selling and marketing expenses in the third quarter of 2010 amounted to \$751 million, an increase of 12% from the comparable quarter of 2009. As a percentage of sales, selling and marketing expenses in the third quarter of 2010 decreased to 17.7% from 18.9% in the third quarter of 2009. The increase in dollar terms was primarily due to higher royalty payments made on generic products in the U.S. (mainly our generic versions of Effexor XR<sup>®</sup>, Pulmicort<sup>®</sup>, Yaz<sup>®</sup> and Mirapex<sup>®</sup>). The consolidation of ratiopharm's results commencing August 2010 as well as our higher sales also contributed to the increase. The increase was partially offset by the termination of the obligation to pay Sanofi-Aventis 25% of the in-market sales of Copaxone<sup>®</sup> in the U.S. and Canada, as described below, as well as changes in foreign exchange rates.

In April 2008, we assumed the distribution of Copaxone<sup>®</sup> in the U.S. and Canada from our former partner, Sanofi-Aventis. Under the terms of our agreements with Sanofi-Aventis, we were required to pay Sanofi-Aventis 25% of the in-market sales of Copaxone<sup>®</sup> in the U.S. and Canada through March 31, 2010, which we recorded as a selling and marketing expense. Accordingly, the first quarter of 2010 was the last quarter in which we recorded such payments to Sanofi-Aventis.

### ***General and Administrative (G&A) Expenses***

G&A expenses were \$236 million in the third quarter of 2010, representing 5.5% of sales, as compared to \$212 million and 6.0% of sales in the third quarter of 2009. The increase in G&A expenses in dollar terms resulted primarily from the inclusion of ratiopharm.

### ***Legal Settlements, Acquisition and Restructuring Expenses and Impairment***

Legal settlements, acquisition and restructuring expenses and impairment resulted in expense of \$53 million in the third quarter of 2010, as compared to \$97 million in expenses in the third quarter of 2009. See Note 13 to the Condensed Consolidated Financial Statements.

### ***Operating Income***

Operating income reached \$1,188 million in the third quarter of 2010, compared to \$753 million in the third quarter of 2009. As a percentage of sales, operating margin was 28.0% compared to 21.2% in the third quarter of 2009. The increase in operating income was mainly a result of higher sales, combined with a more profitable mix of products, the termination of our obligation to pay royalties to Sanofi-Aventis on sales of Copaxone<sup>®</sup> in the U.S. and Canada, and income from legal settlements (as compared to the legal expenses recorded in the third quarter of 2009). The increase in operating income was partially offset by higher royalty payments (which are recorded within selling and marketing expenses), inventory step-up charges and higher R&D expenses.

### ***Financial Expenses***

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Net financial expenses for the third quarter of 2010 amounted to \$3 million, compared with net financial expenses of \$52 million during the comparable quarter in 2009. The decrease is primarily attributable to a gain of \$45 million resulting from the hedging of the euro-denominated purchase price for ratiopharm. Since these transactions do not qualify for hedge accounting, the changes in the fair value of these transactions are recognized under "finance expenses - net".

Excluding these items, financial expenses in the third quarter amounted to \$48 million, a decrease of \$4 million compared to the third quarter of 2009, as a result of hedging gains in the third quarter of 2010 that were partially offset by higher interest expenses resulting from the debt incurred to finance the ratiopharm acquisition.

**Table of Contents*****Tax Rate***

The provision for taxes for the third quarter of 2010 amounted to \$133 million on pre-tax income of \$1,185 million, as compared with \$49 million on pre-tax income of \$701 million in the comparable quarter of 2009. The tax rate is determined by using an estimated annual tax rate of 12% for 2010 as compared with an annual tax rate of 7.5% in 2009. The lower effective tax rate for 2009 was primarily the result of legal settlements, an inventory step-up related to the Barr acquisition, impairments of assets and restructuring expenses, which reduced pre-tax income in jurisdictions whose tax rates are above our average tax rate.

***Net Income and Share Count***

Net income attributable to Teva for the third quarter of 2010 amounted to \$1,050 million, compared to net income attributable to Teva of \$649 million in the third quarter of 2009. This increase is due to the factors previously discussed, including the increase in sales, the termination of the obligation to Sanofi-Aventis relating to sales of Copaxone® in the U.S. and Canada, lower financial expenses, lower restructuring expenses and income from legal settlements, as opposed to legal expenses recorded in the third quarter of 2009. These factors were partially offset by charges for inventory step up, higher royalty payments within selling and marketing expenses, as well as higher R&D and G&A expenses in this quarter. Net income attributable to Teva as a percentage of sales was 24.7% in the third quarter of 2010, compared to 18.3% in the comparable quarter of 2009. Diluted earnings per share were \$1.15 for the third quarter of 2010, compared to \$0.72 for the third quarter of 2009.

Net income attributable to Teva, used for computing diluted earnings per share, is calculated after adding back interest expenses on convertible senior debentures and issuance costs (net of tax benefits) of \$11 million and \$10 million for the three months ended September 30, 2010 and 2009, respectively.

For the third quarter of 2010, the weighted average diluted share count was 921 million, as compared to 915 million for the third quarter of 2009.

During the third quarter of 2010, an aggregate of \$7 million in principal amount of our 0.25% convertible senior debentures due 2024 was converted. As a result of these conversions, approximately 0.2 million Teva shares were issued.

**Comparison of Nine Months Ended September 30, 2010 to Nine Months Ended September 30, 2009*****General***

In general, the factors mentioned above that explain quarterly changes on a year-over-year basis are also relevant to a comparison of the results for the nine months ended September 30, 2010 and 2009. Additional factors affecting the nine month comparison are described below.

The following table presents certain financial data as a percentage of net sales for the periods indicated and the percentage change for each item as compared to the nine months ended September 30, 2010 and 2009.

	Percentage of net sales		Percent change 2010 from 2009 %
	nine months ended		
	September 30, 2010 %	2009 %	
Net sales	100.0	100.0	16
Gross profit	56.4	52.2	25
Research and development expenses	5.7	5.8	14
Selling and marketing expenses	18.3	19.1	12
General and administrative expenses	5.2	6.0	**
Legal settlements, acquisition and restructuring expenses and impairment	0.7	1.6	(52)
Purchase of research and development in process	*		
Operating income	26.5	19.7	55
Financial expenses net	1.5	1.7	1

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Income before income taxes	25.0	18.0	61
Provision for income taxes	2.9	1.7	95
Share in losses of associated companies net	0.1	0.2	(19)
Net income attributable to non-controlling interests	0.1	*	100
Net income attributable to Teva	21.9	16.1	58

\* Less than 0.05%.

\*\* Less than 0.5%.

**Table of Contents****Sales****General**

Net sales for the nine months ended September 30, 2010 reached \$11,703 million, an increase of 16% over the comparable period of 2009.

The following table presents the breakdown of net sales by geographic area for the nine months ended September 30, 2010 and 2009.

**Sales by Geographic Area**

	Nine months ended		% of 2010	% of 2009	Percent change 2010 from 2009
	September 30, 2010	2009			
U.S. dollars in millions					
North America	\$ 7,500	\$ 6,261	64%	62%	20%
Europe*	2,624	2,346	22%	23%	12%
International markets	1,579	1,490	14%	15%	6%
Total	\$ 11,703	\$ 10,097	100%	100%	16%

\* All members of the European Union as well as Switzerland and Norway.

**Sales by Geographic Area****North America**

Sales in North America for the nine months ended September 30, 2010 reached \$7,500 million, an increase of 20% over the comparable period of 2009.

Among the most significant generic products we sold in U.S. in the first nine months of 2010 were generic versions of Effexor XR<sup>®</sup> (venlafaxine HCl ER), Pulmicort<sup>®</sup> (budesonide inhalation), Adderall XR<sup>®</sup> (mixed amphetamine salts ER), Yaz<sup>®</sup> (drospirenone and ethinyl estradiol, which we market as Gianvi), Mirapex<sup>®</sup> (pramipexole dihydrochloride), Accutane<sup>®</sup> (isotretinoin, which we market as Claravis), Yasmin<sup>®</sup> (drospirenone, which we market as Ocella), Protonix<sup>®</sup> (pantoprazole), Lotrel<sup>®</sup> (amlodipine/benazapril), Eloxatin<sup>®</sup> (oxaliplatin injection), and Cozaar<sup>®</sup> (losartan potassium).

In March 2010, President Obama signed healthcare reform legislation into law. With the passage of the legislation, initial improvements in both access to coverage and market reforms will begin this year. While more significant changes to the U.S. healthcare system and additional improvements in coverage and access will not begin until 2014, most companies have begun to incur costs related to the legislation in 2010. A few of the material provisions that will reduce revenue are an increase in the Medicaid rebate rates for both generic and brand products, and the expansion of coverage under the 340B drug pricing program, both of which became effective January 1, 2010; an extension of rebates to cover Medicaid managed care participants, which became effective in March 2010; an extension of the Medicare coverage gap (the donut hole) and certain revisions in the definition of average manufacturer price, both of which will become effective on January 1, 2011; and the imposition of a brand manufacturer tax for the next ten years, which will vary between \$2.5 billion and \$4.2 billion per year, with the first payment due in 2011 based on 2010 data. We have incorporated estimates of the effects of healthcare reform in our results of 2010, based on certain assumptions. However, many of the specific determinations necessary to implement the new legislation have yet to be decided. As a result, our actual results may vary from current estimates.

**Europe**

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Sales in Europe were \$2,624 million in the first nine months of 2010, an increase of 12% over the first nine months of 2009. The growth in sales results from the inclusion, commencing August 2010, of sales of ratiopharm, higher sales of generic pharmaceuticals, higher sales of Copaxone® and Azilect® and higher sales of API.

### *International*

Our International region, which includes countries other than the U.S., Canada, EU member states, Norway and Switzerland, had sales of \$1,579 million in the first nine months of 2010, an increase of 6% over the comparable period of 2009.



**Table of Contents****Sales by Product Line**

The following table presents a breakdown of net sales by product line for the nine months ended September 30, 2010 and 2009:

**Sales by Product Line**

	Nine months ended		% of 2010	% of 2009	Percent change 2010 from 2009
	September 30, 2010	2009			
	U.S. dollars in millions				
Generics and other*	\$ 7,967	\$ 6,737	68%	67%	18%
Innovative products	2,297	1,986	20%	20%	16%
Specialty respiratory products	621	616	5%	6%	1%
Active pharmaceutical ingredients	460	429	4%	4%	7%
Women's health	278	280	2%	3%	(1%)
Biosimilars	80	49	1%	**	63%
<b>Total</b>	<b>\$ 11,703</b>	<b>\$ 10,097</b>	<b>100%</b>	<b>100%</b>	<b>16%</b>

\* Other includes nonpromoted branded products, medical devices, over-the-counter products, distributed products and animal health products.

\*\* Less than 0.5%.

**Generics and Other**

Sales of generics and other products grew by \$1,230 million, or 18%, in the first nine months of 2010 over the comparable period in 2009. Our largest market for generics is the U.S., comprising approximately 57% of the total generics and other sales in the first nine months of 2010 and growing by approximately \$880 million, or 24%, over the comparable period in 2009.

Generics and other products from non-U.S. markets grew by \$350 million, or 11%, in the nine months of 2010 over the comparable period in 2009.

**Innovative Products**

Teva's sales of Copaxone® and Azilect® amounted to \$2,297 million during the first nine months of 2010, an increase of 16% over the first nine months of 2009. Total global in-market sales of Copaxone® and Azilect® in the first nine months of 2010 were \$2,607 million, an increase of 16% over the comparable quarter of 2009.

**Copaxone®.** During the first nine months of 2010, global in-market sales of Copaxone® reached \$2,378 million, an increase of 14% over the comparable period of 2009.

**Azilect®.** Global in-market sales in the first nine months reached approximately \$229 million, an increase of 32% over the comparable period of 2009.

**Specialty Respiratory Products**

Our global respiratory portfolio recorded sales of \$621 million in the first nine months of 2010, as compared to sales of \$616 million during the comparable period of 2009, an increase of approximately 1%.

***Active Pharmaceutical Ingredients (API)***

API sales to third parties reached \$460 million in the first nine months of 2010, an increase of 7% over the comparable period of 2009.

***Women's Health***

Our proprietary women's health business in the U.S. recorded sales of \$278 million, a decrease of 1% from \$280 million sold in the first nine months of 2009.

***Biosimilars***

During the first nine months of 2010, sales of biosimilar pharmaceuticals reached \$80 million, as compared with \$49 million in the comparable period in 2009.

## **Table of Contents**

### **Other Income Statement Line Items**

#### ***Gross Profit***

Gross profit margin was 56.4% in the first nine months of 2010, compared to 52.2% for the comparable period of 2009.

#### ***Research and Development (R&D) Expenses***

Net R&D spending for the first nine months grew by 14% over the comparable period of 2009 and reached \$663 million.

#### ***Selling and Marketing Expenses***

Selling and marketing expenses, which represented 18.3% of net sales, amounted to \$2,147 million in the first nine months of 2010, as compared to 19.1% of net sales and \$1,924 million in the comparable period of 2009.

#### ***General and Administrative (G&A) Expenses***

G&A expenses were \$607 million in the first nine months of 2010, or 5.2% of net sales, compared to 6.0% of net sales for the same period in 2009.

#### ***Legal Settlements, Acquisition and Restructuring Expenses and Impairment***

Legal settlements, acquisition and restructuring expenses and impairment were \$78 million in the first nine months of 2010, as compared to \$163 million in the first nine months of 2009.

#### ***Purchase of Research and Development in Process***

During the first nine months of 2010, we purchased \$9 million of research and development in process. No research and development in process was purchased in the comparable period in 2009.

#### ***Operating Income***

Operating income reached \$3,097 million in the first nine months of 2010, compared to \$1,993 million in the first nine months of 2009. As a percentage of sales, operating margin was 26.5% as compared to 19.7% in the comparable period of 2009.

#### ***Financial Expenses***

Net financial expenses for the first nine months of 2010 were \$178 million, compared with \$176 million during the first nine months of 2009.

#### ***Tax Rate***

The provision for taxes for the first nine months of 2010 amounted to \$336 million on pre-tax income of \$2,919 million, as compared with \$172 million on pre-tax income of \$1,817 million in the comparable period of 2009. The tax rate for the first nine months of 2010 reflects an estimated annual tax rate for 2010 of 12% as compared with an annual tax rate of 7.5% in 2009. The lower effective tax rate in the full year of 2009 was primarily the result of legal settlements, inventory step-up related to the Barr acquisition, impairment of assets and restructuring expenses, which reduced pre-tax income in jurisdictions whose tax rates are above our average tax rate.

#### ***Net Income and Share Count***

Net income attributable to Teva for the first nine months ended September 30, 2010 totaled \$2,560 million, compared to \$1,621 million in the comparable period of 2009. Diluted earnings per share reached \$2.82 for the first nine months of 2010, compared to \$1.81 for the comparable period of 2009. Net income attributable to Teva as a percentage of sales was 21.9% in the first nine months of 2010.

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

For the first nine months of 2010, the weighted average diluted share count was 921 million, as compared to 896 million for the first nine months of 2009. In computing diluted earnings per share for the nine months ended September 30, 2009, no account was taken of the potential dilution of the convertible senior debentures, amounting to 16 million weighted average shares, since they had an anti-dilutive effect on earnings per share.

**Table of Contents****Supplemental Non-GAAP Income Data**

The tables below present supplemental data, in U.S. dollar terms, as a percentage of sales and the change by item as a percentage of the amount for the comparable period, which we believe facilitates an understanding of the factors affecting our business.

In these tables, we exclude the items listed below in the respective time periods:

	Three months ended		Nine months ended	
	September 30, 2010	2009	September 30, 2010	2009
	U.S. dollars in millions			
Amortization of purchased intangible assets	144	146	404	351
Inventory step-up charge ratiopharm acquisition (2010); Barr acquisition (2009)	54	1	54	297
Financial expenses (income) related to hedging of the ratiopharm acquisition	(45)		102	
Restructuring expenses	21	47	34	69
Impairment of long-lived assets and intangible assets	27	37	30	39
Gain from the sale of marketable securities that were previously impaired			(24)	
Acquisition expenses primarily relating to the ratiopharm acquisition	6		21	
Purchase of research and development in process			9	
Expense (income) in connection with legal settlements	(1)	13	(7)	55
Net of corresponding tax benefit	(74)	(87)	(190)	(250)

The data so presented after these exclusions are the results used by management and our board of directors to evaluate our operational performance, to compare against work plans and budgets, and ultimately to evaluate the performance of management. For example, each year we prepare detailed work plans for the next three succeeding fiscal years. These work plans are used to manage the business and are the plans against which management's performance is measured. All such plans are prepared on a basis comparable to the presentation below, in that none of the plans take into account those elements that are factored out in our non-GAAP presentations. In addition, at quarterly meetings of the Board at which management provides financial updates to the Board, presentations are made comparing the current fiscal quarterly results against: (a) the comparable quarter of the prior year, (b) the immediately preceding fiscal quarter and (c) the work plan. Such presentations are based upon the non-GAAP approach reflected in the table below. Moreover, while there are always qualitative factors and elements of judgment involved in the granting of annual cash bonuses, the principal quantitative element in the determination of such bonuses is performance targets tied to the work plan, and thus tied to the same non-GAAP presentation as is set forth below.

**Table of Contents**

In arriving at our non-GAAP presentation, we have in the past factored out items, and would expect in the future to continue to factor out items, that either have a non-recurring impact on the income statement or which, in the judgment of our management, are items that, either as a result of their nature or size, could, were they not singled out, potentially cause investors to extrapolate future performance from an improper base. While not all-inclusive, examples of these items include: legal settlements, including principally settlements in connection with intellectual property lawsuits, purchase accounting adjustments related to acquisitions, including adjustments for write-offs of purchase of research and development in process, amortization of intangible assets and inventory step-ups following acquisitions; restructuring expenses related to efforts to rationalize and integrate operations on a global basis; material tax and other awards or settlements both in terms of amounts paid or amounts received; impairment charges related to intangible and other assets such as intellectual property, product rights or goodwill; and the income tax effects of the foregoing types of items when they occur.

These data are non-GAAP financial measures and should not be considered replacements for GAAP results. We provide such non-GAAP data because management believes that such data provide useful information to investors. However, investors are cautioned that, unlike financial measures prepared in accordance with GAAP, non-GAAP measures may not be comparable with the calculation of similar measures for other companies. These non-GAAP financial measures are presented solely to permit investors to more fully understand how management assesses our performance. The limitations of using these non-GAAP financial measures as performance measures are that they provide a view of our results of operations without including all events during a period, such as the effects of acquisition, merger-related, restructuring and other charges, and may not provide a comparable view of our performance to other companies in the pharmaceutical industry.

**Investors should consider non-GAAP financial measures in addition to, and not as replacements for, or superior to, measures of financial performance prepared in accordance with GAAP.**

**Supplemental Non-GAAP Income Data**

	Three months ended		Percentage of net sales		Percent change 2010 from 2009
	September 30,		Three months ended		
	2010	2009	2010	2009	
	U.S. dollars and shares in millions				
	(except per share amounts)		%	%	%
Net sales	4,250	3,550	100.0	100.0	20
Gross profit	2,656	2,066	62.5	58.2	29
Operating income	1,439	997	33.9	28.1	44
Income before income taxes	1,391	945	32.7	26.6	47
Provision for income taxes	207	136	4.9	3.8	52
Net income attributable to Teva	1,182	806	27.8	22.7	47
Earnings per share attributable to Teva Diluted	1.30	0.89			46
Weighted average number of shares Diluted	921	915			

	Nine months ended		Percentage of net sales		Percent change 2010 from 2009
	September 30,		Nine months ended		
	2010	2009	2010	2009	
	U.S. dollars and shares in millions				
	(except per share amounts)		%	%	%
Net sales	11,703	10,097	100.0	100.0	16
Gross profit	7,034	5,891	60.1	58.3	19
Operating income	3,642	2,804	31.1	27.8	30
Income before income taxes	3,542	2,628	30.3	26.0	35
Provision for income taxes	526	422	4.5	4.2	25
Net income attributable to Teva	2,993	2,182	25.6	21.6	37
Earnings per share attributable to Teva diluted	3.29	2.43			35
Weighted average number of shares diluted	921	912			

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

For the nine months ended September 30, 2009, the difference between the reported and the non-GAAP diluted weighted average number of shares represents the potential dilution of convertible senior debentures, which would have an anti-dilutive effect on reported earnings per share while being dilutive on a non-GAAP basis.

**Table of Contents****Reconciliation between Reported net income attributable to Teva and Earnings per share to Non-GAAP net income attributable to Teva and Earnings per share**

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
	U.S. dollars in millions (except per share amounts)			
Reported net income attributable to Teva	1,050	649	2,560	1,621
Purchase of research and development in process			9	
Inventory step-up	54	1	54	297
Legal settlements, acquisition and restructuring expenses and impairment	53	97	78	163
Amortization of purchased intangible assets	144	146	404	351
Financial hedging expenses (income) net of gain from sale of marketable securities	(45)		78	
Related tax effect	(74)	(87)	(190)	(250)
Non-GAAP net income attributable to Teva	1,182	806	2,993	2,182
Diluted earnings per share attributable to Teva:				
Reported (\$)	1.15	0.72	2.82	1.81
Non-GAAP (\$)	1.30	0.89	3.29	2.43
Add-back for diluted earnings per share calculation:				
Reported (\$)	11	10	33	1
Non-GAAP (\$)	11	10	33	33
Non-GAAP effective tax rate	15%	14%	15%	16%

**Non-GAAP Effective Tax Rate**

The provision for non-GAAP taxes for the first nine months of 2010 amounted to \$526 million on pre-tax non-GAAP income of \$3,542 million. The provision for taxes in the comparable period of 2009 was \$422 million on pre-tax income of \$2,628 million. The non-GAAP tax rate for the first nine months of 2010 reflects our estimated annual non-GAAP tax rate for 2010 of 15% as compared to an annual non-GAAP tax rate of 16% in 2009. The lower expected annual effective tax rate for 2010, as compared to the annual non-GAAP tax rate in 2009, is primarily the result of expected changes in the geographic mix and type of products sold in the second half of 2010. In general, we benefit more from tax incentives on products for which we produce the API.

**Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the accompanying consolidated financial statements and related footnotes. Actual results may differ from these estimates. To facilitate the understanding of our business activities, certain accounting policies that are important to the presentation of our financial condition and results of operations and that require management's subjective judgments are described in our Annual Report on Form 20-F for the year ended December 31, 2009. We base our judgments on our experience and various assumptions that we believe to be reasonable under the circumstances. The most significant estimates that we make on an ongoing basis relate to revenue recognition, sales reserves and allowances, income taxes, contingencies, inventories and valuation of intangible assets, marketable securities and long-lived assets. Please refer to Note 1 to the Consolidated Financial Statements included in our Annual Report on Form 20-F for the year ended December 31, 2009 for a summary of all significant accounting policies.



## **Table of Contents**

### **Recently Adopted and Issued Accounting Pronouncements**

See the Notes to the Condensed Consolidated Financial Statements included in this report.

### **Impact of Currency Fluctuations and Inflation**

Because our results are reported in U.S. dollars, changes in the rate of exchange between the U.S. dollar and currencies in the markets in which we operate mainly the euro, New Israeli shekel, Canadian dollar, British pound sterling, Hungarian forint, Russian ruble, and the Polish zloty affect our results.

When compared with the third quarter of 2009, certain currencies relevant to our operations declined in value against the U.S. dollar: the euro by 10%, the Hungarian forint by 13%, the British pound by 6%, the Polish zloty by 6% and the Croatian kuna by 9%. These declines were partially offset by an increase in the value of certain other currencies: the Canadian dollar by 6% and the Chilean peso by 7%. All comparisons are on a quarterly average to quarterly average basis.

As a result, exchange rate movements during the third quarter of 2010 as compared to the comparable quarter in 2009 negatively affected overall sales by approximately \$122 million. We also recorded lower expenses due to these currency fluctuations and, as a result, changes in exchange rates had a negligible negative impact on our operating income.

### **Liquidity and Capital Resources**

Total assets amounted to \$39.0 billion at September 30, 2010, compared to \$35.2 billion at June 30, 2010. The increase is mainly due to the acquisition of ratiopharm and the positive effect on assets of currency translation, partially offset by a decrease in cash (which was utilized for the acquisition).

Our working capital balance, which includes accounts receivable, inventories and other current assets net of sales, reserves and allowances ( SR&A ), accounts payable and other current liabilities, amounted to \$4.0 billion at September 30, 2010, compared to \$3.3 billion at June 30, 2010.

Inventory balances amounted to \$3.9 billion, compared with \$3.1 billion at June 30, 2010. The increase reflects the consolidation of ratiopharm s inventory and the positive effect of currency translation. The ratio of inventory days at September 30, 2010 slightly increased to 178 compared to 172 at June 30, 2010, mainly reflecting the effect of the exchange rates on our inventory balances at September 30, 2010.

Accounts receivable, net of SR&A, decreased by \$127 million during the quarter to \$1.9 billion, primarily as a result of increased collections which was partially offset by currency fluctuations. Days sales outstanding (receivables) ( DSO ), net of SR&A, decreased from 50 days at June 30, 2010 to 42 days at September 30, 2010 due to the higher collections achieved during the quarter and the consolidation of ratiopharm s accounts receivables which has a relatively low level of net accounts receivable and DSO. Although we record receivables on a gross basis, and record substantially all of SR&A as a liability, we have used a net figure for the calculation of DSO in order to facilitate a more meaningful comparison with some of our peers, which record receivables net of these reserves.

Accounts payable and accrual days decreased from 144 days at June 30, 2010 to 132 days at September 30, 2010.

Investment in property, plant and equipment in the third quarter of 2010 was \$175 million, compared to \$196 million in the comparable quarter last year and \$719 million for all of 2009. Depreciation amounted to \$115 million in the third quarter of 2010, as compared to \$107 million in the comparable quarter of 2009.

Cash and cash equivalents, short term and long term investments decreased by \$4.0 billion to \$1.2 billion, reflecting the \$5.2 billion paid for ratiopharm, which was partially offset by cash generated during the third quarter of 2010 and ratiopharm s cash balances.

In June 2010, we issued \$2.5 billion principal amount of senior notes and used a portion of the proceeds to prepay \$800 million of the indebtedness assumed in the Barr acquisition. The remainder of the proceeds was used for the acquisition of ratiopharm in the third quarter of 2010.

## Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

During the third quarter of 2010, Teva repaid in full the remaining Barr debt (\$690 million), terminated Barr's \$300 million revolving credit facility and repaid a \$348 million syndicated credit facility with Sumitomo and Deutsche Bank. In July 2010, Teva entered into separate short-term bilateral credit agreements with three banks, each of which provided for \$500 million in committed financing to pay a portion of the purchase price for the ratiopharm acquisition. As of September 30, 2010, the outstanding balance under these facilities, which bear interest at a spread of LIBOR plus less than 1%, was \$1.0 billion. As a result of the above and the increase in shareholders' equity, as well as currency translation effects, our financial leverage ratio decreased from approximately 27% at June 30, 2010 to approximately 25% at September 30, 2010.

**Table of Contents**

The portion of total debt classified as short term increased from 28% to 34% as a result of borrowings during the third quarter of 2010 and repayment of Barr's indebtedness, which had been classified as long-term debt. Teva's 1.75% convertible senior debentures due 2026 were reclassified as short term debt because they are redeemable by the holders on February 1, 2011. Teva's remaining convertible senior debentures due 2024 were reclassified as long term debt because they are not redeemable by the holders until August 1, 2014.

In 2009 and early 2010, we entered into separate bilateral revolving credit agreements with seven banks under which an aggregate of \$1.08 billion of committed financing was made available. As of September 30, 2010, no borrowings were outstanding under any of such facilities.

Our shareholders' equity was \$21.7 billion at September 30, 2010, compared to \$19.3 billion at June 30, 2010. The increase resulted primarily from \$1.5 billion in positive translation differences as a result of the decrease in value of the U.S. dollar relative to most of the major currencies during the third quarter of 2010 and net income attributable to Teva for the quarter of \$1.1 billion. The increase was partially offset by dividend payments of \$0.2 billion.

For purposes of calculating our market capitalization at September 30, 2010, we used approximately 899 million shares. Such number represents ordinary shares outstanding on such date, less shares held by subsidiaries.

Cash flow generated from operating activities during the third quarter of 2010 amounted to \$1,194 million, as compared with \$1,025 million in the third quarter of 2009. The increase in cash flow resulted from higher net income, as well as an improvement in collections in the third quarter of 2010.

Cash flow generated from operating activities, net of cash used for capital investments and dividends paid, in the third quarter of 2010 amounted to \$866 million, \$162 million higher than in the third quarter of 2009. The increase resulted mainly from higher collection levels, which was partially offset by higher dividend payments (an additional \$41 million paid compared to the third quarter of 2009).

Our principal sources of short-term liquidity are our existing cash investments, liquid securities, and available credit facilities, as well as internally generated funds, which we believe are sufficient to meet our on-going operating needs and to fund the contemplated acquisition of Laboratoire Théramex.

***Aggregate Contractual Obligations***

The following table summarizes the material changes to Teva's long-term debt obligations for the nine months ended September 30, 2010. The table reflects the issuance of senior notes and the repayment of the remaining Barr indebtedness.

	Total	Payment due by period		
		Less than 1 year	1-3 years	3-5 years
U.S. \$ in millions				
Long-term debt obligations, including estimated interest	\$ 1,204	\$ (156)	\$ 306	\$ 1,054
	\$ 1,204	\$ (156)	\$ 306	\$ 1,054

**RISK FACTORS**

There are no material changes to the risk factors previously disclosed in our Annual Report on Form 20-F for the year ended December 31, 2009.

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Reference is made to "Quantitative and Qualitative Disclosures About Market Risk" (Item 11) in our Annual Report on Form 20-F for the year ended December 31, 2009.

**LEGAL PROCEEDINGS**

We are subject to various litigation and other legal proceedings. For a discussion of these matters, see Contingencies, Note 14 to the consolidated financial statements included in this report.

Table of Contents

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on our behalf by the undersigned, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED  
(Registrant)

Date: November 2, 2010

By: /s/ EYAL DESHEH  
Name: **Eyal Desheh**  
Title: **Chief Financial Officer**

37