

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

July 28, 2011

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 July 2011**

**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**

	<b>Page</b>
<u>Consolidated Statements of Income</u>	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>	21
<u>Risk Factors</u>	41
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	41
<u>Legal Proceedings</u>	41

**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 six months ended June 30, 2011, 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>
Exhibit 1.1	Amendment to Memorandum of Association of Teva Pharmaceutical Industries Limited, dated as of June 29, 2010 (English translation or summary from Hebrew original, which is the official version)
Exhibit 2.1	Framework Agreement dated as of May 16, 2011 by and among TAIYO Pharmaceutical Industry Co., Ltd., certain shareholders thereof and Asaph Farmaceutische Onderneming B.V.
Exhibit 2.2	Bridge Loan Agreement dated as of June 13, 2011 among Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Finance Company B.V. and Teva Pharmaceutical Finance N.V., as borrowers, Citibank, N.A., as administrative agent, HSBC Bank PLC, as documentation agent, and the Lenders party thereto
Exhibit 2.3	Term Loan Facilities Credit Agreement dated as of June 13, 2011 among Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Finance Company B.V. and Teva Pharmaceutical Finance N.V., as borrowers, Citibank, N.A., as administrative agent, and HSBC Bank PLC, as documentation agent, and the Lenders party thereto
Exhibit 2.4	Amended and Restated Senior Unsecured Revolving Credit Agreement dated as of June 13, 2011 among Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals USA, Inc., Teva Finance Services B.V., Teva Finance Services II B.V. and Teva Capital Services Switzerland GmbH, as borrowers, Citibank, N.A., as administrative agent, and HSBC Bank PLC, as documentation agent, and the Lenders party thereto
Exhibit 2.5	1-Year Senior Unsecured Japanese Yen Revolving Credit Agreement dated as of July 6, 2011 among Teva Pharmaceutical Industries Limited, as guarantor, Asaph Farmaceutische Onderneming B.V., as initial borrower, Sumitomo Mitsui Banking Corporation, as administrative agent and the Lenders party thereto
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



**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		Six months ended	
	June 30,		June 30,	
	2011	2010	2011	2010
Net sales	\$ 4,212	\$ 3,800	\$ 8,292	\$ 7,453
Cost of sales	2,012	1,679	3,904	3,319
Gross profit	2,200	2,121	4,388	4,134
Research and development expenses net	243	217	482	424
Selling and marketing expenses	804	644	1,636	1,396
General and administrative expenses	284	189	505	371
Legal settlements, acquisition and restructuring expenses and impairment	272	(9)	301	25
Purchase of research and development in process		5		9
Operating income	597	1,075	1,464	1,909
Financial (income) expenses net	(20)	148	18	175
Income before income taxes	617	927	1,446	1,734
Provision for income taxes	27	118	76	203
	590	809	1,370	1,531
Share in losses of associated companies net	10	9	25	17
Net income	580	800	1,345	1,514
Net income attributable to non-controlling interests	4	3	8	4
Net income attributable to Teva	\$ 576	\$ 797	\$ 1,337	\$ 1,510
Earnings per share attributable to Teva:				
Basic	\$ 0.65	\$ 0.89	\$ 1.49	\$ 1.69
Diluted	\$ 0.64	\$ 0.88	\$ 1.49	\$ 1.66
Weighted average number of shares (in millions):				
Basic	892	895	895	894
Diluted	896	921	899	921

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)

	<b>June 30, 2011 Unaudited</b>	<b>December 31, 2010 Audited</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 1,139	\$ 1,248
Short-term investments	18	36
Accounts receivable	5,469	5,476
Inventories	4,458	3,866
Deferred taxes and other current assets	1,514	1,416
<b>Total current assets</b>	<b>12,598</b>	<b>12,042</b>
<b>Long-term investments and receivables</b>	<b>650</b>	<b>632</b>
<b>Deferred taxes, deferred charges and other assets</b>	<b>88</b>	<b>138</b>
<b>Property, plant and equipment, net</b>	<b>4,815</b>	<b>4,357</b>
<b>Identifiable intangible assets, net</b>	<b>6,080</b>	<b>5,751</b>
<b>Goodwill</b>	<b>15,926</b>	<b>15,232</b>
<b>Total assets</b>	<b>\$ 40,157</b>	<b>\$ 38,152</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities:</b>		
Short-term debt and current maturities of long term liabilities	\$ 1,927	\$ 1,432
Convertible senior debentures short term	531	1,339
Sales reserves and allowances	3,727	3,403
Accounts payable and accruals	2,678	2,467
Other current liabilities	1,183	1,053
<b>Total current liabilities</b>	<b>10,046</b>	<b>9,694</b>
<b>Long-term liabilities:</b>		
Deferred income taxes	1,392	1,348
Other taxes and long term payables	830	777
Employee related obligations	221	221
Senior notes and loans	3,920	4,097
Convertible senior debentures long term		13
<b>Total long term liabilities</b>	<b>6,363</b>	<b>6,456</b>
<b>Contingencies, see note 14</b>		
<b>Total liabilities</b>	<b>16,409</b>	<b>16,150</b>
<b>Equity:</b>		
<b>Teva shareholders equity:</b>		
Ordinary shares as of June 30, 2011 and December 31, 2010: authorized 2,500 million shares; issued 940 million shares and 937 million shares, respectively	50	49
Additional paid-in capital	13,341	13,246

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

Retained earnings	10,256	9,325
Accumulated other comprehensive income	1,556	350
Treasury shares as of June 30, 2011 and December 31, 2010 50 million ordinary shares and 40 million ordinary shares, respectively	(1,518)	(1,023)
	23,685	21,947
<b>Non-controlling interests</b>	63	55
<b>Total equity</b>	23,748	22,002
<b>Total liabilities and equity</b>	\$ 40,157	\$ 38,152

**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>Six months ended June 30,</b>	
	<b>2011</b>	<b>2010</b>
<b>Operating activities:</b>		
Net income	\$ 1,345	\$ 1,514
Adjustments to reconcile net income to net cash provided by operating activities:		
Change in working capital items	590	(217)
Depreciation and amortization	490	468
Deferred income taxes net and uncertain tax positions	(174)	6
Loss (gain) from sale of long lived assets and investments	(64)	29
Stock-based compensation	47	41
Impairment of long lived assets	14	3
Purchase of research and development in process		9
Other items net	(24)	(13)
<b>Net cash provided by operating activities</b>	<b>2,224</b>	<b>1,840</b>
<b>Investing activities:</b>		
Purchase of property, plant and equipment	(460)	(301)
Acquisitions of subsidiaries, net of cash acquired	(446)	
Proceeds from sale of long lived assets and investments	141	585
Purchase of investments and other assets	(117)	(400)
Other items net	(34)	(23)
<b>Net cash used in investing activities</b>	<b>(916)</b>	<b>(139)</b>
<b>Financing activities:</b>		
Redemption of convertible debentures	(814)	(45)
Proceeds from senior notes, net of issuance costs of \$2 million and \$6 million in the six months ended June 30, 2011 and 2010, respectively	748	2,492
Net decrease in short-term credit	(511)	(16)
Purchase of treasury shares	(495)	
Dividends paid	(406)	(329)
Proceeds from exercise of options by employees	31	125
Repayment of long-term loans and other long-term liabilities	(12)	(930)
Proceeds from long-term loans and other long-term liabilities	1	43
Other items net	4	10
<b>Net cash (used in) provided by financing activities</b>	<b>(1,454)</b>	<b>1,350</b>
<b>Translation adjustment on cash and cash equivalents</b>	<b>37</b>	<b>(192)</b>
<b>Net change in cash and cash equivalents</b>	<b>(109)</b>	<b>2,859</b>
<b>Balance of cash and cash equivalents at beginning of period</b>	<b>1,248</b>	<b>1,995</b>

**Balance of cash and cash equivalents at end of period** \$ 1,139 \$ 4,854

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

During the six months ended June 30, 2011 and 2010, \$12 million and \$83 million, respectively, principal amount of convertible senior debentures was converted into approximately 0.3 million and 2.3 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, 2010, as filed with the Securities and Exchange Commission. The results of operations for the six months ended June 30, 2011 are not necessarily indicative of results that could be expected for the entire fiscal year.

Following recent acquisitions, the Company reassessed its estimates of the useful lives of property and machinery used in the determination of depreciation, based on management's review of actual physical condition and usage, normal wear and tear, technological change, and industry practice. Following this change in estimates, the estimated useful life of buildings was changed from a range of 25 to 50 years to an aggregate useful life of 40 years, and the estimated useful life of machinery was changed to a range of useful life of 15 to 20 years from a range of 7 to 15 years. The impact of the change in estimates is not material to the financial statements.

**NOTE 2 Certain transactions:**

**a. Ratiopharm acquisition**

On August 10, 2010, Teva acquired Merckle ratiopharm Group ( "ratiopharm" ), for a total cash consideration of \$5.2 billion. The 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 \$2.5 billion in senior notes and credit lines, including credit agreements for an aggregate amount of \$1.5 billion that were repaid by June 30, 2011.

During the first half of 2011, no significant adjustments were recorded to the assets acquired or to the liabilities assumed and the resulting goodwill.

**b. Laboratoire Theramex acquisition**

On January 5, 2011, Teva completed the acquisition of Theramex, Merck KGaA's European-based women's health business, for \$267 million in cash (approximately \$355 million) and certain limited performance-based milestone payments.

Theramex has a broad portfolio of women's health and gynecology products sold in over 50 countries, primarily France and Italy. Theramex's pipeline includes NOMAC/E2, a new oral contraceptive based on natural estrogens, which has successfully completed phase III studies and was submitted for approval in Europe.

During the second quarter of 2011, no significant adjustments were recorded to the assets acquired or to the liabilities assumed and the resulting goodwill.

**c. Corporación Infarmasa acquisition**

On January 26, 2011, Teva acquired Corporación Infarmasa ( "Infarmasa" ), a top ten pharmaceutical company in Peru, from The Rohatyn Group and Altra Investments.

Infarmasa manufactures and commercializes branded and unbranded generic drugs, primarily corticosteroids, antihistamines, analgesics and antibiotics. Infarmasa's product offerings will greatly enhance Teva's portfolio in the market, especially in the area of antibiotics, where Infarmasa

has the leading brand in Peru.

During the second quarter of 2011, no significant adjustments were recorded to the assets acquired or to the liabilities assumed and the resulting goodwill.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)****d. Consumer health care partnership with Procter & Gamble**

On March 24, 2011, Teva and The Procter & Gamble Company ( P&G ) announced the signing of a master agreement to create a consumer health care partnership that will combine the companies' over-the-counter pharmaceutical businesses ( OTC ) in all markets outside North America. As part of the partnership, Teva will manufacture products to supply the joint venture's markets as well as P&G's existing North American OTC business. On July 20, 2011, Teva and P&G entered into definitive agreements with respect to the establishment of the partnership. The transaction is expected to close in the fall of 2011, subject to the receipt of required regulatory approvals.

**e. Cephalon Inc. acquisition**

On May 1, 2011, Teva entered into a merger agreement to acquire Cephalon Inc. ( Cephalon ) for approximately \$6.8 billion in cash. Cephalon is a global biopharmaceutical company with a strong marketed portfolio and pipeline of branded products. The acquisition will diversify Teva's branded portfolio and is expected to enhance Teva's late-stage innovative pipeline. On July 14, Cephalon's stockholders approved the merger. Subject to the receipt of regulatory approvals, the transaction is expected to be completed in October 2011.

**f. Taiyo acquisition**

On May 16, 2011, Teva signed an agreement to acquire Taiyo Pharmaceutical Industry Co. Ltd. ( Taiyo ). On July 14, 2011, Teva completed the acquisition and a related tender offer, purchasing effectively 100% of Taiyo's outstanding shares for \$934 million in cash. Taiyo has developed one of the largest portfolios of generic products in Japan with over 550 marketed products and its advanced production facilities enable it to produce a wide range of dosage forms on a large scale.

**NOTE 3 Issuance of senior notes:**

In March 2011, a finance subsidiary of the Company issued an aggregate of \$750 million principal amount of senior notes as described in the table below. All such notes are guaranteed by Teva.

<b>Issuer</b>	<b>Annual interest rate %</b>	<b>Principal amount issued (U.S. \$ in millions)</b>	<b>Due</b>
Teva Pharmaceutical Finance III, B.V.	LIBOR plus 0.5	\$ 500	March 2014
Teva Pharmaceutical Finance III, B.V. *	1.70	\$ 250	March 2014

\* In March 2011, the Company entered into interest rate swap agreements with respect to these notes (see note 11).

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)****NOTE 4 Inventories:**

Inventories consisted of the following:

	<b>June 30, 2011</b>	<b>December 31, 2010</b>
	<b>U.S. \$ in millions</b>	
	<b>Unaudited</b>	<b>Audited</b>
Finished products	\$ 2,264	\$ 1,948
Raw and packaging materials	1,413	1,237
Products in process	638	579
	4,315	3,764
Materials in transit and payments on account	143	102
	\$ 4,458	\$ 3,866

**NOTE 5 Convertible senior debentures:**

During the six months ended June 30, 2011, convertible senior debentures were redeemed or converted as follows:

	<b>Six months ended June 30, 2011</b>	
	<b>Principal amount redeemed/converted (U.S. \$ in millions)</b>	<b>Number of shares converted into (In millions)</b>
1.75% convertible senior debentures due 2026	\$ 814	1.2
0.25% convertible senior debentures due 2024	9	0.2
0.50% convertible senior debentures due 2024	3	0.1
0.25% convertible senior debentures due 2026	*	*
	\$ 826	1.5

\* Less than \$0.5 million of principal amount was converted into less than 0.05 million shares.

**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.

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

In computing diluted earnings per share for the three and six months ended June 30, 2011 and 2010, 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 six months ended June 30, 2011, no account was taken of the potential dilution of the 1.75% convertible senior debentures due 2026, amounting to 1 million weighted average shares, since they had an anti-dilutive effect on earnings per share.

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 six months ended June 30, 2011 and 2010 are as follows:

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

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
	(in millions)			
Net income attributable to Teva	\$ 576	\$ 797	\$ 1,337	\$ 1,510
Interest expense on convertible senior debentures and issuance costs, net of tax benefits	*	11	*	22
Net income used for the computation of diluted earnings per share	\$ 576	\$ 808	\$ 1,337	\$ 1,532
Weighted average number of shares used in the computation of basic earnings per share	892	895	895	894
Add:				
Additional shares from the assumed exercise of employee stock options and unvested RSUs	3	7	3	7
Weighted average number of additional shares issued upon the assumed conversion of convertible senior debentures	1	19	1	20
Weighted average number of shares used in the computation of diluted earnings per share	896	921	899	921

\* Less than \$0.5 million.

**NOTE 7 Revenue recognition:**

The Company recognizes revenues from product sales, including sales to distributors when persuasive evidence of an arrangement exists, delivery has occurred, the selling price is fixed or determinable and collectability is reasonably assured. This generally occurs when products are shipped and title and risk and rewards for the products are transferred to the customer.

Revenues from product sales are recorded net of provisions for estimated chargebacks, rebates, returns, cash discounts and other deductions, such as shelf stock adjustments, which can be reasonably estimated. When sales provisions are not considered reasonably estimable by Teva, the revenue is deferred to a future period when more information is available to evaluate the impact.

Provisions for chargebacks, rebates including Medicaid and other governmental program discounts, including those required by the U.S. health care reform, rebates and other promotional items, such as shelf stock adjustments, are included in sales reserves and allowances under current liabilities. These provisions are recognized concurrently with the sales of products. Provisions for doubtful debts and prompt payment discounts are netted against Accounts receivable.

Calculations for these deductions from sales are based on historical experience and the specific terms in the individual agreements. Chargebacks and rebates are the largest components 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. Rebates are recognized based on contractual obligations in place at the time of sales with consideration given to relevant factors that may affect the payment as well as historical experience for estimated market activity. Shelf-stock adjustments are granted to customers based on the existing inventory of a customer following decreases in the invoice or contract price of the related product and are estimated based on expected market performance. Teva records a reserve for estimated sales returns by applying historical experience of customer returns to the amounts invoiced and the amount of returned products to be destroyed versus products 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 Equity:****a. Comprehensive income (loss)**

Comprehensive income (loss) is as follows:

	Three months ended June 30, U.S. \$ in millions		Six months ended June 30, U.S. \$ in millions	
	2011	2010	2011	2010
Net income	\$ 580	\$ 800	\$ 1,345	\$ 1,514
Other comprehensive income (loss), net of tax:				
Currency translation adjustment, net of tax	338	(1,022)	1,281	(1,344)
Unrealized gain (loss) on derivative financial instruments	(22)	7	(53)	7
Unrealized gain (loss) from available-for-sale securities, net of tax	(20)	(18)	(21)	29
Realization and reclassification adjustment on available for sales securities, net of tax	(1)	(26)	(1)	(26)
Total comprehensive income (loss)	875	(259)	2,551	180
Comprehensive income attributable to the non-controlling interests	(4)	(3)	(8)	(4)
Comprehensive income (loss) attributable to Teva	\$ 871	\$ (262)	\$ 2,543	\$ 176

**b. Share repurchase program**

In December 2010, Teva's Board of Directors authorized the Company to repurchase up to an aggregate of \$1 billion of its ordinary shares/ADSs over a period of 12 months.

During the three and six months ended June 30, 2011, Teva spent approximately \$95 million and \$495 million, respectively, to repurchase approximately 2.0 million and 9.9 million of its shares.

**NOTE 9 Entity-wide disclosures:**

Net sales by geographic area were as follows:

	Three months ended June 30, U.S. \$ in millions		Six months ended June 30, U.S. \$ in millions	
	2011	2010	2011	2010
North America	\$ 2,099	\$ 2,467	\$ 4,163	\$ 4,776
Europe	1,478	811	2,822	1,623
International markets	635	522	1,307	1,054

\$ 4,212    \$ 3,800    \$ 8,292    \$ 7,453

**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.

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.

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

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.

Financial items carried at fair value as of June 30, 2011 and December 31, 2010 are classified in the tables below in one of the three categories described above:

	June 30, 2011			Total
	Level 1	Level 2	Level 3	
U.S. \$ in millions				
Cash and cash equivalents:				
Money markets	\$ 129	\$	\$	\$ 129
Cash deposits and other	1,010			1,010
Marketable securities*:				
Auction rate securities			41	41
Collateral debt obligations	5		1	6
Equity securities	110			110
Structured investment vehicles		102		102
Other	8			8
Derivatives **::				
Liabilities derivatives mainly options and forward contracts		(17)		(17)
Interest rate and cross-currency swaps (liabilities)		(133)		(133)
Asset derivatives mainly options and forward contracts		33		33
Interest rate swaps		3		3
<b>Total</b>	<b>\$ 1,262</b>	<b>\$ (12)</b>	<b>\$ 42</b>	<b>\$ 1,292</b>

	December 31, 2010			Total
	Level 1	Level 2	Level 3	
U.S. \$ in millions				
Cash and cash equivalents:				
Money markets	\$ 389	\$	\$	\$ 389
Cash deposits and other	859			859
Marketable securities*:				
Auction rate securities			77	77
Collateral debt obligations	9		1	10
Equity securities	109			109
Structured investment vehicles		82		82
Other mainly debt securities	23			23
Derivatives **::				
Liabilities derivatives mainly options and forward contracts		(16)		(16)
Interest rate and cross currency swaps (liabilities)		(70)		(70)
Assets derivatives mainly options and forward contracts		17		17
<b>Total</b>	<b>\$ 1,389</b>	<b>\$ 13</b>	<b>\$ 78</b>	<b>\$ 1,480</b>

- \* 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.

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

\*\* Derivatives primarily represent foreign currency and option contracts, interest rate and cross-currency swaps which are valued primarily based on observable inputs including interest rate curves and both forward and spot prices for currencies.

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

	June 30, 2011	December 31, 2010
	U.S. \$ in millions	
Carrying value at the beginning of the period	\$ 78	\$ 76
Amount realized	(54)	(9)
Net change to fair value:		
Included in earnings financial (income) expenses net	18	7
Included in other comprehensive income (loss)		4
Carrying value at the end of the period	\$ 42	\$ 78

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 and the interest rate and cross currency swap agreements included under long-term liabilities amounted to \$5,066 million and \$4,289 million at June 30, 2011 and December 31, 2010, 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 \$3 million at June 30, 2011.

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 \$33 million and \$17 million (derivatives) and liabilities of \$610 million and \$1,232 million (convertible senior debentures and derivatives) at June 30, 2011 and December 31, 2010, 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. At June 30, 2011 and December 31, 2010, the credit loss was \$174 million and \$266 million, respectively.

**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 3.00% Senior Notes due 2015. The purpose of these interest rate and cross-currency swap agreements was to convert the notes' denomination from dollars to euros. As a result of these agreements, 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.

During the first quarter of 2011, the Company entered into swap agreements with respect to its \$250 million principal amount of 1.70% Senior Notes due 2014. The purpose of these interest rate swap agreements was to change the interest rate from fixed to floating rate. As a result of

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

these agreements, Teva is currently paying an effective interest rate of three months LIBOR plus an average 0.39% on the \$250 million principal amount, as compared to the stated 1.70% fixed rate.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

In April 2011, Teva entered into short term hedge transactions to reduce the exposure resulting mainly from payroll costs denominated in New Israeli Shekel.

The above transactions qualify for hedge accounting.

In April 2011, Teva entered into interest rate swap agreements with respect to its 6.15% Senior Notes due 2036. As a result, Teva was to pay an effective interest rate of three months LIBOR plus an average 1.88% on the \$986 million principal amount and receive a fixed rate of 6.15% on such amount. The transaction was terminated in May 2011 with a net gain of \$53 million, which is reflected in financial (income) expenses.

In May 2011, Teva entered into economic hedge transactions to help protect Teva's European subsidiaries from anticipated sales exposure resulting from the strengthening of the US dollar against the Euro, the result of which is reflected in financial (income) expenses.

**b. Derivative instrument disclosure**

The fair value of derivative instruments consists of:

- a. Asset derivatives, comprising interest rate swap agreements, designated as hedging instruments. These are reported under long-term investments and receivables, and the fair value amounted to \$3 million at June 30, 2011.
- b. 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 \$33 million and \$17 million at June 30, 2011 and December 31, 2010, respectively.
- c. Liability derivatives, comprising interest rate and cross currency swap agreements, designated as hedging instruments. These are reported under senior notes and loans, and the fair value amounted to \$133 million and \$70 million at June 30, 2011 and December 31, 2010, respectively.
- d. 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 \$17 million and \$16 million at June 30, 2011 and December 31, 2010, 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, gains of \$121 million and losses of \$118 million were recognized under financial (income) expenses-net for the six months ended June 30, 2011 and 2010, respectively, and gains of \$71 million and a loss of \$80 million were recognized under financial (income) expenses-net for the three months ended June 30, 2011 and 2010, respectively. Such losses offset the revaluation of the balance sheet items also booked under financial (income) expenses-net.

With respect to the interest rate and cross-currency swap agreements, gains of \$10 million and \$8 million were recognized under financial (income) expenses-net for the six months ended June 30, 2011 and 2010, respectively, and gains of \$5 million and \$4 million were recognized under financial (income) expenses-net for the three months ended June 30, 2011 and 2010, respectively. Such gains mainly reflect the differences between the fixed interest rate and the floating interest rate.



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

In June 2011, the Financial Accounting Standard Board ( FASB ) amended its comprehensive income presentation guidance. The amendment requires entities to report components of comprehensive income in either a continuous statement of comprehensive income or two separate but consecutive statements. The guidance is effective for interim and annual periods beginning after December 15, 2011. Teva believes that the adoption will not have a material impact on its consolidated financial statements.

In May 2011, the FASB amended its fair value measurements and disclosures guidance. The amendment clarifies the existing guidance and adds new disclosure requirements. The guidance is effective for interim and annual periods

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

beginning after December 15, 2011. Teva believes that the adoption will not have a material impact on its consolidated financial statements.

In December 2010, the FASB issued amendments to the disclosure of pro forma information for business combinations. These amendments are effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. The amendments clarify the acquisition date that should be used for reporting the pro forma financial information disclosures when comparative financial statements are presented. The amendments also improve the usefulness of the pro forma revenue and earnings disclosures by requiring a description of the nature and amount of material, nonrecurring pro forma adjustments that are directly attributable to the business combination(s). Teva believes that the adoption will not have a material impact on its consolidated financial statements.

In December 2010, the FASB issued a clarification of the accounting treatment of fees paid to the federal U.S. government by pharmaceutical manufacturers. These amendments were effective on January 1, 2011, when the fee initially became effective. According to the clarification, these fees are recorded as an operating expense in the consolidated financial statements of income. Implementing this clarification did not have a material effect on our consolidated financial statements.

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, 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 method for allocating arrangement considerations. The provisions of the amendment were adopted on January 1, 2011, with no significant impact on our 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:

	<b>Three months ended June 30, U.S. \$ in millions</b>		<b>Six months ended June 30, U.S. \$ in millions</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Legal settlements and reserves	\$ 221	\$ (23)	\$ 217	\$ (6)
Restructuring expenses	39	11	60	13
Acquisition expenses	9		10	15
Impairment of long-lived assets	3	3	14	3
<b>Total</b>	<b>\$ 272</b>	<b>\$ (9)</b>	<b>\$ 301</b>	<b>\$ 25</b>

On May 31, 2011, Teva announced that it had reached a settlement with Pfizer Inc. of patent litigation related to generic versions of Pfizer's Neurontin® (gabapentin) capsules and tablets sold by Teva and its subsidiary IVAX Pharmaceuticals. The settlement between the parties provides for a full release of Teva and its subsidiaries, and a one-time payment to Pfizer, which was made in the second quarter. The financial terms of the settlement are confidential.

On July 20, 2011, Teva signed a settlement agreement with Novartis regarding patent litigation related to amlodipine/benazepril (Lotrel®). The settlement provides for a full release for past sales and a royalty-free license for future sales of all strengths. The financial terms of the settlement are confidential. During the second quarter of 2011, Teva established a provision fully covering the settlement.

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

Teva has reached a settlement in principle with the plaintiffs in approximately one-third of the propofol product liability cases where hepatitis C infection was alleged, and has established a provision in the financial statements covering both the settlement and the estimated cost of the remainder of these cases.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

**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 or settlement 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 (if any) 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.

Teva records a provision to the extent that it concludes that a contingent liability is probable and the amount thereof is estimable. Because litigation outcomes and contingencies are unpredictable, and because excessive verdicts can occur, these assessments involve complex judgments about future events and can rely heavily on estimates and assumptions. Based on currently available information, Teva believes that none of the proceedings brought against the Company 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 final judgments against Teva, such judgments could be material to its results of operations and cash flow in a given period. In addition, Teva may incur significant legal and related expenses in the course of defending its positions even if the facts and circumstances of a particular litigation do not give rise to a provision in the financial statements.

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 products and 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. Furthermore, insurance for additional products may be difficult to obtain.

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. All such sales figures given below are based on IMS data. In addition, the launch of an authorized generic and other generic competition may be relevant to the damages estimation. Except as otherwise noted, all of the litigation matters disclosed below involve claims arising in the U.S. Although the legislation concerning generic pharmaceuticals, as well as patent law, is different in countries other than the U.S. 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



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

insurance; in addition, it may be subject to claims for which insurance coverage is denied 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 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. 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, finding that their products did not infringe Pfizer's patent. In September 2007, the Court of Appeals for the Federal Circuit (the Federal Circuit) reversed the summary judgment decision and remanded the case for further proceedings. On April 5, 2011, the District Court denied Teva's motion for summary judgment, in which Teva had asserted that Pfizer should be precluded from claiming lost profits damages and should instead be limited to seeking a reasonable royalty. The patent at issue expires in 2017. On May 16, 2011, a trial in this matter commenced. On May 31, 2011, this case was dismissed pursuant to a settlement between the parties, which provides for a full release of Teva and a one-time payment to Pfizer. The financial terms of the settlement are confidential. Alpharma also entered into a settlement with Pfizer, toward which Teva contributed a portion pursuant to the terms of Teva's agreement with Alpharma.

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. 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. On July 20, 2011, this case was dismissed pursuant to a settlement between the parties, which provides for a full release of Teva. The financial terms of the settlement are confidential, and a provision has been included in the financial statements.

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. In June 2007, the Federal Court 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 expired on April 24, 2011, was held by the Federal Court to be invalid. In July 2010, the Federal Court of Appeal set aside the judgment, with two grounds of invalidity being sent back to the Federal Court for reconsideration in accordance with the Court of Appeal's instructions. The hearing on the two remaining grounds of invalidity took place in January 2011, and judgment has been reserved. On February 10, 2011, the Supreme Court of Canada denied Teva Canada's application for leave to appeal the decision of the Federal Court of Appeal. Were Lilly ultimately to be successful, Teva Canada could be required to pay damages related to its sales of olanzapine tablets.

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. Teva's sales of its pantoprazole sodium tablets to date are approximately \$1.1 billion. 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 expired on January 19, 2011. In April 2010, the jury returned a verdict finding that the patent is not invalid, and in July 2010, the District Court denied Teva's motion to overturn the verdict. Teva believes that it has substantial grounds for appeal of the District

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

Court's decision on invalidity and intends to pursue its appeals vigorously. On March 3, 2011, the District Court granted Wyeth's motion to strike the patent misuse

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

defenses, but granted Teva leave to replead, which Teva did on April 1, 2011. Wyeth has moved to dismiss the patent misuse claim again and to dismiss Teva's counterclaims of unfair competition and tortious interference. The District Court has not yet ruled on Wyeth's motion. Were Teva to prevail on the patent misuse claim, the patent may be rendered unenforceable. Were Wyeth/Altana ultimately to be successful in its allegation of patent infringement, however, Teva could be required to pay damages relating to the sale of its pantoprazole sodium tablets. The parties are in discovery on the remaining patent and damages issues. While an award of damages is reasonably possible, and the likelihood is higher than Teva believed in May 2011, Teva continues to believe that it is not probable that it will be liable for damages in this matter.

In January 2011, APP Pharmaceuticals and Teva launched gemcitabine HCl for injection in 200 mg and 1 g single dose vials. Gemcitabine HCl for injection is the generic version of Eli Lilly and Company's Gemzar®, which had sales of approximately \$785 million for the twelve months ended December 2010. In March 2010, the United States District Court for the District of Indiana ruled that Lilly could not enforce its method of use patent against Teva based on a ruling in a separate case by Lilly against Sun finding Lilly's patent invalid due to double patenting. Lilly's appeal of the ruling in Teva's case was stayed pending the Federal Circuit's consideration of the appeal in the Sun case. In July 2010, the Federal Circuit affirmed the ruling in the Sun case and in November 2010 denied Lilly's petition for *en banc* review of that decision. On January 28, 2011, Lilly filed a petition for *certiorari* in the Sun case with the United States Supreme Court. On May 16, 2011, the United States Supreme Court denied Lilly's petition. On July 5, 2011, the Federal Circuit issued a mandate summarily affirming the District Court's order, thereby effectively ending Lilly's infringement case against Teva.

\*\*\*

Teva's leading innovative product, Copaxone® (glatiramer acetate), from which it derives substantial revenues and which contributes disproportionately to its profits, faces intense patent challenges, as described below. Although Teva believes that Copaxone® has strong patent protection and that an equivalent generic version would be difficult to develop, if the FDA were to approve one or more generic versions of Copaxone® and Teva's patents were successfully challenged, or if there were a launch at risk, Teva would face generic competition for Copaxone®, which is likely to affect its results of operations adversely.

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® containing Paragraph IV certifications to each of the patents that Teva has listed in the FDA's Orange Book for the product. In August 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 for a period of 30 months. Although the 30-month stay expired in January 2011, Teva has not moved for a preliminary injunction because it does not believe that FDA approval of the Sandoz ANDA is likely in the near future. Sandoz and Momenta 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 2009, Sandoz filed a motion for summary judgment of invalidity based on indefiniteness, which was denied in September 2010. A claim construction hearing was held in January 2010. This case has been consolidated with the ANDA litigation against Mylan and Natco described below, and a trial in the consolidated litigation has been scheduled to begin on September 7, 2011. In December 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. In January 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, and a hearing on the motion was held on January 19, 2011.

In October 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. Discovery concluded at the end of January 2011. In November 2010, Mylan filed a motion for summary judgment of invalidity based on indefiniteness. A hearing on this motion as well as Mylan's





**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

claim construction arguments was held on January 19, 2011. The Mylan litigation has been consolidated with the Sandoz ANDA litigation, and a trial in the consolidated litigation is scheduled to begin on September 7, 2011. Teva's motion for summary judgment of no inequitable conduct was denied on June 17, 2011. A bench trial on this issue, which began on July 11, 2011, concluded on July 22, 2011.

In September 2010, Teva filed a separate complaint against Mylan and Natco alleging infringement of the four marker patents. Mylan has moved to dismiss this complaint.

On March 1, 2011, Generics [UK] Limited initiated a revocation action against Yeda in respect of a U.K. patent relating to Copaxone®. Teva, the exclusive licensee of the patent, is not currently a party to the action. Generics [UK] Limited has also requested a declaration that a generic glatiramer acetate product meeting certain specifications would not infringe that patent. Pursuant to a case management order agreed by the parties and made by the Court on May 6, 2011, a trial has been set to begin on May 8, 2012. The action is currently in the discovery stage.

**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® (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 498 pending. To date, Barr and Duramed products have been identified in 484 of those cases. Additional dismissals are possible. The vast majority of the claims are covered by insurance.

Teva and its subsidiaries have been named as defendants in approximately 2,000 product liability lawsuits brought against them and other manufacturers, including Watson Laboratories, Inc., by plaintiffs claiming injuries from the use of metoclopramide (the generic form of Reglan®). One of Teva's subsidiaries has conditionally agreed to indemnify Watson for certain of the claims that have been asserted against it. The claims in such lawsuits 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. It has not yet been determined how many plaintiffs actually used a Teva product. If the plaintiffs cannot demonstrate that they used a Teva product, Teva expects to be dismissed from at least some of those cases. Certain of these claims are covered by insurance.

Teva Parenteral Medicines, Inc. is a defendant in approximately 185 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 number of commonly owned endoscopy centers of single-patient vials of propofol on more than one patient. The medical practitioners are currently the subject of criminal proceedings relating to their re-use of single patient vials. 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 has reached a settlement in principle with the plaintiffs in approximately one-third of these cases, and has established a provision in the financial statements covering both the settlement and the remainder of these cases. Teva is also named as a defendant in approximately 100 other cases brought on behalf of over 4,000 additional plaintiffs who were 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. Almost all of these cases have been consolidated into a single proceeding.

In May 2010, the jury in the first propofol trial returned a verdict in favor of plaintiffs for \$5.1 million in compensatory damages and awarded \$356 million in punitive damages against Teva and \$144 million in punitive damages against Baxter, the distributor of the product. The trial judge 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 in August 2010. Teva filed several post-trial motions, all of which were denied by the trial judge, who entered judgment in September 2010. Teva believes that it has numerous

grounds for reversal of the jury verdicts, which have been appealed to the Nevada Supreme Court, and does not believe

---

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

that an award of damages in this matter is probable. Two trials have been stayed pending resolution by the Nevada Supreme Court of evidentiary issues, which were argued before the Nevada Supreme Court (en banc) on March 7, 2011. The next trial is scheduled to begin in early August 2011. On May 4, 2011, an arbitration panel ruled, by a 2-1 vote, that Baxter is entitled to indemnification from Teva for the punitive damages awarded by the jury in the first trial, in addition to the compensatory damages. This ruling is now final.

On June 23, 2011, the United States Supreme Court held, in *Pliva, Inc. et al. v. Mensing*, one of the metoclopramide cases, that product liability claims brought under a failure to warn theory against generic pharmaceutical manufacturers are preempted by federal law, which requires that a generic drug have the same label as the branded drug. Teva believes that this decision is likely to reduce its aggregate exposure in currently pending product liability lawsuits, including those described above, although the extent of such effect is uncertain at this time.

**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®), 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® directly from Cephalon from January 2006 until the alleged unlawful conduct 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 did not name Teva or Barr as a defendant. In March 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 initiated by an independent pharmacy in Tennessee. This lawsuit was dismissed in December 2010. In May 2010, another independent pharmacy also filed suit in Ohio with the same allegations. This case has been transferred to the Eastern District of Pennsylvania.

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®) 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 filed a petition for certiorari to the United States Supreme Court, which was denied in June 2009. In April 2010, the Second Circuit also affirmed the grant of summary judgment in the defendants' favor on all claims by the direct purchaser plaintiffs. These plaintiffs filed a petition for certiorari to the United States Supreme Court, which was denied on March 7, 2011. As a result, the federal actions have effectively ended. 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 in August 2009, and directed the entry of final judgment in September 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.



---

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

**Government Reimbursement Investigations and Drug Pricing Litigation**

Together with many other pharmaceutical manufacturers, Teva and/or its subsidiaries in the United States, including Teva Pharmaceuticals USA, Inc. (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, as described below. 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.

A number of state attorneys general, approximately 47 counties in New York and the City of New York have filed various actions against the Teva parties (either collectively or individually) relating to reimbursements or drug price reporting under Medicaid or other programs. The Teva parties have reached settlements with the states of Alaska, Florida, Hawaii, Idaho, Iowa, Kentucky and Texas, as well as with the New York litigants, and remain parties to litigation in Illinois, Kansas, Louisiana, Mississippi, Missouri, Oklahoma, South Carolina, Utah and Wisconsin. In addition to the actions relating to their Medicaid programs, the states of Mississippi and South Carolina have brought actions on behalf of their state health plans. A provision for the cases, including the settlements, has been included in the financial statements.

Additionally, 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 the settlement is awaiting final court approval. 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 defendants have not yet filed any responsive pleading. 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 pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (commonly known as the Superfund law) or other national, federal, provincial or state and local laws imposing liability for alleged non-compliance with various environmental laws and regulations or for 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, for oversight by governmental authorities and the response costs associated with such oversight and for any related damages to natural resources. Teva and/or its subsidiaries have 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

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

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

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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**

**FORWARD-LOOKING STATEMENTS**

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 develop and commercialize additional pharmaceutical products, competition from the introduction of competing generic equivalents and due to increased governmental pricing pressures, the effects of competition on sales of our innovative products, especially Copaxone® (including competition from innovative orally-administered alternatives as well as from potential generic equivalents), potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to our generic version of Protonix®, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products, the extent to which any manufacturing or quality control problems damage our reputation for high quality production and require costly remediation, our ability to identify, consummate and successfully integrate acquisitions (including the pending acquisition of Cephalon), our ability to achieve expected results through our innovative R&D efforts, dependence on the effectiveness of our patents and other protections for innovative products, intense competition in our specialty pharmaceutical businesses, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, our potential exposure to product liability claims to the extent not covered by insurance, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, the impact of continuing consolidation of our distributors and customers, the difficulty of complying with U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority requirements, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, the termination or expiration of governmental programs or tax benefits, 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, 2010, 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, 2010. 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.

**Introduction**

We are a global pharmaceutical company that develops, produces and markets generic drugs covering all major treatment categories. We are the leading generic pharmaceutical company in the world, as well as in the U.S., in terms of both total and new prescriptions. We also have a significant and growing branded pharmaceutical product line, including Copaxone® for multiple sclerosis and Azilect® for Parkinson's disease, respiratory products and women's health products.

The generic pharmaceutical industry as a whole, and therefore our own operations, are affected by demographic trends such as an aging population and a corresponding increase in healthcare costs, governmental budget constraints and spending decisions of healthcare organizations, as well as broad economic trends. In each of our markets around the globe, governments as well as private insurers are working to control growing healthcare costs, and there is an increasing recognition of the importance of generics in providing access to affordable pharmaceuticals, although these conditions also enhance pressure on generic pricing. In addition, the generic pharmaceutical industry, particularly in the U.S., has been significantly affected by consolidation among managed care providers, large pharmacy chains, wholesaling organizations and other buyer groups. Generic pharmaceutical companies also face intense competition from brand-name

## **Table of Contents**

pharmaceutical companies seeking to counter generic products. We believe that our broad pipeline and balanced business model, combining generic as well as branded generic, innovative, respiratory, women's health, over-the-counter and biosimilar pharmaceutical products as well as API, coupled with our geographic diversity, are key strategic assets in addressing these trends.

## **Results of Operations**

### **Comparison of Three Months Ended June 30, 2011 to Three Months Ended June 30, 2010**

#### **Highlights**

Among the highlights of the second quarter of 2011 were:

net sales reached \$4,212 million, an increase of 11%, or \$412 million, over the second quarter of 2010;

net income attributable to Teva was \$576 million, a decline of 28%, or \$221 million, compared to the second quarter of 2010. Operating income was \$597 million, a decline of 44%, or \$478 million, compared to the second quarter of 2010. Earnings per fully-diluted share was \$0.64, a decline of 27% compared to \$0.88 in the second quarter of 2010;

in our European and International markets, sales grew in comparison to the second quarter of 2010; in Europe by \$667 million, or 82%, and in our International markets by \$113 million, or 22%. Sales in North America declined by \$368 million, or 15%, due to lower generic sales in the U.S., partially offset by higher sales of Copaxone®;

global in-market sales of Copaxone® reached a record \$957 million, an increase of 24% over the comparable quarter of 2010, driven primarily by price increases in the U.S. as well as volume growth both in the U.S. and globally;

global in-market sales of Azilect® reached a record \$97 million, an increase of 38% compared to the second quarter of 2010, primarily due to volume growth in the U.S. and Europe;

expenses of \$221 million in connection with legal settlements and reserves, compared with income of \$23 million in connection with legal settlements during the second quarter of 2010;

net financial income of \$20 million, compared with net financial expenses of \$148 million during the second quarter of 2010;

cash flow generated from operating activities of \$1,324 million, as compared with \$954 million in the second quarter of 2010;

the weighted average fully-diluted number of shares declined to 896 million from 921 million in the second quarter of 2010, primarily due to the redemption and conversion of convertible senior debentures, as well as share repurchases;

exchange rate differences between the second quarter of 2011 and the comparable quarter of 2010 had a positive impact on sales of approximately \$222 million and a positive impact on operating income of approximately \$25 million; and

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

in June and July 2011, we entered into syndicated credit agreements totaling \$5 billion for the acquisition of Taiyo and the pending acquisition of Cephalon, under which we borrowed approximately \$1 billion in July.

### **Acquisitions and Joint Ventures**

#### **Cephalon**

On May 1, 2011, Teva entered into a merger agreement to acquire Cephalon Inc. ( Cephalon ) for approximately \$6.8 billion in cash. Cephalon is a global biopharmaceutical company with a strong marketed portfolio and pipeline of branded products. The acquisition will diversify our branded portfolio and is expected to enhance our late-stage innovative pipeline. On July 14, Cephalon's stockholders approved the merger. Subject to the receipt of regulatory approvals, the transaction is expected to be completed in October 2011.

**Table of Contents****Taiyo**

On May 16, 2011, Teva signed an agreement to acquire Taiyo Pharmaceutical Industry Co. Ltd. ( Taiyo ). On July 14, 2011, Teva completed the acquisition and a related tender offer, purchasing effectively 100% of Taiyo s outstanding shares for \$934 million in cash. Taiyo has developed one of the largest portfolios of generic products in Japan with over 550 marketed products and its advanced production facilities enable it to produce a wide range of dosage forms on a large scale.

**Consumer Health Care Partnership with Procter & Gamble**

On March 24, 2011, Teva and The Procter & Gamble Company ( P&G ) announced the signing of a master agreement to create a consumer health care partnership that will combine the companies over-the-counter pharmaceutical businesses ( OTC ) in all markets outside North America. As part of the partnership, Teva will manufacture products to supply the joint venture s markets as well as P&G s existing North American OTC business. On July 20, 2011, Teva and P&G entered into definitive agreements with respect to the establishment of the partnership. The transaction is expected to close in the fall of 2011, subject to the receipt of required regulatory approvals.

**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 first quarter of last year:

	Percentage of net sales		Percentage change 2011 from 2010 %
	Three months ended		
	2011	2010	
	June 30,		
	%	%	
Net sales	100.0	100.0	11
Gross profit	52.2	55.8	4
Research and development expenses net	5.8	5.7	12
Selling and marketing expenses	19.1	16.9	25
General and administrative expenses	6.7	5.0	50
Legal settlements, acquisition and restructuring expenses and impairment	6.4	(0.2)	n/a
Purchase of research and development in process		0.1	(100)
Operating income	14.2	28.3	(44)
Financial (income) expenses net	(0.4)	3.9	n/a
Income before income taxes	14.6	24.4	(33)
Provision for income taxes	0.6	3.1	(77)
Share in losses of associated companies net	0.2	0.2	11
Net income attributable to non-controlling interests	0.1	0.1	33
Net income attributable to Teva	13.7	21.0	(28)

**Sales****General**

Net sales for the three months ended June 30, 2011 reached \$4,212 million, an increase of 11% over the second quarter of 2010. The growth in sales was attributable primarily to the inclusion of ratiopharm s results, which increased our sales (mainly in Europe and Canada), higher Copaxone® sales (primarily in North America), and the inclusion of certain sales from our venture in Japan and sales of Theramex and Infarmasa, as well as the positive effect of exchange rate differences. These increases were partially offset by lower sales of generics in the U.S., as well as a reduction of sales resulting from the disposition of our pharmacy chain in Peru.

**Table of Contents**

The following table presents net sales by geographic area for the three months ended June 30, 2011 and 2010:

**Sales by Geographic Area**

	Three months ended June 30,		% of 2011	% of 2010	Percent change 2011 from 2010
	2011	2010			
	U.S. dollars in millions				
North America	\$ 2,099	\$ 2,467	50%	65%	(15%)
Europe*	1,478	811	35%	21%	82%
International markets	635	522	15%	14%	22%
Total	\$ 4,212	\$ 3,800	100%	100%	11%

\* 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 June 30, 2011 were \$2,099 million, a decrease of 15%, or \$368 million, from the comparable quarter of 2010. The reduction was primarily attributable to lower sales of generic pharmaceuticals in the U.S., which was partially offset by an increase in sales of Copaxone® and an increase in sales in Canada.

The decrease in sales of generics in the U.S. was primarily the result of the following:

the loss of exclusivity and/or increased competition on our generic versions of Yaz® (drospirenone and ethinyl estradiol, which we market as Gianvi ), Cozaar® (losartan potassium), Hyzaar® (losartan potassium and hydrochlorothiazide), Mirapex® (pramipexole dihydrochloride), Protonix® (pantoprazole), Lotrel® (amlodipine and benazepril) and Yasmin® (drospirenone, which we market as Ocella ); and

the cessation of sales of our generic version of Eloxatin® (oxaliplatin injection) in the second quarter of 2010, pursuant to a settlement agreement with Sanofi-Aventis.

This decrease was partially offset by increase in sales of Teva's generic version of Adderall XR® (mixed amphetamine salts ER) and the launch of Nasacort®AQ (triamcinolone acetoneide).

Sales in North America benefited from:

continued growth in sales of Copaxone® in the U.S., which reached \$682 million this quarter, an increase of \$151 million, or 29%, over the second quarter of 2010, due to price and volume increases; and

an increase of 38% in sales in Canada, primarily due to the inclusion of ratiopharm.

Among the most significant generic products we sold in the U.S. in the second quarter of 2011 were generic versions of Pulmicort® (budesonide inhalation), Adderall XR® (mixed amphetamine salts ER), Accutane® (isotretinoin, which we market as Claravis ), Yaz® (drospirenone and ethinyl estradiol, which we market as Gianvi ) and Yasmin® (drospirenone, which we market as Ocella ).

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

In the second quarter of 2011, we maintained our U.S.-leading market share of pharmaceutical prescriptions, with total prescriptions of 610 million in the twelve months ended June 30, 2011, or 15.4% of total U.S. prescriptions for such period. In the same twelve-month period, our generic prescriptions were 581 million, or 19.3% of total U.S. generic prescriptions.

During the second quarter of 2011, we launched five new generic products in the U.S.: generic versions of Antabuse<sup>®</sup> (disulfiram), Aricept<sup>®</sup> (donepezil hydrochloride tablets), Femara<sup>®</sup> (letrozole), Nasacort AQ<sup>®</sup> (triamcinolone acetonide) and Levaquin<sup>®</sup> (levofloxacin tablets).

In addition, generic versions of the following nine branded products were sold during the second quarter of 2011 in the U.S. that were not sold in the comparable quarter of 2010 (listed in order of launch date): Effexor XR<sup>®</sup> (venlafaxine

**Table of Contents**

ER), Amerge<sup>®</sup> (naratriptan), Catapres-TTS<sup>®</sup> (clonidine transdermal), Prozac<sup>®</sup> Weekly (fluoxetine MR), Diastat<sup>®</sup> AcuDial (diazepam), Aricept<sup>®</sup> ODT (donepezil orally disintegrating tablets), Phentermine capsules, Femhrt<sup>®</sup> (norethindrone acetate and ethinyl estradiol) and Femcon<sup>®</sup> Fe (norethindrone and ethinyl estradiol tablets, chewable, and ferrous fumarate tablets).

Below are the abbreviated new drug application (ANDA) approvals that we received from the FDA during the second quarter of 2011:

Product	Form	Approval date	Brand name	Annual brand sales \$ millions (IMS)*
Zolmitriptan	Tablets**	April 13, 2011	Zomig <sup>®</sup>	1,486
Imiquimod	Cream	April 18, 2011	Aldara <sup>®</sup>	321
Eszopiclone	Tablets	May 23, 2011	Lunesta <sup>®</sup>	794
Lamivudine / Zidovudine	Tablets	May 25, 2011	Combivir <sup>®</sup>	313
Donepezil	Tablets	May 31, 2011	Aricept <sup>®</sup>	2,303
Letrozole	Tablets	June 3, 2011	Femara <sup>®</sup>	702
Levofloxacin	Tablets	June 20, 2011	Levaquin <sup>®</sup>	1,573

\* For the 12 months ended March 31, 2011.

\*\* Tentative approval.

We expect that our future sales in North America will be fueled by our strong U.S. generic pipeline, which, as of July 12, 2011, included 185 product registrations awaiting final FDA approval (including some products through strategic partnerships), 41 of which have received tentative approvals. Collectively, the branded products covered by these applications had U.S. sales of over \$116 billion in the twelve months ended March 31, 2011. Of these applications, 126 were Paragraph IV applications challenging patents of the branded products. We believe we are the first to file with respect to 77 of these applications, covering branded products that had U.S. sales of more than \$54 billion in the twelve months ended March 31, 2011. 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 38% in U.S. dollar terms, and by 30% in local currency terms, over the second quarter of 2010. The growth in sales was primarily attributable to the inclusion of ratiopharm's Canadian sales and an increase in royalties related to certain settlement agreements. As a result of the ratiopharm acquisition, Teva Canada became the leading generic pharmaceutical company in Canada in terms of sales.

On January 31, 2011, we received a warning letter from the FDA relating to our oral solid dose manufacturing facility in Jerusalem. The letter cites cGMP deficiencies related to laboratory reporting and systems. We believe that we have addressed the FDA's observations and we are working diligently to resolve any outstanding FDA concerns. The letter does not restrict production or shipment of the products from our facility but had some effect on our supply capabilities. However, unless and until we are able to correct outstanding issues to the FDA's satisfaction, the FDA may withhold approval of pending drug applications listing the Jerusalem facility. The FDA may also withhold permission to export products manufactured at the facility to the U.S. A complete response was submitted to the warning letter, following the implementation of corrective actions. In early June, we received notification from the FDA that the corrective actions we have taken and the commitments we have made appeared to address the concerns in the warning letter. The FDA has conducted a follow-up inspection, which concluded with no observations, and has resumed approving product applications for products manufactured at this site.

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. In April 2011, we resumed limited manufacturing activity. We have been working closely with the FDA and are gradually releasing more products for distribution. During the second quarter of 2011, we incurred uncapitalized production costs, consulting expenses and write-offs of inventory of approximately \$30 million. If we are unable to resume full production and sale of

## **Table of Contents**

injectable products within the timeframe currently expected, or if we further change our plans as to the scale of operations or products, we will incur additional expenses, and there may be further impairment of tangible and intangible assets. At June 30, 2011, we had approximately \$52 million of intangible assets and approximately \$228 million of fixed assets and inventory relating to products produced at the Irvine facility.

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. In October 2010, Teva Animal Health resumed selling certain third party manufactured products. Remediation of the facilities is continuing. At June 30, 2011, we had approximately \$63 million of intangible assets and approximately \$75 million of fixed assets and inventory relating to animal health products.

## **Europe**

Sales in Europe amounted to \$1,478 million, an increase of 82% over the second quarter of 2010. These record sales are primarily due to the inclusion of ratiopharm's sales, higher sales of generic pharmaceuticals on a pro forma basis (i.e., compared to the combined sales of Teva and ratiopharm in the second quarter of 2010), the inclusion of sales of Theramex, higher sales of APIs as well as the positive effect of changes in foreign exchange rates. In local currency terms, sales grew by 60%.

Highlights for the second quarter of 2011 in our European region include the following:

we demonstrated strong pro forma growth in countries where we are the market leader, such as Italy and the U.K.;

we maintained our market position in other major European countries, including Germany and Spain, due to higher sales of generic pharmaceuticals on a pro forma basis;

we maintained our market share position in France despite facing increased competition and pricing pressures;

ratiopharm, our leading brand in Germany, became the number one generic brand in the country in terms of sales value; in addition, we won the most molecules and regions in the AOK (health fund) tender that came into effect on June 1, which will further increase our market share and market presence;

the Theramex acquisition has contributed to growth of the women's health product line in Europe;

Copaxone® sales in Europe were flat due to an increase in manufacturer rebates in Germany, which decreased the net price; however, in countries where Teva assumed the marketing rights from Sanofi-Aventis, sales increased compared to the second quarter of 2010; and

we launched our generic version of Lipitor® (atorvastatin) in the U.K. during the second quarter, although further shipments are currently enjoined pending resolution of litigation brought by Pfizer.

In addition, regulatory measures in Italy and Portugal have reduced reimbursement prices for generic pharmaceuticals this quarter, while in Hungary, laws were passed during the quarter that will significantly increase pricing pressures on generic pharmaceuticals. The Hungarian laws came into effect on July 1, 2011.

## **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 \$635 million in the second quarter of 2011, an increase of 22% over the second quarter of 2010. The growth in



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

sales was attributable to higher sales in Russia, Israel and Latin America as well as the positive effect of changes in foreign exchange rates. Sales also benefited from the consolidation of ratiopharm's and Infarmasa's results as well as the inclusion of certain sales from our venture in Japan. The increase was partially offset by the reduction in sales in Peru resulting from the sale of our pharmacy chain. In local currency terms, sales grew by 15%.

Approximately 33% of our sales in International markets were generated in Latin America, 26% in Russia and other Eastern European markets, 23% in Israel, and 18% in Asia and all other markets.

Sales in our International markets in the second quarter of 2011, in comparison to the second quarter of 2010, primarily reflect the following factors:

in Latin America, sales grew by 7% in dollar terms, and by 4% in local currency terms, primarily driven by strong generics sales in Argentina and Peru due to the inclusion of Infarmasa's sales, commencing February

**Table of Contents**

2011, as well as higher sales on a pro forma basis, and increased sales of Copaxone® in Argentina and Mexico. The increase was partially offset by a reduction in sales as a result of the sale of our pharmacy chain in Peru in February 2011;

our sales in Eastern Europe grew by 34% in dollar terms and by 25% in local currency terms. The growth, in local currency terms, is primarily due to increased sales of generics in Russia as well as high growth in other Commonwealth of Independent States countries (CIS), particularly Ukraine and Kazakhstan. The increase was partially offset by lower sales in Croatia;

in Israel, sales grew by 12% in dollar terms and by 5% in local currency terms, primarily driven by increased sales of generic pharmaceuticals and medical products as well as sales of products for which we act as distributor; and

sales in Asia in the second quarter of 2011 increased compared to the second quarter of 2010, due to the inclusion of certain sales from our venture in Japan in the second quarter of 2011 and higher sales of Copaxone®, as well as higher sales of generic products in South East Asian countries.

**Sales by Product Line**

The following table presents a breakdown of net sales by product line for the three months ended June 30, 2011 and 2010:

**Sales by Product Line**

	Three months ended June 30,		%	%	Percentage change 2011 from 2010
	2011	2010			
	U.S. dollars in millions		of	of	
			2011	2010	
Generics and other*	\$ 2,686	\$ 2,551	64%	67%	5%
Innovative products	947	758	22%	20%	25%
Specialty respiratory products	240	221	6%	6%	9%
Active pharmaceutical ingredients	183	163	4%	4%	12%
Women's health products	119	82	3%	2%	45%
Biosimilars	37	25	1%	1%	48%
Total	\$ 4,212	\$ 3,800	100%	100%	11%

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

**Generics and Other**

Sales of generics and other products grew by \$135 million, or 5%, in the second quarter of 2011 over the second quarter of 2010.

Our largest market for generics is the U.S., accounting for approximately 34% of total sales of generics and other products in the second quarter of 2011, or \$903 million. Sales of generics in the U.S. declined by approximately \$599 million, or 40%, from the second quarter of 2010. U.S. sales included approximately \$73 million of products sold in the second quarter of 2011 that were not sold in the second quarter of 2010, as discussed above under Sales by Geographic Area - North America. Sales of new products were offset by declines in sales of previously-launched products, primarily those where we had exclusive or semi-exclusive rights in the second quarter of 2010, such as the generic versions of Cozaar® (losartan potassium), Hyzaar® (losartan potassium and hydrochlorothiazide), Mirapex® (pramipexole dihydrochloride tablets), Protonix® (pantoprazole), Lotrel® (amlodipine and benazapril), Yaz® (drospirenone and ethinyl estradiol, which we market as Gianvi), and Yasmin® (drospirenone, marketed as Ocella). Furthermore, sales of our generic version of Eloxatin® (oxaliplatin injection) ceased in the second quarter of

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

2010 pursuant to a settlement agreement with Sanofi-Aventis.

Generics and other products in non-U.S. markets grew by \$734 million, or 70%, in the second quarter of 2011 over the comparable period in 2010. The growth primarily reflected the inclusion of ratiopharm's sales, the consolidation of certain sales from our venture in Japan, the addition of Infarmasa's sales, as well as an exchange rate impact of

## **Table of Contents**

approximately \$176 million. The increase was partially offset by the loss of sales of our pharmacy chain operation in Peru following its sale in February 2011. In local currency terms, sales of generics and other products from non-U.S. markets grew approximately by 53%.

### **Innovative Products**

Teva's sales of Copaxone® and Azilect® amounted to \$947 million this quarter, an increase of 25% over the second quarter of 2010. Total global in-market sales of Copaxone® and Azilect® in the quarter were \$1,054 million, an increase of 25% over the comparable quarter of 2010.

**Copaxone®.** In the second quarter of 2011, Copaxone® (glatiramer acetate) continued to be the leading multiple sclerosis therapy in the U.S. and globally. During the second quarter of 2011, global in-market sales of Copaxone® reached record sales of \$957 million, an increase of 24% over the comparable quarter of 2010. Positive currency effects contributed 4% of this growth. U.S. sales increased by 29% to \$682 million, as a result of price increases in 2010 and 2011 as well as volume growth. In-market sales of Copaxone® outside the U.S. totaled \$275 million, an increase of 13% over the second quarter of 2010. Overall unit growth was 9% with strong growth in several European markets, including Spain, France, Germany, Italy and the U.K. This growth was partially offset by the negative impact of pricing pressures in Germany and other markets. U.S. in-market sales accounted for 71% of global Copaxone® sales in the second quarter of 2011 compared with 69% in the second quarter of 2010.

According to June 2011 IMS data, Copaxone® reached a market share in the U.S. in terms of total prescriptions of 40.6%. In new prescription terms, its market share was 38.2%.

**Azilect®.** Our once-daily treatment for Parkinson's disease, Azilect® (rasagiline tablets), continued to grow in the U.S. and Europe. Global in-market sales in the quarter reached \$97 million compared to \$70 million in the second quarter of 2010, an increase of 38%, primarily attributable to volume growth in the U.S. and Europe (principally Germany, France and Italy). According to June 2011 IMS data for the U.S. market, Azilect® reached a record market share of 5.1% in terms of total prescriptions. In new prescription terms, its market share was 4.8%.

### **Specialty Respiratory Products**

Our global respiratory products had sales of \$240 million in the second quarter of 2011, an increase of 9% compared to \$221 million in the second quarter of 2010, primarily driven by higher sales in Europe, as a result of the inclusion of ratiopharm's sales, as well as an increase in Qvar® sales in the U.S. 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. were \$139 million, a 3% decline as compared to second quarter of 2010. ProAir® maintained its leadership in the short-acting beta agonist (SABA) market in the U.S., with an average market share of 50.5% during the quarter. This quarter, Qvar®'s average share of 21.9% of all inhaled corticosteroids, maintained its second-place position in terms of new and total prescriptions.

Respiratory sales outside the U.S. totaled \$101 million, an increase of 29% over the comparable quarter of 2010, primarily as a result of higher sales in the U.K. and Germany.

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

API sales to third parties amounted to \$183 million this quarter, an increase of 12% from the second quarter of 2010. This growth occurred principally in North America and Europe and is largely attributable to increased demand from existing customers, as well as several new product launches.

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

Our global women's health products had sales of \$119 million in the second quarter of 2011, an increase of 45% compared to \$82 million in the second quarter of 2010, primarily driven by the inclusion of the sales of Theramex products in Europe, and to a lesser extent by a 2% increase in sales in the U.S. These figures do not include revenues attributable to products that are sold in the U.S. as generic drugs (e.g., drospirenone and ethinyl estradiol).

### **Biosimilars**

In the second quarter of 2011, sales of biosimilar pharmaceuticals reached \$37 million, as compared with \$25 million in the comparable quarter of 2010. These sales were generated primarily in our European and International markets. The increase is primarily due to the inclusion of ratiopharm's sales and to higher sales on a pro forma basis. We



## **Table of Contents**

currently sell human growth hormone in the U.S., granulocyte colony stimulating factor (GCSF) in most European countries, and epoetin theta in several countries in Europe.

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

#### **Gross Profit**

In the second quarter of 2011, gross profit amounted to \$2,200 million, an increase of 4%, or \$79 million, compared to the second quarter of 2010. The increase in gross profit was a result of higher sales, partially offset by costs related to regulatory actions taken in facilities and higher charges related to amortization of purchased intangible assets as the amortization of ratiopharm's intangible assets commenced in the first quarter of 2011.

The decrease in gross margin from 55.8% to 52.2% primarily reflects the product mix in the U.S., which included fewer high margin generic products compared to the second quarter of 2010, as well as the factors described above. All of these preceding factors were partially offset by an increase in sales of our higher margin innovative products, Copaxone® and Azilect®.

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

Net R&D spending for the quarter totaled \$243 million, an increase of 12% over the comparable quarter in 2010. As a percentage of sales, R&D spending was 5.8% in the second quarter of 2011, compared to 5.7% in the second quarter of 2010. This increase was driven by growth in branded R&D expenditures as well as by the inclusion of ratiopharm and Theramex R&D expenditures in the quarter. Approximately 60% of our R&D expenditures was for our innovative products, respiratory products, women's health products and biosimilar products, and the remainder was for generic R&D.

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 second quarter of 2011 amounted to \$804 million, an increase of 25% over the second quarter of 2010. As a percentage of sales, selling and marketing expenses increased to 19.1% for the second quarter of 2011 from 16.9% in the second quarter of 2010.

The increase in dollar terms was primarily due to the consolidation of ratiopharm's and Theramex's results as well as changes in currency exchange rates. The increase was partially offset by lower royalty payments on generic products in the U.S. (primarily on our generic versions of Yaz®, Mirapex® and Yasmin®).

Teva has an agreement with Sanofi-Aventis for the marketing of Copaxone® in Europe and other markets. Copaxone® is co-promoted with Sanofi-Aventis in Germany, France, Spain, the Netherlands and Belgium, and is marketed solely by Sanofi-Aventis in certain other European markets, Australia and New Zealand. In 2010, we assumed the distribution and marketing responsibilities for Copaxone® in the U.K., the Czech Republic and Poland. By 2012, we expect to assume the marketing responsibilities for Copaxone® in all European countries. Upon termination, Sanofi-Aventis will be entitled to an agreed-upon termination consideration of 6% of the in-market sales of Copaxone® in the applicable countries for an additional two-year period. Although we expect to record higher revenues as a result of this change, we will also become responsible for certain marketing and administrative expenses, which will no longer be shared with Sanofi-Aventis.

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

G&A expenses were \$284 million in the second quarter of 2011, representing 6.7% of sales, as compared to \$189 million and 5.0% of sales in the second quarter of 2010. The increase resulted from the inclusion of ratiopharm and other acquired companies, higher legal expenses (primarily relating to product liability litigation) and exchange rate differences.

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

Legal settlements, acquisition and restructuring expenses and impairment resulted in an expense of \$272 million in the second quarter of 2011, as compared to income of \$9 million in the second quarter of 2010. See Note 13 to the Condensed Consolidated Financial Statements.

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

On May 31, 2011, Teva announced that it had reached a settlement with Pfizer Inc. of patent litigation related to generic versions of Pfizer's Neurontin® (gabapentin) capsules and tablets sold by Teva and its subsidiary IVAX Pharmaceuticals. The settlement between the parties provides for a full release of Teva and its subsidiaries, and a one-

## **Table of Contents**

time payment to Pfizer, which was made in the second quarter. The financial terms of the settlement are confidential.

On July 20, 2011, Teva signed a settlement agreement with Novartis regarding patent litigation related to amlodipine/benazepril (Lotrel®). The settlement provides for a full release for past sales and a royalty-free license for future sales of all strengths. The financial terms of the settlement are confidential. During the second quarter of 2011, Teva established a provision fully covering the settlement.

Teva has reached a settlement in principle with the plaintiffs in approximately one-third of the propofol product liability cases where hepatitis C infection was alleged, and has established a provision in the financial statements covering both the settlement and the estimated cost of the remainder of these cases.

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

During the second quarter of 2010, we purchased \$5 million of research and development in process. No research and development in process was purchased in the second quarter of 2011.

### **Operating Income**

Operating income was \$597 million in the second quarter of 2011, compared to \$1,075 million in the second quarter of 2010. As a percentage of sales, operating income was 14.2% compared to 28.3% in the second quarter of 2010.

The decline in operating income primarily resulted from lower sales of high margin generic products in the U.S., increased expenses in connection with legal settlements in the quarter, higher charges related to amortization of ratiopharm's purchased intangible assets, which commenced in the first quarter of 2011, and higher operating expenses. These factors were partially offset by the increase in overall sales. The decrease in operating margin primarily reflects the increase in operating expenses as well as the product mix in the U.S. as discussed above under **Gross Profit**.

### **Financial (Income) Expenses**

Net financial income for the second quarter of 2011 amounted to \$20 million, compared with expenses of \$148 million during the second quarter of 2010.

T