

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

November 01, 2012

[Table of Contents](#)

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 6-K

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a-16 or 15d-16**

**under the Securities Exchange Act of 1934**

**For the month of November 2012**

**Commission File Number 0-16174**

# TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Translation of registrant's name into English)

**5 Basel Street, P.O. Box 3190**

**Petach Tikva 49131 Israel**

(Address of principal executive offices)

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

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**INDEX**

<u>Consolidated Statements of Income (Loss)</u>	<b>Page</b> 2
<u>Condensed Consolidated Statements of Comprehensive Income (Loss)</u>	3
<u>Consolidated Balance Sheets</u>	4
<u>Consolidated Statements of Cash Flow</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Operating and Financial Review and Prospects</u>	23
<u>Risk Factors</u>	49
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	49
<u>Legal Proceedings</u>	49

**Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
Exhibit 1.1	Articles of Association (translation of official Hebrew original)
EX-101.INS	XBRL Taxonomy Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Presentation Linkbase Document

**INTRODUCTION AND USE OF CERTAIN TERMS**

Unless otherwise indicated or the context otherwise requires, all references to the Company, we, our and Teva refer to Teva Pharmaceutical Industries Limited and its subsidiaries and references to revenue refer to net revenue. 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. References to ROW are to Rest of the World markets. References to P&G are to The Procter & Gamble Company and references to PGT are to PGT Healthcare, the joint venture we formed with P&G.

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

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

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Net revenues	\$ 4,972	\$ 4,344	\$ 15,068	\$ 12,636
Cost of sales	2,371	2,098	7,201	6,002
Gross profit	2,601	2,246	7,867	6,634
Research and development expenses net	324	242	914	724
Selling and marketing expenses	914	806	2,823	2,442
General and administrative expenses	292	112	920	617
Loss contingencies, impairments, settlements and others	1,131	51	1,335	352
Operating income (loss)	(60)	1,035	1,875	2,499
Financial expenses net	73	67	240	85
Income (loss) before income taxes	(133)	968	1,635	2,414
Provision for income tax expense (benefit)	(57)	33	(27)	109
Share in losses of associated companies net	8	17	32	42
Net income (loss)	(84)	918	1,630	2,263
Net (income) loss attributable to non-controlling interests	5	(2)	13	(10)
Net income (loss) attributable to Teva	\$ (79)	\$ 916	\$ 1,643	\$ 2,253
Earnings (loss) per share attributable to Teva:				
Basic	\$ (0.09)	\$ 1.03	\$ 1.88	\$ 2.52
Diluted	\$ (0.09)	\$ 1.03	\$ 1.88	\$ 2.51
Weighted average number of shares (in millions):				
Basic	869	888	873	892
Diluted	869	890	875	896

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

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME****(LOSS)****(U.S. dollars in millions; unaudited)**

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Net income (loss)	\$ (84)	\$ 918	\$ 1,630	\$ 2,263
Other comprehensive income (loss), net of tax:				
Currency translation adjustment	449	(1,300)	374	(19)
Unrealized gain (loss) on derivative financial instruments	(28)	54	12	1
Unrealized gain (loss) from available-for-sale securities	24	(23)	(21)	(44)
Other	6	(1)	(9)	(2)
<b>Total comprehensive income (loss)</b>	<b>367</b>	<b>(352)</b>	<b>1,986</b>	<b>2,199</b>
Comprehensive loss (income) attributable to the non-controlling interests	5	(2)	13	(10)
<b>Comprehensive income (loss) attributable to Teva</b>	<b>\$ 372</b>	<b>\$ (354)</b>	<b>\$ 1,999</b>	<b>\$ 2,189</b>

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

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

(U.S. dollars in millions)

	September 30, 2012 Unaudited	December 31, 2011 Audited
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 1,432	\$ 1,096
Accounts receivable	5,782	6,213
Inventories	5,461	5,012
Deferred taxes and other current assets	2,308	2,132
<b>Total current assets</b>	<b>14,983</b>	<b>14,453</b>
<b>Long-term investments and receivables</b>	<b>1,208</b>	<b>991</b>
<b>Deferred taxes, deferred charges and other assets</b>	<b>148</b>	<b>142</b>
<b>Property, plant and equipment, net</b>	<b>6,281</b>	<b>5,947</b>
<b>Identifiable intangible assets, net</b>	<b>8,295</b>	<b>10,316</b>
<b>Goodwill</b>	<b>18,665</b>	<b>18,293</b>
<b>Total assets</b>	<b>\$ 49,580</b>	<b>\$ 50,142</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities:</b>		
Short-term debt and current maturities of long term liabilities	\$ 571	\$ 3,749
Convertible senior debentures - short term	531	531
Sales reserves and allowances	4,823	4,428
Accounts payable and accruals	3,143	3,572
Other current liabilities	1,557	1,396
<b>Total current liabilities</b>	<b>10,625</b>	<b>13,676</b>
<b>Long-term liabilities:</b>		
Deferred income taxes	1,914	2,610
Other taxes and long term payables	1,281	1,277
Senior notes and loans	12,688	10,236
<b>Total long term liabilities</b>	<b>15,883</b>	<b>14,123</b>
<b>Contingencies, see note 13</b>		
<b>Total liabilities</b>	<b>26,508</b>	<b>27,799</b>
<b>Equity:</b>		
<b>Teva shareholders equity:</b>		
Ordinary shares of NIS 0.10 par value per share; September 30, 2012 and December 31, 2011: authorized 2,500 million shares; issued 943 million shares and 942 million shares, respectively	50	50
Additional paid-in capital	13,460	13,374
Retained earnings	12,250	11,284
Accumulated other comprehensive loss	(233)	(589)
Treasury shares as of September 30, 2012 and December 31, 2011 75 million ordinary shares and 59 million ordinary shares, respectively	(2,593)	(1,924)

	22,934	22,195
<b>Non-controlling interests</b>	138	148
<b>Total equity</b>	23,072	22,343
<b>Total liabilities and equity</b>	\$ 49,580	\$ 50,142

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

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

(U.S. dollars in millions)

(Unaudited)

	<b>Nine months ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Operating activities:</b>		
Net income	\$ 1,630	\$ 2,263
Adjustments to reconcile net income to net cash provided by operations:		
Depreciation and amortization	1,315	737
Impairment of long lived assets	576	30
Deferred income taxes net and uncertain tax positions	(503)	(222)
Long-term receivables	(164)	(10)
Net change in working capital items	130	(7)
Stock-based compensation	61	69
Other non-cash items	(38)	61
Gain from sale of long lived assets and investments	(12)	(215)
<b>Net cash provided by operating activities</b>	<b>2,995</b>	<b>2,706</b>
<b>Investing activities:</b>		
Purchases of property, plant and equipment	(777)	(736)
Proceeds from sales of long lived assets and investments	200	175
Other investing activities	(75)	(47)
Purchases of investments and other assets	(73)	(142)
Acquisitions of subsidiaries, net of cash acquired		(1,360)
<b>Net cash used in investing activities</b>	<b>(725)</b>	<b>(2,110)</b>
<b>Financing activities:</b>		
Net change in short-term credit	(2,514)	905
Proceeds from senior notes, net of issuance costs of \$6 million and \$2 million in the nine months ended September 30, 2012 and 2011, respectively	1,798	748
Proceeds from long-term loans and other long-term liabilities	1,240	1
Repayment of loans and other long-term liabilities	(1,184)	(220)
Purchases of treasury shares	(667)	(749)
Dividends paid	(641)	(610)
Proceeds from exercise of options by employees	24	55
Purchase of non-controlling interest		(75)
Redemption of convertible debentures		(814)
Other financing activities		3
<b>Net cash used in financing activities</b>	<b>(1,944)</b>	<b>(756)</b>
<b>Translation adjustment on cash and cash equivalents</b>	<b>10</b>	<b>(3)</b>
<b>Net change in cash and cash equivalents</b>	<b>336</b>	<b>(163)</b>
<b>Balance of cash and cash equivalents at beginning of period</b>	<b>1,096</b>	<b>1,248</b>



<b>Balance of cash and cash equivalents at end of period</b>	<b>\$ 1,432</b>	<b>\$ 1,085</b>
--------------------------------------------------------------	-----------------	-----------------

**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 fairly state 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, 2011, as filed with the Securities and Exchange Commission. Amounts at December 31, 2011 were derived from the audited balance sheet at that date, but all disclosures required by accounting principles generally accepted in the United States are not included. The results of operations for the nine months ended September 30, 2012 are not necessarily indicative of results that could be expected for the entire fiscal year.

**NOTE 2 Certain transactions:****Cephalon acquisition**

On October 14, 2011, Teva acquired Cephalon, Inc. ( "Cephalon" ) for total cash consideration of \$6.5 billion. Cephalon was a global biopharmaceutical company with a marketed portfolio and a pipeline of branded products. The acquisition diversified Teva's branded portfolio and enhanced Teva's late-stage innovative pipeline.

The acquisition was financed by borrowings under credit facilities and by the issuance of long-term debt.

Cephalon's results of operations and balance sheet were included in Teva's consolidated reports commencing October 2011.

At the closing, Cephalon had contingent consideration liabilities related to future milestone payments due to several acquisitions in an aggregate fair value amount of \$171 million.

The table below summarizes the estimates of the fair value of assets acquired, liabilities assumed and resulting goodwill as of the acquisition date.

	U.S. \$ in millions
Current assets	\$ 2,855
Investment and non-current assets	506
Property, plant and equipment	359
Identifiable intangible assets:	
Existing product rights and trade name	2,564
Research and development in-process	1,296
Goodwill	3,191
 Total assets acquired	 10,771
 Current liabilities	 827
Short term debt	2,082
Long-term liabilities, including deferred taxes	1,101
Contingent consideration	171

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

Total liabilities assumed	4,181
Non controlling interest	79
Net assets acquired	\$ 6,511

The appraisals of the fair value of assets acquired and liabilities assumed and resulting goodwill have been finalized.

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

Adjustments during the measurement period did not have a significant impact on Teva's consolidated statements of income, balance sheets or cash flows and, therefore, we have not retrospectively adjusted our financial statements. These adjustments for identifiable intangible assets during the measurement period reflect changes in the estimated fair value of certain acquired intangibles, principally in-process research and developed assets, primarily to better reflect market participant assumptions about facts and circumstances existing as of the acquisition date. The adjustments did not result from intervening events subsequent to the acquisition date.

Some of Cephalon's in-process R&D was impaired during the third quarter of 2012. These impairments are described in note 12.

**Sale of animal health activity**

On September 14, 2012, Teva entered into an agreement to sell its U.S.-based animal health activity for up to \$145 million. The purchase price includes a payment of \$60 million at closing and up to \$85 million in milestone payments.

The transaction is expected to close in 2013, subject to antitrust clearance and satisfaction of other conditions.

**Acquisition of Neurosearch A/S assets**

On October 25, 2012, Teva acquired from Neurosearch A/S, a Danish company, the rights, assets and obligations relating to Huntexil® (pridopidine / ACR16), a drug candidate being developed for the symptomatic treatment of hand movement, balance and gait disturbances in Huntington's disease for approximately \$26 million. Regulatory and commercialization milestone payments may result in additional payments to NeuroSearch.

**NOTE 3 Issuance of senior notes and term loan:**

In March 2012, Teva entered into a ¥100.5 billion senior unsecured fixed rate term loan credit agreement for 5 and 7 years with interest rates of 0.99% and 1.42%, respectively. In April 2012, Teva drew down the entire amount available under the facility (\$1.2 billion) and repaid the borrowings used to finance the acquisition of Taiyo (approximately \$1 billion).

In April 2012, finance subsidiaries of the Company issued an aggregate of 1 billion euro and 450 million CHF principal amounts of senior notes as described in the table below. All such notes are guaranteed by Teva.

Issuer	Annual interest rate %	Principal amount issued (U.S. \$ in millions)	Due
Teva Pharmaceutical Finance IV B.V.	2.875	\$ 1,316	April 2019
Teva Pharmaceutical Finance V B.V.	1.5	\$ 493	October 2018

**NOTE 4 Inventories:**

Inventories consisted of the following:

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

	September 30, 2012	December 31, 2011
	U.S. \$ in millions	
	Unaudited	Audited
Finished products	\$ 2,748	\$ 2,502
Raw and packaging materials	1,805	1,589
Products in process	771	781
Materials in transit and payments on account	137	140
	\$ 5,461	\$ 5,012

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

**NOTE 5 Earnings (loss) per share:**

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

In computing diluted earnings per share for the nine months ended September 30, 2012 and 2011, respectively, and the three months ended September 30, 2011, 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 the loss per share for the three months ended September 30, 2012, no adjustment was made to take into account any possible dilution to the basic loss per share in light of the loss.

In computing diluted earnings per share for the nine months ended September 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.

Add back for the three and nine months ended September 30, 2012 and 2011 was less than \$0.5 million.

**NOTE 6 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 rebates and chargebacks 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. Rebates and chargebacks are the largest components of sales reserves and allowances. 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. Provisions for estimating chargebacks are determined using historical chargeback experience, or expected chargeback levels and wholesaler sales information for new products, which are compared to externally obtained distribution channel reports for reasonableness. Shelf-stock adjustments are granted to customers based on 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.

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

Revenue resulting from the achievement of milestone events stipulated in the agreements is recognized when the milestone is achieved. Milestones are based upon the occurrence of a substantive element specified in the contract or as a measure of substantive progress towards completion under the contract.

Revenues and other arrangements from licensees, sales of licensed products and technology, are recorded in accordance with the contract terms, when third-party sales can be reliably measured and collection of the funds is reasonably assured.

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

Sales reserves and allowances consisted of the following:

	September 30, 2012	December 31, 2011
	U.S. \$ in millions	
Rebates	\$ 2,890	\$ 2,752
Chargebacks	1,273	1,052
Returns	490	510
Other	170	114
	\$ 4,823	\$ 4,428

**NOTE 7 Equity:****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.

In December 2011, Teva's board of directors authorized the Company to repurchase up to an aggregate of \$3 billion of its ordinary shares/ADSs. This repurchase authorization has no time limit.

The following table summarizes the shares which were repurchased and the amount Teva spent on these repurchases:

	Three months ended September 30, 2012		Nine months ended September 30, 2011	
	(in millions)			
Amount spent on shares repurchased	\$	\$ 254	\$ 667	\$ 749
Number of shares repurchased		6.1	15.4	16.0



**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)****NOTE 8 Entity-wide disclosure:**

Revenues by geographic area were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
	U.S. \$ in millions			
United States:				
Generic	\$ 1,074	\$ 863	\$ 3,347	\$ 2,715
Branded	1,468	1,090	4,330	3,034
Others	59	2	140	6
<b>Total United States</b>	<b>2,601</b>	<b>1,955</b>	<b>7,817</b>	<b>5,755</b>
Europe*:				
Generic	798	917	2,457	2,828
Branded	376	242	1,143	772
Others	183	185	546	566
<b>Total Europe</b>	<b>1,357</b>	<b>1,344</b>	<b>4,146</b>	<b>4,166</b>
Rest of the World:				
Generic	620	695	1,919	1,671
Branded	177	132	571	433
Others	217	218	615	611
<b>Total Rest of the World</b>	<b>1,014</b>	<b>1,045</b>	<b>3,105</b>	<b>2,715</b>
<b>Total revenues</b>	<b>\$ 4,972</b>	<b>\$ 4,344</b>	<b>\$ 15,068</b>	<b>\$ 12,636</b>

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

**NOTE 9 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.

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

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

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

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

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

Financial items carried at fair value as of September 30, 2012 and December 31, 2011 are classified in the tables below in one of the three categories described above:

	September 30, 2012			Total
	U.S. \$ in millions			
	Level 1	Level 2	Level 3	
Cash and cash equivalents:				
Money markets	\$ 126	\$	\$	\$ 126
Cash deposits and other	1,306			1,306
Marketable securities*:				
Auction rate securities			28	28
Collateral debt obligations	4		1	5
Equity securities	467			467
Structured investment vehicles		100		100
Other	4			4
Derivatives **::				
Liabilities derivatives - mainly options and forward contracts		(46)		(46)
Interest rate and cross-currency swaps (liabilities)		(46)		(46)
Asset derivatives - mainly options and forward contracts		37		37
Interest rate and cross-currency swaps (assets)		31		31
Contingent consideration in connection with Cephalon acquisition			(117)	(117)
Total	\$ 1,907	\$ 76	\$ (88)	\$ 1,895

	December 31, 2011			Total
	U.S. \$ in millions			
	Level 1	Level 2	Level 3	
Cash and cash equivalents:				
Money markets	\$ 73	\$	\$	\$ 73
Cash deposits and other	1,023			1,023
Marketable securities*:				
Auction rate securities			31	31
Collateral debt obligations	4		1	5
Equity securities	505			505
Structured investment vehicles		91		91
Other - mainly debt securities	20			20
Derivatives **::				
Liabilities derivatives - mainly options and forward contracts		(57)		(57)
Interest rate and cross-currency swaps (liabilities)		(53)		(53)
Assets derivatives - mainly options and forward contracts		17		17
Interest rate and cross-currency swaps (assets)		25		25
Contingent consideration in connection with Cephalon acquisition			(171)	(171)
Total	\$ 1,625	\$ 23	\$ (139)	\$ 1,509

\* 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. Changes in fair value of available for sale securities, net of taxes, are reflected in other comprehensive income (loss). Unrealized losses considered to be temporary are reflected in other comprehensive income (loss); unrealized losses that are considered to be other-than-temporary are charged to income as an impairment charge.

At September 30, 2012 and December 31, 2011, the remaining credit loss was \$5 million and \$164 million, respectively.

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

	September 30, 2012	December 31, 2011
	U.S. \$ in millions	
Carrying value at the beginning of the period	\$ (139)	\$ 78
Amount realized	(6)	(61)
Contingent consideration in connection with Cephalon acquisition	54	(171)
Net change to fair value:		
Included in earnings - financial expense - net	3	22
Included in accumulated other comprehensive loss		(7)
Carrying value at the end of the period	\$ (88)	\$ (139)

Cephalon had contingent consideration liabilities related to future milestone payments due to the acquisition of Gemin X Pharmaceuticals, Inc. in April 2011, the acquisition of Ception Therapeutics, Inc. in February 2010, the acquisition of BioAssets Development Corporation in November 2009, and the inclusion of Alba Therapeutics Corporation in February 2011.

We determined the fair value of the liability for the contingent consideration based on a probability weighted discounted cash flow analysis. This fair value measurement is based on significant unobservable inputs in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value of the contingent consideration liability associated with future milestone payments was based on several factors, including:

Cash flows projected from the success of unapproved product candidates in the U.S. and Europe;

Probability of success for product candidates including risks associated with uncertainty, achievement and payment of milestone events;

Time and resources needed to complete the development and approval of product candidates;

Life of the potential commercialized products and associated risks of obtaining regulatory approvals in the U.S. and Europe; and

Risk adjusted discount rate for fair value measurement.

The contingent consideration payments have been recorded as a liability, and their fair value will be evaluated quarterly or more frequently if circumstances dictate. Changes in the fair value of contingent consideration will be recorded in earnings.

Significant changes in unobservable inputs, mainly the probability of success and cash flows projected, could result in material changes to the contingent consideration liability.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)****Financial Instruments Not Measured at Fair Value**

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 approximates their carrying value. The fair value of long-term bank loans mostly approximates their carrying value, since they bear interest at rates close to the prevailing market rates.

The fair value of the financial instruments that are measured on a basis other than fair value are presented in the below table:

	Estimated fair value*	
	September 30, 2012	December 31, 2011
	U.S. \$ in millions	
Senior notes included under long term liabilities	\$ (10,570)	\$ (8,662)
Senior notes and convertible senior debentures included under short term liabilities	(769)	(1,555)
Carrying value at the end of the period	\$ (11,339)	\$ (10,217)

\* The fair value was estimated based on quoted market prices, where available.

**Marketable Securities**

At September 30, 2012 and December 31, 2011, the fair value, amortized cost and gross unrealized holding gains and losses of such securities were as follows:

	Fair value	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses
	US \$ in millions			
September 30, 2012	\$ 728	\$ 860	\$ 20	\$ 152
December 31, 2011	725	836	26	137

**NOTE 10 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.

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

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 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.

During the fourth quarter of 2011, the Company entered into swap agreements with respect to its \$1.1 billion principal amount of three month LIBOR plus 0.9% Senior Notes due 2013. The purpose of these interest rate swap agreements was to change the interest rate from floating to fixed rate. As a result of these agreements, Teva is currently paying an effective interest rate of 1.61% on the \$1.1 billion principal amount, as compared to the stated three months LIBOR plus an average 0.9% rate.



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

During the fourth quarter of 2011, the Company entered into swap agreements with respect to its \$875 million principal amount of 3.65% Senior Notes due 2021. 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 3.85% on the euro principal amount, as compared to the stated 3.65% fixed rate on the dollar principal amount.

During the first quarter of 2012, Teva entered into short term cash flow hedge transactions to reduce the exposure resulting mainly from payroll costs denominated in new Israeli shekels.

During the first quarter of 2012, Teva entered into short term cash flow hedge transactions to help protect Teva's European subsidiaries from anticipated exposure on 2012 sales and partially cover that exposure resulting from the fluctuation of the U.S. dollar against the Euro.

During the third quarter of 2012, Teva entered into cash flow hedge transactions to help protect Teva's European subsidiaries from anticipated exposure on 2013 sales and partially cover that exposure resulting from the fluctuation of the U.S. dollar against the Euro.

The above transactions were accounted for by Teva as hedge accounting.

**b. Derivative instrument disclosure**

The fair value of derivative instruments consists of:

	Reported under	September 30, 2012	December 31, 2011
U.S. \$ in millions			
Asset derivatives, comprising interest rate and cross-currency swap agreements, designated as hedging instruments	Long-term investments and receivables	\$ 31	\$ 25
Asset derivatives, comprising primarily foreign exchange contracts, not designated as hedging instruments	Deferred taxes and other current assets	37	17
Liability derivatives, comprising interest rate and cross currency swap agreements, designated as hedging instruments	Senior notes and loans	46	53
Liability derivatives, comprising primarily foreign exchange contracts, not designated as hedging instruments	Accounts payable	46	57

Derivatives on foreign exchange contracts hedge Teva's balance sheet items from currency exposure but are not designated as hedging instruments for accounting purposes. With respect to such derivatives, losses of \$32 million and gains of \$66 million were recognized under financial expenses-net for the nine months ended September 30, 2012 and 2011, respectively, and losses of \$27 million and \$55 million were recognized under financial expenses -net for the three months ended September 30, 2012 and 2011, respectively. Such gains offset the revaluation of the balance sheet items also booked under financial expenses - net.

With respect to the interest rate and cross-currency swap agreements, gains of \$14 million were recognized under financial expenses - net for each of the nine months ended September 30, 2012 and 2011, and gains of \$4 million were recognized under financial expenses - net for each of

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

the three months ended September 30, 2012 and 2011. Such gains mainly reflect the differences between the fixed interest rate and the floating interest rate.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

**NOTE 11 Recently adopted and issued accounting pronouncements:**

In July 2012, the Financial Accounting Standard Board ( FASB ) issued ASU 2012-02, *Intangibles Goodwill and Other (Topic 350): Testing Indefinite Intangibles Assets for Impairment*, which amends the guidance in ASC 350-302 on testing indefinite-lived intangible assets, other than goodwill, for impairment allowing an entity to perform a qualitative impairment assessment. If the entity determines, on the basis of qualitative factors, that the fair value of the indefinite-lived intangible asset is not more likely than not (i.e., a likelihood of more than 50 percent) impaired, the entity would not need to calculate the fair value of the asset and perform a quantitative impairment test. In addition, the standard does not amend the requirement to test these assets for impairment between annual tests if there is a change in events or circumstances; however, it does revise the examples of events and circumstances that an entity should consider in interim periods. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption being permitted. Teva believes that the adoption of this standard will not have a material impact on its consolidated statements.

In December 2011, the FASB issued an accounting standard update ASU No. 2011-11, *Balance Sheet (210): Disclosures about Offsetting Assets and Liabilities*, which requires additional disclosures about the nature of an entity's rights of setoff and related arrangements associated with its financial instruments and derivative instruments. The disclosure requirements are effective for annual reporting periods beginning on or after January 1, 2013, and interim periods therein, with retrospective application required. Teva believes that the adoption will not have a material impact on Teva's consolidated financial statements.

In September 2011, the FASB amended the guidance for goodwill impairment testing and issued ASU No. 2011-08 *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. The amendment provides entities testing goodwill for impairment the option of performing a qualitative assessment before calculating the fair value of the reporting unit. If, on the basis of qualitative factors, it is not more likely than not that the fair value of the reporting unit is less than the carrying amount, further testing of goodwill for impairment would not be required. The amendment also removes the carry forward option of the reporting unit fair value from one year to the next. The amendment is effective for annual and interim goodwill impairment tests performed in fiscal years beginning after December 15, 2011. The adoption did not have a significant impact on Teva's consolidated financial statements.

In June 2011, the FASB amended its comprehensive income presentation guidance and issued ASU No. 2011-05 *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*. 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.

In May 2011, the FASB amended its fair value measurements and disclosures guidance and issued ASU No. 2011-04 *Fair Value Measurement (Topic 820) Amendments to Achieve Common Fair Market Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. The amendment clarifies the existing guidance and adds new disclosure requirements. The guidance is effective for interim and annual periods beginning after December 15, 2011. The adoption did not have a material impact on Teva's consolidated financial statements.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes To Condensed Consolidated Financial Statements (Continued)****(Unaudited)****NOTE 12 Loss contingencies, impairments, settlements and others:**

Loss contingencies, impairments, settlements and others consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Provision for loss contingency	\$ 670	\$	\$ 670	\$ 30
Impairment of long-lived assets	481	16	576	30
Contingent consideration	(59)		(33)	
Restructuring and acquisition expenses	20	36	85	106
Legal settlements and reserves	19	(1)	37	186
Total	\$ 1,131	\$ 51	\$ 1,335	\$ 352

During the third quarter of 2012, Teva recorded \$670 million in Provision for loss contingency. This amount is an accrual relating to pending patent litigation concerning Teva's generic pantoprazole. For additional information, please see note 13.

During the third quarter of 2012, Teva impaired in-process R&D purchased in the Cephalon acquisition, based on management decisions consistent with Teva's long-term strategic goals. A total of \$415 million in impairment was recognized, along with a corresponding reduction in contingent consideration liability of \$80 million. The following pipeline products constitute the majority of the impairment: obatoclox for the treatment of small cell lung cancer and CEP-37247 anti-tumor necrosis factor for the treatment of sciatica. Teva also impaired armodafinil (Nuvigil®) for the treatment of bi-polar disorder to reflect a settlement agreement with Mylan. In addition, Teva recognized other impairments in the amount of \$66 million.

**NOTE 13 Contingencies:****General**

From time to time, Teva and its subsidiaries are subject to 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 that it has meritorious defenses to all actions brought against it and vigorously pursues the defense or settlement of each such action. Except as described below, Teva does not currently have a reasonable basis to estimate the loss, or range of loss, that is reasonably possible with respect to such actions.

Teva records a provision in its financial statements to the extent that it concludes that a contingent liability is probable and the amount thereof is estimable. Based upon the status of these cases, management's assessment of the likelihood of damages, and the advice of counsel, no provisions have been made except as noted below. 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 it 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 versions of patent-protected pharmaceuticals for sale prior to patent expiration in various territories. In the United States, to obtain approval for most generics 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

---

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

1984, as amended. To the extent that Teva 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. Although the laws concerning generic pharmaceuticals, as well as patent laws, are different in countries other than the United States where Teva does business, from time to time Teva is also involved in litigation regarding corresponding patents in those countries.

Additionally, depending upon a complex analysis of a variety of legal and commercial factors, Teva may, in certain circumstances, elect to market a generic version 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. In the event of a finding of willful infringement, the damages may be up to three times the profits lost by the patent owner, although courts have typically awarded much lower multiples. 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 ultimately be found to relate to damages that are not covered by Teva's policy, and insurance for additional products may be difficult to obtain. Furthermore, any insurance recovery would not be recognized for financial statement purposes until collection is assured.

If Teva were to be required to pay damages in any patent infringement case, the general rule is that the patentee should be compensated as if the infringement had not occurred. If damages were determined based on a reasonable royalty, the amount would relate to the sales of Teva's generic version. If damages were determined based on lost profits, the amount would relate to the sales of the branded product. The launch of an authorized generic and other generic competition may be relevant to the damages calculation. In addition, a patentee may seek consequential damages.

Teva's business inherently exposes it to potential product liability claims. As Teva's portfolio of available medicines continues to expand, the number of product liability claims asserted against Teva has increased. Teva maintains product liability insurance coverage in amounts and with terms that it believes are reasonable and prudent in light of its business and related risks. However, Teva sells, and will continue to sell, pharmaceuticals that are not covered by 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.

Except as otherwise noted, all of the litigation matters disclosed below involve claims arising in the United States. All third-party sales figures given below are based on IMS data.

***Intellectual Property Matters***

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. Following the launch, Lilly sued Teva Canada for patent infringement. In October 2009, the patent at issue (which expired in April 2011) was held by the Federal Court to be invalid. In July 2010, the Federal Court of Appeal set aside the judgment and sent back two grounds of invalidity for reconsideration. In November 2011, the Federal Court again held the patent to be invalid. Lilly's subsequent appeal of the Federal Court's reconsideration decision was heard and dismissed from the bench by the Federal Court of Appeal on September 10, 2012. Lilly has until November 9, 2012 to appeal to the Supreme Court of Canada.

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. Altana Pharma and Wyeth Pharmaceuticals (collectively, Wyeth) had previously sued Teva for patent infringement. In September 2007, the United States District Court for the District of New Jersey denied Wyeth's motion for a preliminary injunction. In May 2009, the Court of

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

Appeals for the Federal Circuit affirmed the District Court's denial of the preliminary injunction. Subsequently, a jury trial was held, and in April 2010, the jury returned a verdict finding that the patent was not invalid. In July 2010, the District Court denied Teva's motion to overturn the verdict. The jury verdict cannot be appealed until the damages phase of the trial, which is scheduled to begin June 3, 2013, is completed. The patent at issue expired in July 2010, and Wyeth was granted pediatric exclusivity, which expired in January 2011. Were Wyeth ultimately to be successful in its allegation of patent infringement, Teva could be required to pay damages arising from its sales of pantoprazole sodium tablets, which were approximately \$1.1 billion for the relevant period.

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

In January 2012, Wyeth filed confidential expert reports asserting claims for damages and prejudgment interest of approximately \$2.1 billion. Wyeth has also asserted that Teva may be responsible for some or all of the damages allegedly caused by co-defendant Sun Pharmaceutical Industries, Ltd. Teva submitted its expert reports in April 2012, which estimated damages significantly below Wyeth's assessment. Although Wyeth's complaint alleged that defendants' infringement was willful, its subsequent written discovery responses stated that it did not intend to seek increased damages for willful infringement. Teva vigorously disputes Wyeth's claims as well as any liability for damages allegedly caused by Sun. Teva also disputes the amount of Wyeth's alleged damages and will contend that any damages allegedly caused by Teva are substantially less than asserted by Wyeth. On July 13, 2012, the parties filed various partial summary judgment motions related to damages and patent misuse issues, which have not yet been decided. In light of a legal development in the third quarter of 2012 in an unrelated case pertaining to one of Teva's patent infringement defenses, management has recorded a provision in the amount of \$670 million in the financial statements for this matter. Management estimates that the ultimate resolution of this matter could result in a loss of up to \$1.4 billion in excess of the amount accrued.

\*\*\*

Teva's leading innovative medicine, Copaxone® (glatiramer acetate), which is responsible for a very significant contribution to Teva's profits and cash flow from operations, faces patent challenges in various jurisdictions, including the United States, the United Kingdom and France. In August 2008, following the submission by Sandoz Inc. and Momenta Pharmaceuticals, Inc. of an ANDA for a generic version of Copaxone®, Teva sued Sandoz, its parent Novartis AG and Momenta in the United States District Court for the Southern District of New York for infringement of four Orange Book patents, which expire on May 21, 2014. An additional five patents are at issue in the litigation, including one process patent that expires on September 1, 2015. This case has been consolidated with a subsequently-filed patent infringement suit against Mylan Laboratories and Natco Pharma Limited. In August 2011, the District Court issued its claim construction opinion, which adopted all relevant interpretations by Teva and rejected all of the interpretations put forth by Sandoz/Momenta and Mylan/Natco (collectively, the Defendants). A trial on inequitable conduct took place in June 2011, and a trial on validity and infringement took place in September 2011. On June 22, 2012, the District Court issued its trial decision, in which it upheld the validity and enforceability of the nine patents at issue and found that Defendants' purported generic products would infringe all nine patents. As a result of this decision, on July 24, 2012, the District Court enjoined the FDA from granting final approval to the Defendants' ANDAs prior to May 24, 2014, and enjoined the Defendants from selling their purported generic products until September 1, 2015. The Defendants have appealed the injunctions.

In April 2012, Teva filed suit in the United States District Court for the Southern District of New York against Synthon Pharmaceuticals following its submission of an ANDA for a generic version of Copaxone®. 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.

Other innovative or branded medicines, including Azilect®, Provigil®, Nuvigil®, Amrix®, Fentora® and ProAir® HFA, are also subject to patent challenges.

**Product Liability Matters**

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

Teva subsidiaries Barr Pharmaceuticals 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





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

that has been prescribed to women receiving estrogen-containing hormone therapy). A much smaller number of cases involves Cenestin® (an estrogen-containing medicine 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 on that basis. There are approximately 412 cases pending, and additional dismissals are possible. Of the 412 pending cases, 324 are in multidistrict litigation in an Arkansas federal court and involve the alleged ingestion of generic drugs. In 75 of those cases, plaintiffs did not file amended complaints in response to a court order allowing plaintiffs until October 2, 2012 to plead claims that are not preempted by federal law. The vast majority of the claims are covered by insurance.

Teva and its subsidiaries have been named as defendants in over 2,500 product liability lawsuits brought against them and other manufacturers by approximately 4,500 plaintiffs claiming injuries (including allegations of neurological disorders, such as tardive dyskinesia) from the use of metoclopramide (the generic form of Reglan®). Certain of these claims are covered by insurance. 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 disorder 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. Approximately 40% of plaintiffs are parties to cases against Teva that are part of a mass tort proceeding in the Philadelphia County Court of Common Pleas. All of the cases in the Philadelphia court have been stayed with respect to the generic defendants pending resolution of appeals regarding whether the claims should be dismissed due to federal preemption. Oral argument for those appeals is scheduled for November 28, 2012. In addition to the Philadelphia mass tort proceeding, there are mass tort proceedings underway in state courts in California and New Jersey. In the California litigation, which now includes about half of the total plaintiffs, the trial court denied an attempt by the defendants to dismiss the case. The California Court of Appeals declined to review the trial court's ruling, and the defendants are now seeking review by the California Supreme Court. In the New Jersey proceeding, the trial court granted the defendants' motion to dismiss, on federal preemption grounds, all claims other than those based on an alleged failure to timely update the label.

***Competition Matters***

In April 2006, Teva and its subsidiary Barr Laboratories were named, 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, by an individual indirect purchaser, certain retail chain pharmacies 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. In March 2010, the District 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.

On October 31, 2011, the District Court hearing the antitrust cases described above, as well as patent claims brought by plaintiff Apotex, issued its decision regarding Apotex's invalidity claims as to Cephalon's Patent No. RE 37,516, finding the patent to be invalid based on obviousness, among other things, and unenforceable based on inequitable conduct. On March 29, 2012, the District Court ruled that Apotex's product does not infringe Cephalon's patent.



**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

Cephalon appealed this ruling on May 7, 2012. On July 16, 2012, the United States Court of Appeals for the Third Circuit issued its decision in the *In re K-Dur Antitrust Litigation*, finding that the agreement should be analyzed not under a scope of the patent test that other federal Courts of Appeals have applied, but under a quick look rule of reason analysis. In doing so, it found that if a brand pharmaceutical company makes a payment to a generic pharmaceutical company under a settlement agreement in order to resolve patent litigation, the payment creates a rebuttable presumption that the agreement is an unreasonable restraint on trade. Because of the split in the Courts of Appeal, it is unclear what effect, if any, this ruling will have on the modafinil antitrust litigation or on other litigations listed herein. The defendants in the *K-Dur* case have filed petitions for a writ of *certiorari* to the United States Supreme Court and in the modafinil litigations has stayed proceedings pending the Supreme Court's disposition of that petition, which is still pending. The District Court has not yet set a schedule for pretrial or trial proceedings in the antitrust litigation.

In April 2011, the European Commission opened a formal investigation against both Cephalon and Teva to assess whether the 2005 settlement agreement between the parties may have had the object or effect of hindering the entry of generic modafinil. The opening of proceedings indicates that the Commission will investigate the case as a matter of priority, but does not mean that there has been a definitive finding of violation of law.

Barr has been named as a co-defendant with Bayer Corporation, The Rugby Group, Inc. and others in approximately 38 class action complaints filed in state and federal courts by direct and indirect purchasers of ciprofloxacin (Cipro<sup>®</sup>) from 1997 to the present. The complaints allege that a 1997 Bayer-Barr patent litigation settlement agreement was anti-competitive and violated federal antitrust laws and/or state antitrust and consumer protection laws. 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. Following unsuccessful appeals and petitions for *certiorari* that were denied by the United States Supreme Court, the federal actions have effectively ended. In addition, all but three state cases (California, Kansas and Florida) have been dismissed. In the California case, the trial court granted defendants' summary judgment motions, and the California Court of Appeal affirmed in October 2011. Plaintiffs petitioned for review by the California Supreme Court, which has decided to hear the appeal, however, the California Supreme Court has suspended the briefing pending the Supreme Court's disposition of the *K-Dur* petition for *certiorari*. The Kansas action is stayed, and the Florida action is in the very early stages, with no hearings or schedule set to date.

In December 2011, three groups of plaintiffs sued Wyeth and Teva for violation of the antitrust laws in connection with entering into a settlement agreement to resolve the underlying patent litigation between the parties involving finished venlafaxine ER (generic Effexor<sup>®</sup> ER). The cases have been filed by a purported class of direct purchasers, certain chain pharmacies and a purported class of indirect purchasers. Plaintiffs' claims against Wyeth and Teva are that the settlement agreement unlawfully delayed generic entry. Plaintiffs also have asserted claims against Wyeth alone for fraud on the Patent Office. The cases seek unspecified damages. Teva filed motions to dismiss on April 6, 2012. The Court has stayed the cases in their entirety pending the Supreme Court's disposition of the *K-Dur* petition for *certiorari*.

In February 2012, two purported classes of direct-purchaser plaintiffs sued GlaxoSmithKline and Teva for violation of the antitrust laws in connection with a settlement agreement to resolve the underlying patent litigation between the parties involving finished lamotrigine (generic Lamictal<sup>®</sup>). In August 2012, a purported class of indirect purchaser plaintiffs filed a nearly identical complaint against GSK and Teva. Plaintiffs claim that the settlement agreement unlawfully delayed generic entry. The cases seek unspecified damages. GSK and Teva filed motions to dismiss on August 15, 2012. Briefing on the motions will be completed on November 9, 2012. The defendants filed motions to stay discovery pending resolution of the motions to dismiss. The court has refused to stay the cases in their entirety pending the Supreme Court's disposition of the *K-Dur* petition for *certiorari*, subject to reconsideration in the event *certiorari* is granted in *K-Dur*.

In September 2012, plaintiffs in seven cases, including overlapping purported class actions, sued AstraZeneca and Teva for violating the antitrust laws by entering into a settlement agreement to resolve the esomeprazole (generic Nexium<sup>®</sup>) patent litigation. These cases are currently pending in the Eastern District of Pennsylvania, the District of Massachusetts, and the District of New Jersey. On September 12, 2012, one plaintiff filed a motion with the Judicial Panel on Multidistrict Litigation to transfer and consolidate all cases in the District of New Jersey with the court that handled the underlying patent litigation. The defendants and some other plaintiffs subsequently joined in that motion, while one set of plaintiffs has argued for consolidation in Massachusetts. The parties are awaiting a decision from the panel, and have begun to enter into stipulations deferring the defendants' obligation to file answers or motions to dismiss until the venue issue is resolved. The panel has scheduled oral argument on the motion to transfer for November 29, 2012.



---

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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

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

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

A number of state attorneys general and others 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 reached settlements in most of these cases, and remain parties to litigation in Illinois, Missouri, Oklahoma, and Wisconsin. A settlement in principle has been reached in the Missouri case, and a settlement agreement was recently signed in the Oklahoma case. Trial in the Illinois case is scheduled to begin on October 23, 2013. A provision for the cases, including the settlements and settlements in principle, was included in the financial statements.

In December 2009, the United States District Court for the District of Massachusetts unsealed a complaint alleging that numerous drug manufacturers, including Teva USA and other subsidiaries, violated the federal False Claims Act in connection with Medicaid reimbursement for certain vitamins, dietary supplements and DESI products that were allegedly ineligible for reimbursement. The Department of Justice declined to join in the matter. The defendants, including Teva USA, filed a motion to dismiss, which has not yet been decided.

***Other Government Investigations***

In 2008, Cephalon entered into settlement agreements with the U.S. government and various parties and states relating to allegations of off-label promotion of Actiq®, Provigil® and Gabitril®. In connection with the settlements, Cephalon agreed to plead guilty to one misdemeanor violation of the U.S. Food, Drug, and Cosmetic Act, pay a fine and settlement, and enter into a five-year corporate integrity agreement with the Office of the Inspector General of the Department of Justice. Cephalon continues to defend against putative class action and other complaints regarding its sales and marketing practices with respect to such products. Additionally, Cephalon has received and is responding to subpoenas related to Treanda®, Nuvigil®, Provigil® and Fentora®.

Teva received a subpoena dated July 9, 2012 from the SEC to produce documents with respect to compliance with the Foreign Corrupt Practice Act (FCPA) in Latin America. On October 10 and October 26, 2012, the Department of Justice sent informal document requests to the Company as well. Teva is cooperating with the government. Teva is also conducting a voluntary investigation into certain business practices which may have FCPA implications and has engaged independent counsel to assist in its investigation. These matters are in their early stages, and no conclusion can be drawn at this time as to any likely outcomes.

***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, including for oversight by governmental authorities, the response costs associated with such oversight and for any related damages to natural resources. Teva and/or certain of its subsidiaries have been made a party to these proceedings, along



**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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 and/or its subsidiaries (or its predecessors') facilities or former facilities that may have adversely impacted the environment.

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 and other 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, the amounts of which 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 identifiable and estimable, which do not include reductions for potential recoveries of cleanup costs from insurers, indemnitors, former site owners or operators or other potentially responsible parties. In addition, civil proceedings relating to alleged federal and state regulatory violations at some of Teva's facilities may result in the imposition of significant civil penalties (in amounts not expected to materially adversely affect Teva's results of operations) and the recovery of certain state costs and natural resource damages, and may 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 medicines, especially Copaxone<sup>®</sup> (including competition from innovative orally-administered alternatives as well as from potential generic equivalents), potential liability for sales of generic medicines prior to a final resolution of outstanding patent litigation, including that relating to our generic version of Protonix<sup>®</sup>, the extent to which we may obtain U.S. market exclusivity for certain of our new generic medicines, 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 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 medicines, intense competition in our specialty pharmaceutical businesses, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based medicines, 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 instability and adverse economic conditions, 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, 2011, 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, 2011. 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 company that combines a world-leading generics business with a specialty pharmaceuticals business, as well as a joint venture focused on over-the-counter ( OTC ) medicines.

The pharmaceutical industry is affected by demographic and socioeconomic trends, such as aging populations and increased demand for effective treatments of diseases, as well as broad economic trends. As a result of these trends, there are increasing healthcare costs, governmental budget constraints and enhanced pressure on reimbursement pricing, and resource-constrained spending decisions of healthcare organizations, all of which lead to increased recognition of the importance of providing access to affordable pharmaceuticals. We believe that our balanced business model, which includes generic, branded and OTC medicines (together with other product offerings and services), along with our expansive geographic reach and globally integrated infrastructure, which create economies of scale, positions us to take advantage of these trends.

## **Table of Contents**

### **Results of Operations**

#### **Comparison of Three Months Ended September 30, 2012 to Three Months Ended September 30, 2011**

#### **Highlights**

Our revenues amounted to \$4,972 million, an increase of 14% over the third quarter of 2011, primarily driven by the inclusion of Cephalon's revenues commencing in October 2011, higher sales of generic medicines in the United States and higher sales of Copaxone®, partially offset by lower revenues from generic medicines in our European and Rest of the World (ROW) markets. Revenues were negatively impacted by foreign currency fluctuations.

Revenues in the United States increased \$646 million, due to higher sales of both branded and generic medicines. Revenues in Europe increased slightly, reflecting higher sales of branded medicines but lower sales of generic medicines. Our revenues in our ROW markets decreased slightly, mainly due to lower sales of generic medicines.

Global generics revenues amounted to \$2,492 million, 1% higher than the third quarter of 2011. Our branded medicines portfolio generated revenues of \$2,021 million, an increase of 38% over the third quarter of 2011 primarily due to Cephalon acquisition.

Our sales of Copaxone® reached \$1,046 million, a 13% increase compared to the third quarter of 2011 and the highest quarterly sales to date, primarily due to the assumption of distribution and marketing rights from Sanofi, and unusually high tender sales in Russia.

Gross profit amounted to \$2,601 million, an increase of 16%, or \$355 million, compared to the third quarter of 2011. Gross margins increased from 51.7% to 52.3%.

Loss contingencies, impairments, settlements and others in the quarter amounted to \$1,131 million, consisting primarily of an accrual of \$670 million relating to pending patent litigation and impairments of \$481 million.

Operating loss amounted to \$60 million, due to the foregoing loss contingency and impairments. Net loss attributable to Teva amounted to \$79 million.

Cash flow from operating activities amounted to \$1,048 million, as compared to \$482 million in the third quarter of 2011.

Exchange rate differences, primarily the decline in value of the euro relative to the U.S. dollar, between the third quarter of 2012 and the comparable quarter of 2011 had a negative impact of approximately \$202 million on revenues, a minimal net positive impact on operating income and a positive impact of \$0.45 billion on our equity.

#### **Sale of Animal Health Activity**

On September 14, 2012, Teva entered into an agreement to sell its U.S.-based animal health activity for up to \$145 million. The purchase price includes a payment of \$60 million at closing and up to \$85 million in milestone payments. This transaction reflects Teva's commitment to focus its efforts on human health and its core expertise of providing quality generic and branded medicines.

The transaction is expected to close in 2013, subject to antitrust clearance and satisfaction of other conditions.

**Acquisition of Neurosearch A/S Assets**

On October 25, 2012, Teva acquired from Neurosearch A/S, a Danish company, the rights, assets and obligations relating to Huntexil® (pridopidine / ACR16), a drug candidate being developed for the symptomatic treatment of hand movement, balance and gait disturbances in Huntington's disease for approximately \$26 million. Regulatory and commercialization milestone payments may result in additional payments to NeuroSearch.

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

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

	Percentage of Net Revenues		Percentage Change 2012 from 2011 %
	Three Months Ended		
	September 30, 2012 %	2011 %	
Net revenues	100.0	100.0	14
Gross profit	52.3	51.7	16
Research and development expenses net	6.5	5.6	34
Selling and marketing expenses	18.4	18.6	13
General and administrative expenses	5.9	2.6	161
Loss contingencies, impairments, settlements and others	22.7	1.1	n/a
Operating income (loss)	(1.2)	23.8	n/a
Financial expenses net	1.5	1.5	9
Income (loss) before income taxes	(2.7)	22.3	n/a
Provision for income tax expense (benefit)	(1.1)	0.8	n/a
Share in losses of associated companies net	0.2	0.4	(53)
Net (income) loss attributable to non-controlling interests	0.1	*	n/a
Net income (loss) attributable to Teva	(1.7)	21.1	n/a

\* Less than 0.05%.

**Table of Contents****Revenues****General**

Revenues for the three months ended September 30, 2012 were \$4,972 million, an increase of 14% over the third quarter of 2011. Growth was primarily driven by the consolidation of Cephalon commencing in October 2011, higher sales of generics in the United States and higher sales of Copaxone®, partially offset by lower sales of generics in Europe and in our ROW markets as well as exchange rate fluctuations.

**Revenues by Geographic Area**

The following table presents revenues by geographic area for the three months ended September 30, 2012 and 2011:

	Three Months Ended September 30,		% of 2012	% of 2011	Percentage Change 2012 from 2011
	2012	2011			
	U.S. \$ in millions				
United States:					
Generic	\$ 1,074	\$ 863	22%	20%	24%
Branded	1,468	1,090	29%	25%	35%
Others	59	2	1%	§	2,850%
Total United States	2,601	1,955	52%	45%	33%
Europe*:					
Generic	798	917	16%	21%	(13%)
Branded	376	242	8%	6%	55%
Others	183	185	4%	4%	(1%)
Total Europe	1,357	1,344	28%	31%	1%
Rest of the World:					
Generic	620	695	12%	16%	(11%)
Branded	177	132	4%	3%	34%
Others	217	218	4%	5%	§
Total Rest of the World	1,014	1,045	20%	24%	(3%)
Total Revenues	\$ 4,972	\$ 4,344	100%	100%	14%

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

§ Less than 0.5%

**United States**

In the third quarter of 2012, we had revenues of \$2,601 million, a 33% increase over the comparable quarter of 2011. We significantly increased our presence in the branded arena, due to the acquisition of Cephalon, and have maintained our leading position in the generics business. Total prescriptions in the twelve months ended September 30, 2012 amounted to 549 million, representing 13.8% of total U.S. prescriptions, and new prescriptions amounted to 299 million. Our U.S. market leadership position has been enhanced due to the acquisition of Cephalon and the resulting expansion of our branded business, and as a result of our ability to introduce new generic equivalents for brand-name products on a timely basis, emphasis on customer service, the breadth of our product line, our commitment to regulatory compliance and our cost-effective production.



**Table of Contents****Generic Medicines**

Revenues from generic medicines in the United States during the third quarter of 2012 amounted to \$1,074 million, an increase of 24% compared to \$863 million in the comparable quarter of 2011. The increase resulted mainly from \$253 million of products sold in the third quarter of 2012, several of which were either exclusive or semi-exclusive or otherwise had limited competition, that were not sold in the third quarter of 2011. Sales of new products were partially offset by declines in sales of previously-launched products, primarily those where we had exclusive or semi-exclusive rights in the third quarter of 2011.

Among the most significant generic medicines we sold in the U.S. during the third quarter of 2012 were generic versions of Pulmicort® (budesonide inhalation), Adderall XR® (mixed amphetamine salts ER), Lexapro® (escitalopram oxalate), Actos® (pioglitazone), Adderall IR® (amphetamine salts IR), Provigil® (modafinil), Actoplus met® (pioglitazone/metformin), Accutane® (isotretinoin, which we market as Claravis ) and Yaz® (drospirenone and ethinyl estradiol, which we market as Gianvi ).

**Launches.** In the third quarter of 2012, we launched generic versions of the following branded medicines in the U.S. (listed by month of launch):

Generic Name	Brand Name	Month of Launch	Total Annual Branded Medicines Market at Time of Generic Launch \$ millions (IMS)*
Fluvastatin capsules 20 & 40 mg	Lescol®	Jul-2012	\$ 22
Methylphenidate ER capsules 20, 30 & 40 mg	Ritalin® LA	Jul-2012	\$ 53
Montelukast sodium tablets 10 mg	Singulair®	Aug-2012	\$ 3,714
Montelukast sodium chewable tablets 4 & 5 mg	Singulair®	Aug-2012	\$ 1,165
Pioglitazone HCl tablets 15, 30 & 45 mg	Actos®	Aug-2012	\$ 2,736
Pioglitazone HCl & metformin HCl tablets 15 / 500 & 15 / 850 mg	Actoplus met®	Aug-2012	\$ 413
Clozapine orally disintegrating tablets 12.5, 25 & 100 mg	FazaClo ODT	Aug-2012	\$ 40
Methylphenidate ER capsules 10, 20, 30, 40, 50 & 60 mg	Metadate CD®	Sep-2012	\$ 144
Quinine sulfate capsules 324 mg	Qualaquin®	Sep-2012	\$ 31

\* Branded medicines annual market size as quoted by IMS is a commonly used measurement of the relative significance of a potential generic product. The figures given are for the twelve months ended in the calendar quarter closest to our launch. Generic equivalents of any given product are typically sold at prices substantially lower than the branded product price.

We expect that our revenues in the U.S. will continue to benefit from our strong generic pipeline, which, as of October 19, 2012, had 143 product registrations awaiting FDA approval, including 40 tentative approvals. Collectively, the branded versions of these 143 products had annual U.S. sales exceeding \$84 billion. Of these applications, 101 were Paragraph IV applications challenging patents of branded medicines. We believe we are first to file with respect to 63 of these products, the branded versions of which had annual U.S. sales of more than \$44 billion. IMS reported brand sales are one of the many indicators of future potential value of a launch, but equally important are the mix and timing of competition, as well as cost effectiveness. However, potential advantages of being the first filer with respect to some of these products may be subject to forfeiture and/or shared exclusivity.

The FDA requires companies to submit abbreviated new drug applications (ANDAs) for approval to manufacture and market generic forms of brand-name drugs. In most instances, FDA approval is granted upon the expiration of the underlying patents. However, companies may be rewarded with a 180-day period of marketing exclusivity, as provided by law, for being the first generic applicant to successfully challenge these patents. As part of our strategy, we actively review pharmaceutical patents and seek opportunities to challenge patents that we believe are either invalid or not infringed by our generic version. In addition to the commercial benefit of obtaining marketing exclusivity, we believe that our patent challenges ultimately improve healthcare by allowing consumers earlier access to more affordable, high-quality medications.

During the third quarter of 2012, we received the following tentative approvals. A tentative approval letter indicates that the FDA has substantially completed its review of an application and final approval is expected once the relevant patent expires, a court decision is reached, a 30-month regulatory stay lapses or a 180-day exclusivity period awarded to another manufacturer either expires or is forfeited.





**Table of Contents**

Generic Name	Brand Name	Total Branded Market \$ millions (IMS)*
Methylphenidate HCl ER capsules 10 mg	Ritalin® LA	\$ 16
Carbamazepine ER capsules 100, 200 & 300 mg	Equetro	\$ 5,378
Aripiprazole tablets 2, 5, 10, 15, 20 & 30 mg	Abilify®	\$ 7

\* Figures given are for the twelve months ended June 30, 2012.

In December 2009, the FDA issued a warning letter relating to our Irvine, California injectables 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. On October 23, 2012, we received a letter from the FDA acknowledging that our corrective actions have addressed the violations noted in the December 2009 warning letter. During the third quarter of 2012, we incurred uncapitalized production costs, consulting expenses and write-offs of inventory of approximately \$16 million relating to this facility. If we are unable to resume full production and sale of injectables, 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 September 30, 2012, we had approximately \$44 million of intangible assets and approximately \$219 million of fixed assets and inventory relating to injectables produced at the Irvine facility.

**Branded Medicines**

In the third quarter of 2012, our revenues from branded medicines in the United States amounted to \$1,468 million, an increase of 35% over the comparable quarter of 2011. The main factors affecting such revenues were:

the inclusion of sales of Cephalon's branded medicines, primarily Treanda®, Nuvigil®, Provigil®, and Fentora®;

a slight increase in sales of Copaxone®, primarily due to a price increase;

4% decrease in revenue of ProAir™ and a 16% decrease in revenue of Qvar® over the comparable quarter of 2011 as a result of additional Medicaid rebates partially offset by increases in market share and price; and

a decline in sales of our branded women's health medicines.

For our branded medicines, we maintain distribution services agreements ( DSAs ) with wholesalers. During the first quarter of 2012, we renegotiated these agreements and established a different fee structure. We believe that the revised terms should provide our customers with incentives to hold inventory levels more closely aligned with actual product demand. As a result, there have been reductions in the levels of inventory of our products. We expect these reductions will continue to have a positive impact on our supply chain management.

**Other Revenues**

In the third quarter of 2012, other revenues in the United States amounted to \$59 million, compared to \$2 million in the comparable quarter of 2011. The increase in revenues was due to the inclusion, beginning in the fourth quarter of 2011, of OTC sales to P&G pursuant to a manufacturing agreement.

**Europe**

Revenues in Europe in the third quarter of 2012 amounted to \$1,357 million, a slight increase of 1% compared to the comparable quarter of 2011. In local currency terms, revenues increased by 13%. The increase in revenue in local currency terms was due to the completion of the transition of the distribution and marketing rights for Copaxone® and the consolidation of Cephalon. This increase was partially offset by the ongoing macro-economic conditions and by healthcare reforms in key European markets, which increased generic penetration while lowering prices of generic medicines.



---

## **Table of Contents**

Based on our internal assessment of the situation in Europe, Greece and Portugal are experiencing the most significant economic stress, followed by Italy, Hungary, Spain and Belgium. We are closely monitoring our exposure in these countries and adjust our commercial practices to the changing environment as needed.

As in previous years, European regulatory measures aimed at reducing healthcare and drug expenditures have led to a slowing of the growth of the generic medicines market, and have adversely affected our revenues. In France, Spain, Italy, Poland, Hungary and Portugal, governmental measures have reduced reimbursement rates. In several countries, particularly Spain, Italy, Portugal and Hungary, reductions in reimbursement rates have been combined with other reforms aimed at reducing drug expenditures, such as mandatory prescription by International Nonproprietary Names ( INN ) for select product groups. In addition, in certain countries, mainly Hungary and Italy, mandatory rebates were increased or introduced. We have implemented measures to adjust our market strategy to address these market changes, and have shifted from a purely market share driven approach to a model emphasizing growth that is both profitable and sustainable.

### ***Generic Medicines***

Revenues from generic medicines in Europe in the third quarter of 2012 were \$798 million, a decrease of 13%. In local currency terms, revenues decreased by 3%. This decrease was driven primarily by the ongoing macro-economic conditions and healthcare reforms in key European markets, as well as by a more selective approach to participation in tenders in Germany, which resulted in lower revenues from tender sales. Additionally, revenues in the comparable quarter were high as a result of the launch of a generic version of Lipitor® (atorvastatin). The decrease was partially offset by the inclusion of the generic activities of Cephalon in Europe. During the quarter we successfully launched the following medications: irbesartan, tolterodine and drospirenone/ethynil estradiol. We maintained our market positions in major markets.

### ***Branded Medicines***

In the third quarter of 2012, sales of branded medicines in Europe amounted to \$376 million, an increase of 55% compared to the third quarter of 2011. In local currency terms, revenues increased by 73%. The change was driven by the inclusion of Cephalon and increased sales of Copaxone® mainly resulting from the completion of the transition of the distribution and marketing rights for Copaxone® from Sanofi in Europe.

The Cephalon branded medicines Provigil®, Effentora® and Myocet® contributed significantly to our performance this quarter.

### ***Other Revenues***

Other revenues, mainly from our distribution activities in Hungary and from our consumer healthcare partnership with P&G, amounted to \$183 million in the third quarter of 2012, compared to \$185 million in the third quarter of 2011. In local currency terms revenues increased by 12%. Our partnership with P&G resulted in the launch of Vicks® in Hungary and the Czech Republic during the quarter.

*Listed below are highlights for the third quarter of 2012 in our largest European markets (in local currency terms):*

**Germany:** Revenues in Germany increased slightly despite adverse local market conditions and our focus on profitable and sustainable growth for our generics business, which resulted in a more selective approach to our participation in tenders. Our branded sales increased primarily due to the inclusion of Cephalon and the assumption of the distribution and marketing responsibility for Copaxone® and Azilect®.

**France:** Revenues in France increased significantly, primarily due to the inclusion of Cephalon and the assumption of the distribution and marketing responsibility for Copaxone®. Sales of branded medicines, including Copaxone®, increased and now account for approximately half of revenues. New healthcare reforms in France had a positive effect on the penetration of generic medications in France. We maintained our position as the third largest generic pharmaceutical company in the French generic market in terms of sales, and successfully launched irbesartan during the quarter.

**United Kingdom:** Revenues in the U.K. decreased compared to the third quarter of last year, in which revenues were high as a result of the launch of a generic version of Lipitor® (atorvastatin). During the current quarter, we successfully launched tolterodine. We maintained our position as the largest generic pharmaceutical company in the U.K. in terms of sales, though the market for generic

pharmaceuticals declined slightly in value.

---

**Table of Contents**

**Italy:** Our revenues in Italy were lower than in the comparable quarter due to lower revenues from generic medicines. We maintained our leading position in the Italian market for generic pharmaceuticals, despite a slight reduction in our market share. The branded business developed positively, with growth of both Copaxone® and Cephalon branded medicines.

**Spain:** Compared to the third quarter of 2011, sales in Spain grew, driven by growth in the sales of branded medications. The market for generic pharmaceuticals in Spain is growing at a slower pace, impacted by government measures aimed at reducing healthcare spending. An amendment to Spanish legislation was implemented in May 2012, allowing dispensing of only the lowest priced product within certain product groups. We maintained our leading position in the Spanish generic market.

***Rest of the World ( ROW ) Markets***

These markets include all countries other than the United States and the countries we include as Europe. ROW markets range from pure generic markets, such as Canada and Israel, to markets in which generic medicines are marketed and sold under brand names, such as several Asian and Latin American markets. Sales of branded generic medicines usually generate higher gross margins, but involve higher marketing expenditures than non-branded generics. These markets also vary widely in size, growth rates, availability of biosimilar approval pathways and the importance and acceptance of OTC products.

Our revenues in the third quarter of 2012 in ROW markets amounted to \$1,014 million, a decline of 3% as compared to the third quarter of 2011. This decline was primarily due to lower generic revenues in Canada as well as changes in currency exchange rates, partially offset by higher sales of Copaxone® and other branded medicines, increased distribution revenues and higher OTC sales. In local currency terms, revenues grew 1%. Sales of generic medicines amounted to \$620 million, which represented 61% of the total revenues in the region; sales of branded medicines amounted to \$177 million, or 17% of total revenues; and other revenues were \$217 million, or 22% of total sales.

Approximately 23% of our ROW revenues were generated in Japan and other Asian markets, 22% in Latin America, 22% in Russia and other Eastern European markets, 18% in Canada and other markets and 15% in Israel.

Our sales in Asia in the third quarter of 2012 decreased 3% compared to the third quarter of 2011 due to lower API sales. In local currency terms, sales grew 2%. In Japan, our sales were flat compared to the third quarter of 2011. Our results in Japan mainly reflect the full consolidation of the sales from our Japanese ventures as of September 2011, partially offset by lower prices. The Japanese generics market as a whole has been growing more slowly, as a result of the healthcare reforms instituted by the government in April, which included price reductions for generic products.

In Latin America, revenues in the third quarter of 2012 grew 6% in dollar terms and 10% in local currency terms, as compared to the third quarter of 2011. The increase was primarily driven by higher sales of generic medicines, the performance by our OTC businesses and growth in sales of branded medicines, including women's health and CNS products. In the near term, revenues are expected to be negatively affected by drug price legislation, as well as by exchange rate fluctuations, in certain Latin American markets.

Our revenues in Russia and other Eastern European markets in the third quarter of 2012 grew 23% in dollar terms and 31% in local currency terms, as compared to the third quarter of 2011. The growth was mainly attributable to unusually high sales of Copaxone®, due to the fact that Russian government tenders for Copaxone® in the quarter included supplies for a portion of 2013. We expect that changes in the Russian government tender system in 2013 will result in significant variations from quarter to quarter in our future Copaxone® sales. Higher sales of generic medicines and OTC products also contributed to the growth this quarter. Our market share in Russia continued to grow, solidifying our position as the second largest generic pharmaceutical company by value. Most other Eastern European markets grew during the quarter despite challenging macro-economic conditions.

In Canada, where we are second in the generic pharmaceutical market, revenues in the third quarter of 2012 decreased by 33%. The decrease reflects the effect of government-imposed price reforms and a decline in market share in the current quarter due to increased competition. As of September 30, 2012, we had 64 product registrations awaiting approval by the Therapeutic Products Directorate of Health Canada. Collectively, the branded versions of these products had annual Canadian sales of approximately \$2 billion.

Revenues in Israel in the third quarter of 2012 decreased 6% in dollar terms but increased by 3% in local currency terms, as compared to the third quarter of 2011. The increase in local currency terms was primarily driven by higher distribution revenues.

**Table of Contents****Revenues by Product Line**

The following table presents a breakdown of revenues by product line for the three months ended September 30, 2012 and 2011:

	Three Months Ended September 30,		% of 2012	% of 2011	Percentage Change 2012 from 2011
	2012	2011			
	U.S. \$ in millions				
<b>Generic Medicines</b>	<b>2,492</b>	<b>2,475</b>	<b>50%</b>	<b>57%</b>	<b>1%</b>
API	195	183	4%	4%	7%
<b>Branded Medicines</b>	<b>2,021</b>	<b>1,464</b>	<b>41%</b>	<b>34%</b>	<b>38%</b>
CNS	1,366	999	28%	23%	37%
Copaxone®	1,046	928	21%	21%	13%
Provigil®	53		1%		
Azilect®	77	71	2%	2%	8%
Nuvigil®	94		2%		
Respiratory	201	210	4%	5%	(4%)
ProAir	109	113	2%	3%	(4%)
Qvar®	62	67	1%	2%	(7%)
Women's Health	96	123	2%	3%	(22%)
Oncology	221	29	4%	1%	662%
Treanda®	160		3%		
Other Branded	137	103	3%	2%	33%
<b>All Others</b>	<b>459</b>	<b>405</b>	<b>9%</b>	<b>9%</b>	<b>13%</b>
OTC	252	183	5%	4%	38%
Other Revenues	207	222	4%	5%	(7%)
<b>Total</b>	<b>4,972</b>	<b>4,344</b>	<b>100%</b>	<b>100%</b>	<b>14%</b>

**Generic Medicines**

Our generics category includes sales of generic medicines as well as API sales to third parties.

Revenues from our generic medicines grew by \$17 million, or 1%, in the third quarter of 2012 over the third quarter of 2011.

Our largest market for generics is the United States, with revenues of \$1,074 million, up 24% from the third quarter of 2011. The increase resulted from \$253 million of products sold in the third quarter of 2012 that were not sold in the third quarter of 2011, several of which were either exclusive or semi-exclusive or otherwise had limited competition. Sales of new products were partially offset by declines in sales of previously-launched products, primarily those where we had exclusive or semi-exclusive rights in the third quarter of 2011. The U.S. market generated 43% of total generics revenues in the third quarter of 2012.

Revenues from generic medicines in Europe in the third quarter of 2012 amounted to \$798 million, a decrease of 13% compared to the third quarter of 2011. In local currency terms, sales declined by 3%. The decrease was primarily due to the ongoing macro-economic conditions and healthcare reform in key European markets, as well as lower market share in several European countries due, in part, to a more selective approach to participation in tenders in Germany, which resulted in lower revenues from tender sales. Additionally, revenues in the comparable quarter were high as a result of the launch of a generic version of Lipitor® (atorvastatin). This decline was partially offset by the inclusion of Cephalon's European generic sales. The European market generated approximately 32% of our global generics revenues in the third quarter of 2012.

## **Table of Contents**

In our ROW markets, revenues from generic medicines amounted to \$620 million, a decrease of 11% compared to \$695 million in the third quarter of 2011. In local currency terms, sales decreased by 8%. The decrease was mainly due to lower revenues in Canada, partially offset by higher sales of generic medicines in Israel and other markets. The ROW markets generated approximately 25% of total generics revenues in the third quarter of 2012.

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

API sales to third parties in the third quarter of 2012 amounted to \$195 million, an increase of 7% over the third quarter of 2011. The increase was mainly driven by higher sales in the United States.

### **Branded Medicines**

In 2011, we revised our classification of certain products and grouped our branded medicines into five categories: Central Nervous System, Respiratory, Women's Health, Oncology and Other.

Our revenues from branded medicines amounted to \$2,021 million in the third quarter of 2012, an increase of 38% over the comparable quarter of 2011, mainly due to the inclusion of sales of Cephalon's branded medicines and higher revenues from Copaxone® and Azilect®, which were partially offset by a decline in revenues of several of our women's health and respiratory products.

### ***Central Nervous System ( CNS )***

Our central nervous system line includes Copaxone® and Azilect®, as well as additions from the Cephalon acquisition, such as Provigil® and Nuvigil® for wakefulness and Fentora® for the treatment of pain. In the third quarter of 2012, our CNS sales reached \$1,366 million, an increase of 37% over the comparable quarter of 2011, primarily due to the addition of the Cephalon acquired products commencing in the fourth quarter of 2011 and an increase in Copaxone® revenues.

**Copaxone®.** In the third quarter of 2012, Copaxone® (glatiramer acetate injection) continued to be the leading multiple sclerosis therapy in the U.S. and globally. Teva's sales of Copaxone® during the period grew by 13% compared to Teva's sales for the third quarter of 2011. In local currency terms, Copaxone® grew by 15%.

Until February 2012, global in-market sales represented sales of Copaxone® from Sanofi and Teva to other third parties. In February 2012, we completed the transition of the marketing and distribution rights of Copaxone® back to us. Therefore, commencing with the second quarter of 2012, all global sales were made by Teva. Global in-market sales for the quarter amounted to \$1,046 million, an increase of 2% over the in-market sales of the comparable period.

In the third quarter of 2012, sales of Copaxone® in the United States increased by 3% to \$775 million due to a price increase, which was partially offset by a decrease in volume. U.S. market shares in terms of new and total prescriptions were 38.4% and 40.4% respectively, according to September 2012 IMS data.

U.S. sales accounted for 74% of global Copaxone® sales in the third quarter of 2012, similar to the third quarter of 2011 in terms of in-market sales.

Teva's non-U.S. Copaxone® revenues amounted to \$271 million during the quarter, 54% higher than the third quarter of 2011, an increase of 68% in local currency terms. The increase was driven primarily by our assumption of distribution and marketing responsibility for Copaxone® from Sanofi in Europe, which was completed in February 2012, and by unit growth, particularly in Russia due to unusually high tender sales. Sanofi is entitled to receive 6% of the in-market sales of Copaxone® in the applicable European countries for a period of two years from our assumption of the distribution and marketing responsibilities. This termination of our arrangements with Sanofi has resulted in increases both in our net revenues and in our selling and marketing expenses.

Non-U.S. in-market sales of Copaxone® remained stable compared to the third quarter of 2011. In local currency terms, non-U.S. in-market sales of Copaxone® increased 10% over the third quarter of 2011. The increase in local currency terms in non-U.S. in-market sales was driven by unit growth, primarily in Russia due to the timing of tenders, and in Latin America.

Generic glatiramer acetate was approved recently in Argentina, though not launched. Teva is appealing the decision. We do not expect this to materially affect our sales of Copaxone®.

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

In a governmental tender procedure in Mexico, a local manufacturer was allowed to bid on generic glatiramer acetate and was awarded part of the tender. We are not certain of the approval status of the local company's product and we are pursuing legal action. We do not expect this to materially affect our sales of Copaxone®.



## **Table of Contents**

In August 2012, a study investigating the efficacy, safety and tolerability of a 20 mg/0.5 ml formulation of glatiramer acetate versus placebo in patients with relapsing-remitting multiple sclerosis was terminated.

**Provigil®.** Following the acquisition of Cephalon, our sales of Provigil® (modafinil) amounted to \$53 million in the third quarter of 2012. Provigil® began to face generic competition in the United States beginning in March 2012 and, as a result, Provigil® sales decreased substantially.

**Azilect®.** Our once-daily treatment for Parkinson's disease, Azilect® (rasagiline tablets), continued to grow in the United States and in some countries in Europe. We jointly market Azilect® with Lundbeck in certain key European countries. We exclusively market Azilect® in the United States and Germany and certain other markets, while Lundbeck exclusively markets Azilect® in the remaining European countries and certain other international markets.

Global in-market sales, which represent sales from Lundbeck and Teva to third parties, reached \$103 million in the third quarter of 2012 million compared to \$97 million in the third quarter of 2011, an increase of 6%. The increase in sales is attributable mainly to increases of both price and volume in the United States, as well as to volume growth in Europe partially offset by currency effects.

Our sales of Azilect® amounted to \$77 million, an increase of 8% compared to the third quarter of 2011.

**Nuvigil®.** Following the acquisition of Cephalon, our Nuvigil® (armodafinil) sales amounted to \$94 million in the third quarter of 2012. Nuvigil®'s exit market share in terms of total prescriptions of the U.S. wake category was 45.8%.

### ***Respiratory Products***

Our respiratory product line includes only our branded respiratory products, the main ones being ProAir™ and Qvar®. Sales of generic medicines indicated for the treatment of respiratory disease are reported as part of our generic medicines revenues.

Revenues from our respiratory branded medicines amounted \$201 million in the third quarter of 2012, a decrease of 4% compared to the third quarter of 2011, primarily due to lower revenues in the United States that were partially offset by higher sales in Europe.

**ProAir** (albuterol HFA), which we sell only in the United States, is a short-acting beta-agonist (SABA) for the treatment of bronchial spasms linked to asthma or COPD and exercise-induced bronchospasm. ProAir revenues amounted to \$109 million, a decrease of 4% compared to the third quarter of 2011 resulting from additional Medicaid rebates, partially offset by a volume increase. ProAir maintained its leadership in the SABA market, with an average market share of 51.6% in terms of total number of prescriptions during the period, up 1.3 points from the third quarter of 2011.

**Qvar®** (beclomethasone dipropionate HFA) is an inhaled corticosteroid for long-term control of chronic bronchial asthma. Qvar® global revenues amounted \$62 million, a decrease of 7% from the prior year quarter primarily due to additional Medicaid rebates in the United States. Qvar® maintained its second-place position in the inhaled corticosteroids category in the United States with an average market share of 25.8% of total of prescriptions during the third quarter of 2012, an increase of 3.6 points over the third quarter of 2011.

Due to the prevalence of respiratory diseases among patients with Medicaid health insurance, revenues from respiratory products are more affected by changes in Medicaid rebates as compared to other branded products. We expect Medicaid rebates in the U.S. to continue to affect revenues in the near future.

### ***Oncology***

Our branded oncology line includes certain Cephalon medicines, as well as biosimilars that are indicated mainly for the supportive treatment of oncology patients. Sales of these medicines reached \$221 million in the third quarter of 2012 as compared to \$29 million in the comparable quarter of 2011. The increase resulted primarily from the inclusion of Cephalon's cancer treatments as of the fourth quarter of 2011, the largest of which is Treanda®.

Sales of Treanda® amounted to \$160 million in the third quarter of 2012. During the period, sales of biosimilar oncology pharmaceuticals amounted to \$30 million, \$1 million higher than in the third quarter of 2011. In August 2012, Treanda® was approved in Canada. Lundbeck began marketing Treanda® in September 2012.



## **Table of Contents**

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

This line includes revenues only from our branded women's health medicines, which had revenues of \$96 million in the third quarter of 2012, a decrease of 22% from \$123 million in the comparable quarter of 2011. The decrease was primarily due to lower sales in the United States resulting from the introduction in the third quarter of 2011 of generic competition to our oral contraceptive product, Seasonique<sup>®</sup>, and from generic competition to our emergency contraceptive Plan B One-Step<sup>®</sup> beginning in the third quarter of 2012. Outside the U.S., sales were negatively affected by exchange rate differences.

### **All Others**

#### ***OTC***

Our sales of OTC products for the third quarter of 2012 amounted to \$252 million. Our sales related to PGT Healthcare amounted to \$195 million, an increase of 6% compared to sales of \$183 million in the third quarter of 2011. In local currency terms, sales grew by 15%. The increase was mainly due to growth in sales in Latin America and Europe. During the quarter, the Vicks<sup>®</sup> product line was launched in Hungary and the Czech Republic.

PGT Healthcare's in-market sales for the third quarter of 2012 amounted to \$341 million. This amount represents sales of the combined OTC portfolios of Teva and P&G outside North America.

Sales in the quarter of OTC products in the United States to P&G, which commenced in the fourth quarter of 2011 pursuant to a manufacturing agreement, amounted to \$57 million.

#### ***Other Revenues***

Other revenues include sales of third party products for which we act as distributors (mostly in Israel and Hungary), animal health products and medical products, as well as miscellaneous items.

In the third quarter of 2012, our revenues in this category amounted to \$207 million, down from \$222 million in the third quarter of 2011 mainly due to the negative effect of exchange rate fluctuations. In local currency terms, revenues grew by 5%.

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

#### **Gross Profit**

In the third quarter of 2012, gross profit amounted to \$2,601 million, an increase of 16%, or \$355 million, compared to the third quarter of 2011. The increase in gross profit was mainly a result of our higher overall revenues, especially of our branded medicines and generic medicines in United States. The increase was partially offset by lower sales of generic medicines in Canada and by higher charges related to the amortization of purchased intangible assets primarily of Cephalon (which commenced in part in the fourth quarter of 2011).

The charges related to the amortization of purchased intangible assets, which negatively impacted our gross profit, increased from \$151 million in the third quarter of 2011 to \$288 million in the third quarter of 2012.

Gross margin increased from 51.7% in the third quarter of 2011 to 52.3% in the current quarter. This 0.6% increase in gross margin primarily reflects an increase in sales of our higher margin branded medicines, mainly due to the newly acquired Cephalon products Treanda<sup>®</sup>, Nuvigil<sup>®</sup> and Provigil<sup>®</sup>, as well as Copaxone<sup>®</sup> and other products (which increased the gross margin by approximately 5.4 points). This increase was partially offset by charges related to the amortization of purchased intangible assets and costs related to regulatory actions taken in various manufacturing facilities, (which, in the aggregate, decreased gross margin by approximately 2.2 points) as well as higher sales of products with lower gross margins (which decreased the gross margin by approximately 2.6 points).

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

Net R&D spending for the quarter totaled \$324 million, an increase of 34% compared to the third quarter of 2011, driven mainly by the acquisition of Cephalon. As a percentage of revenues, R&D spending was 6.5% in the third quarter of 2012, compared to 5.6% in the third quarter of 2011.

Approximately 62% of our R&D expenditures were for our branded medicines, and the remainder were for generic R&D.

---

## **Table of Contents**

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

### **Selling and Marketing Expenses**

Selling and marketing expenses in the third quarter of 2012 amounted to \$914 million, an increase of 13% over the third quarter of 2011. As a percentage of revenues, selling and marketing expenses decreased from 18.6% in the third quarter of 2011 to 18.4% in the third quarter of 2012.

The increase in U.S. dollar terms was primarily due to the consolidation of Cephalon, as well as the assumption of distribution and marketing responsibility for Copaxone® in Europe. The increase was partially offset by currency fluctuations and lower royalty payments made on generic medicines in the U.S.

The decrease as a percentage of revenues resulted from reduced selling and marketing expenses for our generics medicines and a reduction in royalty payments on generic medicines in the U.S. These reductions were partially offset by an increase in the proportion of branded medicines sold, which have higher than average selling and marketing expenses.

In February 2012, we completed the assumption of distribution and marketing responsibility for Copaxone® in Europe from Sanofi. Sanofi is entitled to receive 6% of the in-market sales of Copaxone® in the applicable European countries for a period of two years from our assumption of the distribution and marketing responsibilities. As of March 1, 2012, Sanofi no longer shares any of our Copaxone® selling and marketing expenses.

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

G&A expenses were \$292 million in the third quarter of 2012, representing 5.9% of revenues, as compared to \$112 million and 2.6% of revenues in the third quarter of 2011. The increase was mainly due to gains recorded in the comparable quarter of 2011, which reduced our expenses in that quarter, as well as higher expenses this quarter due to the acquisition of Cephalon. The gains recorded in the comparable quarter of 2011 were mainly due to our acquisition of additional holdings in CureTech and in our Japanese venture, which allowed us to gain control of these entities, triggering a gain of \$135 million, relating to our prior holdings in these companies.

### **Loss Contingencies, Impairments, Settlements and Others**

Loss contingencies, impairments, settlements and others amounted to \$1,131 million in the third quarter of 2012, as compared to \$51 million in the third quarter of 2011.

The increase reflects a provision for loss contingency as well as impairments. These consist primarily of an accrual of \$670 million relating to pending patent litigation concerning Teva's generic pantoprazole in the third quarter of 2012, as well as impairments of \$481 million, compared to \$16 million in the third quarter of 2011. The impairments consist primarily of write-downs to in-process R&D, including \$268 million relating to obatoclox for the treatment of small cell lung cancer and \$88 million relating to CEP-37247 anti-tumor necrosis factor for the treatment of sciatica. These impairments were recorded in connection with our ongoing overall review of our R&D portfolio. We also impaired armodafinil (Nuvigil®) for the treatment of bi-polar disorder by \$59 million to reflect a settlement agreement with Mylan.

Following the Cephalon acquisition, we are in the process of restructuring our operations in France, and therefore expect to incur considerable restructuring expenses for these activities. In addition, we may incur additional restructuring expenses following completion of a review of our network of manufacturing facilities.

### **Operating Income (Loss)**

Operating loss was \$60 million in the third quarter of 2012, compared to operating income of \$1,035 million in the third quarter of 2011. As a percentage of revenues, operating loss was 1.2% compared to operating income of 23.8% in the third quarter of 2011.

The decrease in operating income was due to factors previously discussed, primarily increased provisions for loss contingency, impairments of long-lived assets, higher G&A expenses, higher S&M expenses, higher R&D expenses as well as higher expenses in connection with legal settlements and reserves that were partially offset by higher revenues, higher gross profit, and income from contingent consideration as well as lower restructuring, acquisition and other expenses. Foreign exchange rate fluctuations had a minimal net positive effect, compared to the third quarter of 2011.

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

The decrease of 25.0 points in operating income as a percentage of revenues is mainly due to the increase in provisions for loss contingency (13.5 points), impairments of long-lived assets (9.3 points), higher general and administrative margin (3.3 points), higher R&D margin (0.9 points), as well as higher legal settlements and reserves (0.4 points), partially offset by income from contingent consideration (1.2 points), lower restructuring, acquisition and other expenses (0.4 points), higher gross margin (0.6 point) as well as lower selling and marketing margin (0.2 points).

## **Table of Contents**

### **Financial Expenses**

Net financial expenses for the third quarter of 2012 amounted to \$73 million, compared to financial expense of \$67 million during the third quarter of 2011. The current quarter's financial expenses were higher due to higher interest expenses resulting from the additional debt incurred in connection with the acquisition of Cephalon, partially offset by gains from exchange rate fluctuations and hedging activity, compared with losses in the third quarter of 2011.

### **Tax**

Tax benefit for the third quarter of 2012 amounted to \$57 million, on a pre-tax loss of \$133 million, compared with an expense of \$33 million on pre-tax income of \$968 million in the comparable quarter of 2011.

The tax benefit for the quarter resulted from the release of reserves for uncertain tax positions and losses incurred in low-tax jurisdictions. On an annual basis we expect the tax rate for 2012 to be lower than the tax rate for 2011.

### **Net Income (Loss) and Share Count**

Net loss attributable to Teva for the third quarter of 2012 amounted to \$79 million, compared to net income attributable to Teva of \$916 million in the third quarter of 2011. This decrease was due to the factors previously discussed, primarily our operating loss, partially offset by a tax benefit for the quarter.

Diluted loss per share was \$0.09 for the third quarter of 2012, compared to diluted earnings per share of \$1.03 for the third quarter of 2011. In computing the loss per share for the third quarter of 2012, no adjustment was made to take into account any possible dilution to the basic loss per share in light of the loss.

For the third quarter of 2012, the weighted average fully diluted share count was 869 million, as compared to 890 million for the third quarter of 2011, primarily due to share repurchases during 2011 and 2012. At September 30, 2012, the share count for calculating Teva's market capitalization was approximately 868 million.

Since the beginning of the year, we have repurchased approximately 15.4 million shares at an average price of \$43.34 per share, for an aggregate amount of approximately \$667 million. These purchases were made pursuant to the board authorization in December 2011 of a repurchase plan of up to \$3 billion. The repurchase program has no time limit, but is expected to be completed over a three-year period. During the third quarter of 2012, there were no share repurchases.

**Table of Contents****Comparison of Nine Months Ended September 30, 2012 to Nine Months Ended September 30, 2011****General**

In general, the factors mentioned above that explain quarterly changes on a year-over-year basis are also relevant to a comparison of the results for the nine months ended September 30, 2012 and 2011. Additional factors affecting the nine months comparison are described below.

The following table presents certain financial data as a percentage of net revenues for the periods indicated and the percentage change for each item as compared to the nine months ended September 30, 2012 and 2011:

	Percentage of Net Revenues		Percentage Change 2012 from 2011
	Nine months ended September 30, 2012	2011	
	%	%	%
Net revenues	100.0	100.0	19
Gross profit	52.2	52.5	19
Research and development expenses net	6.1	5.7	26
Selling and marketing expenses	18.7	19.3	16
General and administrative expenses	6.1	4.9	49
Loss contingencies, impairments, settlements and others	8.9	2.8	279
Operating income	12.4	19.8	(25)
Financial expenses net	1.6	0.7	182
Income before income taxes	10.8	19.1	(32)
Provision for income tax expense (benefit)	(0.2)	0.9	n/a
Share in losses of associated companies net	0.2	0.3	(24)
Net (income) loss attributable to non-controlling interests	0.1	(0.1)	n/a
Net income attributable to Teva	10.9	17.8	(27)



**Table of Contents****Revenues****General**

Revenues for the nine months ended September 30, 2012 reached \$15,068 million, an increase of 19% over the comparable period of 2011.

**Revenues by Geographic Area**

The following table presents revenues by geographic area for the nine months ended September 30, 2012 and 2011:

	Nine Months Ended September 30,		% of 2012	% of 2011	Percentage Change 2012 from 2011
	2012 U.S. \$ in millions	2011			
<b>United States:</b>					
Generic	\$ 3,347	\$ 2,715	22%	22%	23%
Branded	4,330	3,034	29%	24%	43%
Others	140	6	1%	§	2,233%
<b>Total United States</b>	<b>7,817</b>	<b>5,755</b>	<b>52%</b>	<b>46%</b>	<b>36%</b>
<b>Europe*:</b>					
Generic	2,457	2,828	16%	22%	(13%)
Branded	1,143	772	7%	6%	48%
Others	546	566	4%	5%	(4%)
<b>Total Europe</b>	<b>4,146</b>	<b>4,166</b>	<b>27%</b>	<b>33%</b>	<b>§</b>
<b>Rest of the World:</b>					
Generic	1,919	1,671	13%	13%	15%
Branded	571	433	4%	3%	32%
Others	615	611	4%	5%	1%
<b>Total Rest of the World</b>	<b>3,105</b>	<b>2,715</b>	<b>21%</b>	<b>21%</b>	<b>14%</b>
<b>Total Revenues</b>	<b>\$ 15,068</b>	<b>\$ 12,636</b>	<b>100%</b>	<b>100%</b>	<b>19%</b>

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

§ Less than 0.5%

**United States**

In the nine months ended September 30, 2012, we had revenues of \$7,817 million, a 36% increase over the comparable period of 2011. We have significantly increased our presence in the branded arena, due to the acquisition of Cephalon, and have maintained our leading position in the generics business.

**Generic Medicines**

Revenues from generic medicines in the United States in the nine months ended September 30, 2012 amounted to \$3,347 million, an increase of 23% compared to \$2,715 million in the comparable period of 2011.

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

Among the most significant generic medicines sold in the U.S. during the nine months ended September 30, 2012 were generic versions of Pulmicort® (budesonide inhalation), Lexapro® (escitalopram oxalate), Adderall XR® (mixed amphetamine salts ER), Provigil® (modafinil), Accutane® (isotretinoin, which we market as Claravis®), Adderall IR® (amphetamine salts IR), and Avapro® (irbesartan). Net revenues in the United States also benefited from our agreement with Ranbaxy related to their sales of atorvastatin.

## **Table of Contents**

### ***Branded Medicines***

In the nine months ended September 30, 2012, our revenues from branded medicines in the United States amounted to \$4,330 million, an increase of 43% over the comparable period of 2011.

### ***Other Revenues***

In the nine months ended September 30, 2012, other revenues in the United States amounted to \$140 million, compared to \$6 million in the comparable period of 2011.

### ***Europe***

Total revenues in Europe in the nine months ended September 30, 2012 amounted to \$4,146 million, compared to \$4,166 million in the comparable period of 2011. In local currency terms, revenues increased by 9%.

### ***Generic Medicines***

Revenues for generic medicines in Europe in the nine months ended September 30, 2012 were \$2,457 million, a decrease of 13%. In local currency terms, revenues decreased by 5%.

During the nine months ended September 30, 2012, Teva received 816 generic approvals in Europe relating to 180 compounds in 333 formulations, including 6 European Medicines Agency (EMA) approvals valid in all EU member states. In addition, Teva had approximately 2,240 marketing authorization applications pending approval in various European countries, relating to 249 compounds in 506 formulations, including two applications pending with the EMA. During 2012, we will continue to register products in the EU, using both the mutual recognition procedure (submission of applications in other member states following approval by a so-called reference member state) and the decentralized procedure (simultaneous submission of applications to chosen member states). We continue to use the centralized procedure to register our generic equivalent version of reference products that originally used this procedure.

### ***Branded Medicines***

In the nine months ended September 30, 2012, sales of branded medicines in Europe amounted to \$1,143 million, an increase of 48% compared to the third quarter of 2011. In local currency terms, revenues increased by 62%. The change was driven by the inclusion of Cephalon and increased sales of Copaxone<sup>®</sup>, as well the transition of the distribution and marketing rights for Copaxone<sup>®</sup> to us from Sanofi in several European countries, which was completed on February 1, 2012.

### ***Other Revenues***

Other revenues, mainly from our distribution activities in Hungary and from our consumer healthcare partnership with P&G, amounted to \$546 million for the nine months ended September 30, 2012, compared to \$566 million in the comparable period of 2011. In local currency terms revenues increased by 10%.

### ***Rest of the World ( ROW ) Markets***

Our revenues in the nine months ended September 30, 2012 in ROW markets reached \$3,105 million, an increase of 14% as compared to the comparable period of 2011. In local currency terms, revenues grew 19%. Sales of generic medicines amounted to \$1,919 million, which represented 62% of the total revenues in the region; sales of branded medicines amounted to \$571 million, or 18% of total revenues in the region; and other revenues were \$615 million, or 20% of total sales in the region.

Approximately 24% of our ROW revenues were generated in Japan and other Asian markets, 21% in Russia and other Eastern European markets, 21% in Latin America, 19% in Canada and other markets, and 15% in Israel.

Our sales in Asia in the nine months ended September 30, 2012 grew substantially compared to the comparable period of 2011, primarily due to the inclusion of sales from our Japanese acquisitions.

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

Our revenues in Russia and other Eastern European markets in the nine months ended September 30, 2012 grew 19% in dollar terms and 27% in local currency terms, as compared to the comparable period of 2011.

In Latin America, revenues in the first nine months of 2012 grew 9% in dollar terms and 14% in local currency terms, as compared to the same period of 2011.

**Table of Contents**

In Canada, revenues in the nine months ended September 30, 2012 decreased by 18% compared to the comparable period of 2011 primarily due to price reforms and increased competition.

Sales in Israel in the nine months ended September 30, 2012 increased 1% in dollar terms and 8% in local currency terms, as compared to the comparable period of 2011.

**Revenues by Product Line**

The following table presents a breakdown of revenues by product line for the nine months ended September 30, 2012 and 2011:

	Nine Months Ended September 30,		% of 2012	% of 2011	Percentage Change 2012 from 2011
	2012	2011			
	U.S. \$ in million				
<b>Generic Medicines</b>	<b>7,723</b>	<b>7,214</b>	<b>51%</b>	<b>57%</b>	<b>7%</b>
API	594	550	4%	4%	8%
<b>Branded Medicines</b>	<b>6,044</b>	<b>4,239</b>	<b>40%</b>	<b>34%</b>	<b>43%</b>
CNS	4,124	2,850	27%	23%	45%
Copaxone®	2,937	2,643	19%	21%	11%
Provigil®	392		3%	0%	
Azilect®	244	207	2%	1%	18%
Nuvigil®	269		2%	0%	
Respiratory	600	603	4%	5%	§
ProAir	286	291	2%	2%	(2%)
Qvar®	205	212	1%	2%	(3%)
Women's Health	316	345	2%	3%	(8%)
Oncology	627	78	4%	1%	704%
Treanda®	447		3%	0%	
Other Branded	377	363	3%	3%	4%
<b>All Others</b>	<b>1,301</b>	<b>1,183</b>	<b>9%</b>	<b>9%</b>	<b>10%</b>
OTC	667	548	5%	4%	22%
Other Revenues	634	635	4%	5%	§
<b>Total</b>	<b>15,068</b>	<b>12,636</b>	<b>100%</b>	<b>100%</b>	<b>19%</b>

§ Less than 0.5%

**Generic Medicines**

Revenues from our generic medicines grew by \$509 million, or 7%, in the first nine months of 2012 over the comparable period of 2011.

Our largest market for generics is the United States, with revenues of \$3,347 million for the period, up 23%.

Revenues from generic medicines in Europe in the nine months ended September 30, 2012 amounted to \$2,457 million, a decrease of 13% from the comparable period of 2011. In local currency terms, revenues from generic medicines declined by 5%.

In our ROW markets, revenues from generic medicines in the nine months ended September 30, 2012 amounted to \$1,919 million, an increase of 15% over the comparable period of 2011, primarily due to the inclusion of sales from our Japanese acquisitions. In local currency terms, revenues grew by 17%.



## **Table of Contents**

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

API sales to third parties in the nine months ended September 30, 2012 amounted to \$594 million, an increase of 8% from the comparable period of 2011.

### **Branded Medicines**

Our revenues from branded medicines amounted to \$6,044 million in the nine months ended September 30, 2012, an increase of 43% over the comparable period of 2011.

### ***Central Nervous System ( CNS )***

In the nine months ended September 30, 2012, our CNS sales reached approximately \$4,124 million, an increase of 45% over the comparable period of 2011, primarily due to the addition of Cephalon in October 2011 and an increase in Copaxone® revenues.

**Copaxone®.** Our sales of Copaxone® during the period amounted to \$2,937 million, compared to \$2,643 million in the comparable period of 2011. Global in-market sales grew by 3% over the comparable period of 2011, reaching \$2,969 million for the nine months ended September 30, 2012. Sales of Copaxone® in the United States amounted to \$2,093.

**Provigil®.** Sales of Provigil® were \$392 million in the nine months ended September 30, 2012.

**Azilect®.** Our sales of Azilect® amounted to \$244 million, an increase of 18% compared to the comparable period of 2011. Global in-market sales of Azilect® reached \$307 million in the nine months ended September 30, 2012 compared to \$284 million in the comparable period of 2011, an increase of 8%.

**Nuvigil®.** Sales of Nuvigil® were \$269 million in the nine months ended September 30, 2012.

### ***Respiratory Products***

In the nine months ended September 30, 2012, revenues from our respiratory branded products were \$600 million, as compared to \$603 million in the comparable period of 2011, primarily due to lower sales in Europe, partially offset by higher sales in the United States.

**ProAir** sales were \$286 million, as compared to \$291 million in the first nine months of 2011.

**Qvar®** global sales were \$205 million, a decrease of 3% from the prior year.

In April 2012, we launched Qnasl® (beclomethasone dipropionate HFA), the first HFA nasal aerosol indicated for perennial allergic rhinitis and seasonal allergic rhinitis.

### ***Oncology Products***

Sales of our branded oncology products reached \$627 million in the first nine months of 2012 as compared to \$78 million in the comparable period of 2011. The increase resulted primarily from the inclusion of Cephalon's cancer treatments as of the fourth quarter of 2011, the largest of which is Treanda®.

Sales of Treanda® amounted to \$447 million.

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

Our global women's health branded medicines had revenues of \$316 million in the nine months ended September 30, 2012, a decrease of 8% from \$345 million in the comparable period of 2011.

Zoely® was launched in France, Belgium and Italy during the first quarter of 2012 and in Spain during the second quarter of 2012.





## **Table of Contents**

### **All Others**

#### ***OTC***

Our sales of OTC products for the first nine months of 2012 amounted to \$667 million. Our sales related to PGT Healthcare for the first nine months of 2012 amounted to \$535 million. In the comparable period of 2011 our OTC sales were \$548 million, 2% higher. PGT Healthcare's in-market sales for the first nine months of 2012 amounted to \$966 million.

Sales of OTC products in the first nine months of 2012 in the United States to P&G, which commenced in the fourth quarter of 2011 pursuant to a manufacturing agreement, amounted to \$132 million.

#### ***Other Revenues***

In the first nine months of 2012, our revenues in this category amounted to \$634 million, down slightly from \$635 million in the comparable period of 2011. In local currency terms, revenues grew by 12%. This increase was partially offset by the elimination of sales of our pharmacy chain in Peru, which was sold in February 2011.

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

#### **Gross Profit**

Gross profit amounted to \$7,867 million in the first nine months of 2012, compared to \$6,634 million in the comparable period of 2011. Gross margin was 52.2% in the first nine months of 2012, compared to 52.5% for the comparable period of 2011.

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

Net R&D spending for the first nine months grew by 26% over the comparable period of 2011 and reached \$914 million. This increase was primarily driven by the inclusion of Cephalon R&D.

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

Selling and marketing expenses, which represented 18.7% of net sales, amounted to \$2,823 million in the first nine months of 2012, as compared to 19.3% of net sales and \$2,442 million in the comparable period of 2011.

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

G&A expenses were \$920 million in the first nine months of 2012, or 6.1% of net sales, compared to \$617 million, or 4.9% of net sales for the same period in 2011. Expenses in the comparable period were lower due to gain from one time items recorded in the third quarter of 2011, our acquisitions of Cephalon and Taiyo and the formation of our OTC joint venture with P&G, all of which occurred in the second half of 2011.

#### **Loss Contingencies, Impairments, Settlements and Others**

Loss contingencies, impairments, settlements and others were \$1,335 million in the first nine months of 2012, as compared to \$352 million in the first nine months of 2011.

#### **Operating Income**

Operating income amounted to \$1,875 million in the first nine months of 2012, compared to \$2,499 million in the first nine months of 2011. As a percentage of sales, operating margin was 12.4% as compared to 19.8% in the comparable period of 2011.

#### **Financial Expenses**

Net financial expenses for the first nine months of 2012 were \$240 million, compared with \$85 million during the first nine months of 2011. The financial expenses in the first nine months of 2011 included gains from interest rate swap agreements entered into in connection with the \$1

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

billion principal amount 6.15% senior notes due 2036, as well as gains resulting from the sale of securities. The higher expenses during the first nine months of 2012 were also due to higher interest expenses resulting from the additional debt incurred in connection with the acquisitions of Cephalon and Taiyo.

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

Tax benefit for the first nine months of 2012 amounted to \$27 million on pre-tax income of \$1,635 million, compared with an expense of \$109 million on pre-tax income of \$2,414 million in the comparable period of 2011.

The tax benefit for the first nine months of 2012 resulted from the release of reserves for uncertain tax positions and from mergers between recently-acquired companies and our subsidiaries. Because of the above we also expect a lower annual tax provision for 2012 compared to 2011.

**Net Income and Share Count**

Net income attributable to Teva for the nine months ended September 30, 2012 totaled \$1,643 million, compared to \$2,253 million in the comparable period of 2011. Diluted earnings per share was \$1.88 for the first nine months of 2012, compared to \$2.51 for the comparable period of 2011. Net income attributable to Teva as a percentage of revenues was 10.9% in the first nine months of 2012, compared to 17.8% in the comparable period of 2011.

For the first nine months of 2012, the weighted average fully diluted share count was 875 million, as compared to 896 million for the first nine months of 2011.

The weighted average fully diluted share count for the nine months ended September 30, 2012 has been reduced by approximately 10 million shares as a result of the repurchases since the beginning of the year.

**Supplemental Non-GAAP Income Data**

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

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

	Three months ended		Nine months ended	
	September 30,	September 30,	September 30,	September 30,
	2012	2011	2012	2011
	U.S. dollars in millions			
Provision for loss contingency	670		670	30
Impairment of long-lived assets	481	16	576	30
Amortization of purchased intangible assets	299	161	988	481
Contingent consideration	(59)		(33)	
Costs related to regulatory actions taken in facilities	25	35	103	130
Restructuring, acquisition and other expenses	20	36	85	106
Expense (income) in connection with legal settlements and reserves	19	(1)	37	186
Purchase of research and development in process	5	15	5	15
Inventory step-up		19	63	44
Net of corresponding tax benefit	(269)	(86)	(608)	(244)

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



**Table of Contents**

In arriving at our non-GAAP presentation, we have in the past factored out items, and would expect in the future to continue to factor out items, that either have a non-recurring impact on the income statement or which, in the judgment of our management, are items that, either as a result of their nature or size, could, were they not singled out, potentially cause investors to extrapolate future performance from an improper base. While not all inclusive, examples of these items include: legal settlements and reserves, purchase accounting expense adjustments related to acquisitions, including adjustments for write-offs of R&D in-process, amortization of intangible assets and inventory step-ups following acquisitions; changes in the fair value of contingent consideration related to business combination; restructuring expenses related to efforts to rationalize and integrate operations on a global basis; material tax and other awards or settlements both in terms of amounts paid or amounts received; impairment charges related to intangible and other assets such as intellectual property, product rights or goodwill; the income tax effects of the foregoing types of items when they occur; and costs related to regulatory actions taken at our facilities (such as uncapitalized production costs, consulting expenses or write-offs of inventory related to remediation). Included in restructuring expenses are severance, shut down costs, contract termination costs and other costs that we believe are sufficiently large that their exclusion is important to understanding trends in our financial results.

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

**Table of Contents**

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

The following table presents the GAAP measures, the corresponding non-GAAP amounts and related non-GAAP adjustments for the applicable periods:

	Three months ended September 30, 2012				Three months ended September 30, 2011			
	U.S. dollars and shares in millions (except per share amounts)							
	GAAP	Non-GAAP Adjustments	Non-GAAP Revenues	% of Net Revenues	GAAP	Non-GAAP Adjustments	Non-GAAP Revenues	% of Net Revenues
Gross profit <sup>1</sup>	2,601	313	2,914	59%	2,246	205	2,451	56%
Operating income (loss) <sup>1,2</sup>	(60)	1,460	1,400	28%	1,035	281	1,316	30%
Net income (loss) attributable to Teva <sup>1,2,3</sup>	(79)	1,191	1,112	22%	916	195	1,111	26%
Earnings (loss) per share attributable to Teva Diluted <sup>4</sup>	(0.09)	1.37	1.28		1.03	0.22	1.25	
(1) Amortization of purchased intangible assets		288				151		
Costs related to regulatory actions taken in facilities		25				35		
Inventory step-up						19		
Gross profit adjustments		313				205		
(2) Provision for loss contingency		670						
Restructuring, acquisition and other expenses		(34)				51		
Amortization of purchased intangible assets		11				10		
Impairment of long-lived assets		481				16		
Expense (income) in connection with legal settlements and reserves		19				(1)		
		1,147				76		
Operating profit adjustments		1,460				281		
(3) Tax benefit		(269)				(86)		
Net income adjustments		1,191				195		

(4) The weighted average number of shares was 870 million and 890 million for the three months ended September 30, 2012 and 2011, respectively. Non-GAAP earnings per share can be reconciled with GAAP earnings per share by dividing each of the amounts included in footnotes 1-3 above by the applicable weighted average share number. For the third quarter of 2012 we took the Non-GAAP weighted average number of shares which is one million shares higher than the GAAP weighted average number of shares.

**Table of Contents**

	Nine months ended September 30, 2012				Nine months ended September 30, 2011			
	U.S. dollars and shares in millions (except per share amounts)							
	GAAP	Non-GAAP Adjustments	Non-GAAP Revenues	% of Net	GAAP	Non-GAAP Adjustments	Non-GAAP Revenues	% of Net
Gross profit <sup>1</sup>	7,867	1,123	8,990	60%	6,634	628	7,262	57%
Operating income <sup>1,2</sup>	1,875	2,494	4,369	29%	2,499	1,022	3,521	28%
Net income attributable to Teva <sup>1,2,3</sup>	1,643	1,886	3,529	23%	2,253	778	3,031	24%
Earnings per share attributable to Teva Diluted	1.88	2.15	4.03		2.51	0.87	3.38	
(1) Amortization of purchased intangible assets		957				454		
Costs related to regulatory actions taken in facilities		103				130		
Inventory step-up		63				44		
Gross profit adjustments		1,123				628		
(2) Provision for loss contingency		670				30		
Impairment of long-lived assets		576				30		
Restructuring, acquisition and other expenses		57				121		
Amortization of purchased intangible assets		31				27		
Expense in connection with legal settlements and reserves		37				186		
Operating profit adjustments		1,371				394		
(3) Tax benefit		(608)				(244)		
Net income adjustments		1,886				778		

- (4) The weighted average number of shares was 875 and 896 million for the nine months ended September 30, 2012 and 2011, respectively. Non-GAAP earnings per share can be reconciled with GAAP earnings per share by dividing each of the amounts included in footnotes 1-3 above by the applicable weighted average share number.

**Non-GAAP Tax**

The provision for non-GAAP taxes for the first nine months of 2012 amounted to \$581 million of pre-tax non-GAAP income of \$4,129 million. The provision for taxes in the comparable period of 2011 was \$353 million on pre-tax income of \$3,436 million.

The tax rate for the first nine months of 2012 was affected by the release of reserves for uncertain tax positions and tax benefits as a result of mergers between recently acquired companies and our subsidiaries. On an annual basis, we expect a higher tax rate for 2012 compared to the annual tax rate in 2011, primarily as a result of the Cephalon acquisition and the impact of the change in the geographical mix and type of products expected to be sold during 2012 as compared to 2011.

## **Table of Contents**

### **Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the accompanying consolidated financial statements and related footnotes. Actual results may differ from these estimates. To facilitate the understanding of our business activities, certain accounting policies that are important to the presentation of our financial condition and results of operations and that require management's subjective judgments are described in our Annual Report on Form 20-F for the year ended December 31, 2011. We base our judgments on our experience and various assumptions that we believe to be reasonable under the circumstances. The most significant estimates that we make on an ongoing basis relate to revenue recognition, sales reserves and allowances, income taxes, contingencies, inventories and valuation of intangible assets, marketable securities and long-lived assets, including reassessment of useful lives. Please refer to Note 1 to the Consolidated Financial Statements included in our Annual Report on Form 20-F for the year ended December 31, 2011 for a summary of all significant accounting policies.

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

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

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

Because our results are reported in U.S. dollars, changes in the rates of exchange between the U.S. dollar and the local currencies in the markets in which we operate (primarily the euro, new Israeli shekel, Russian ruble, Japanese yen, Hungarian forint, Canadian dollar, British pound sterling, and certain Latin American currencies) affect our results.

When compared with the third quarter of 2011, certain currencies relevant to our operations decreased in value against the U.S. dollar: the euro by 12%, the new Israeli shekel by 12%, the Canadian dollar by 2%, the British pound sterling by 2%, the Russian ruble by 10%, the Hungarian forint by 17% and the Japanese yen by 1%. All comparisons are on a quarterly average to quarterly average basis.

As a result, exchange rate movements during the third quarter of 2012 as compared to the third quarter of 2011 negatively affected overall revenues by approximately \$202 million. We also recorded lower expenses due to these currency fluctuations and, as a result, changes in exchange rates had a minimal net positive impact on our operating income.

Exchange rates also had a significant impact on our balance sheet, as approximately 61% of our net assets in the quarter (including both non-monetary and monetary assets), were in currencies other than the U.S. dollar. When compared with the second quarter of 2012, changes in currency rates had a positive impact of \$0.45 billion on our equity, mainly due to the increase in value against the U.S. dollar of the euro by 2%, the Czech koruna by 3%, the Swiss franc by 1%, the Polish zloty by 4%, and the pound sterling by 3%; All comparisons are on a quarter-end to quarter-end basis.

### **Liquidity and Capital Resources**

Total assets amounted to \$49.6 billion at September 30, 2012, compared to \$48.9 billion at June 30, 2012. The increase was mainly due to the effect of foreign exchange fluctuations as well as an increase in cash balances, partially offset by a reduction in working capital. Our working capital balance, which includes accounts receivable, inventories and other current assets net of sales, reserves and allowances (SR&A), accounts payable and other current liabilities, was \$4.0 billion at September 30, 2012, compared to \$4.4 billion at June 30, 2012. The decrease in working capital is primarily due to the provision for loss contingency relating to the pantoprazole litigation.

Inventory balances for September 30, 2012 amounted to \$5.5 billion compared to \$5.3 billion on June 30, 2012. At September 30, 2012, inventory days were 207, the same as at June 30, 2012.

Accounts receivable at September 30, 2012, net of SR&A, was \$1.0 billion, compared to \$0.8 billion at June 30, 2012. The increase in accounts receivables was mainly due to the effect of foreign exchange fluctuations.

Days sales outstanding (receivables) (DSO), net of SR&A, were 16 days at September 30, 2012 compared to 21 at June 30, 2012.

We are monitoring closely, on an ongoing basis, the accounts receivable balances in countries which based on our internal assessment are experiencing significant economic stress, and are taking action to limit our exposure in these countries.





## **Table of Contents**

Although we record receivables on a gross basis, and record a large percentage of SR&A as a liability, we have used a net figure for the calculation of DSO in order to facilitate a more meaningful comparison with some of our peers, which record receivables net of these reserves.

Accounts payable and accrual days were 79 days at September 30, 2012, the same as at June 30, 2012. Accounts payable days are calculated based on the average payables balance of the previous and current quarters, divided by operating expenses, including cost of sales.

Investment in property, plant and equipment in the third quarter of 2012 was approximately \$249 million, compared to \$276 million in the comparable quarter last year. Depreciation amounted to \$111 million in the third quarter of 2012, compared to \$85 million in the comparable quarter of 2011. The increase in depreciation was mainly due to the acquisition of Cephalon.

Cash and cash equivalents, short term and long term investments at September 30, 2012 increased to \$2.0 billion compared to \$1.8 billion at June 30, 2012. Of the September amount, \$467 million were equity securities. The increase in cash and cash equivalents reflects free cash flow of \$577 million generated during the quarter net of debt repayment, as described below.

### **2012 Debt Movements**

At September 30, 2012, we had \$13.8 billion of debt, compared to \$14.0 billion at June 30, 2012. The decrease is mainly due to the repayment of the remainder of a term loan incurred in connection with the financing of Cephalon.

Our debt at September 30, 2012 is denominated in the following currencies: 59% U.S. dollars, 25% euro, 13% Japanese yen and 3% Swiss francs.

While most of our debt bears fixed rates of interest, certain of our debt consists of floating-rate bank loans. These borrowings are usually linked to the relevant LIBOR plus a spread of 0.2% - 1.2%.

The portion of total debt classified as short term decreased from 10% at June 30, 2012 to 8% at September 30, 2012.

Our financial leverage decreased from 38% at June 30, 2012 to 37% at September 30, 2012.

### **Shareholders' Equity, Cash Flow and Commitments**

Our shareholders' equity was \$23.1 billion at September 30, 2012 compared to \$22.9 billion at June 30, 2012. The increase resulted primarily from the positive impact of changes in currency rates of \$0.45 billion, partially offset by dividends declared of \$213 million and our net loss of \$79 million.

Cash flow generated from operating activities during the third quarter of 2012 amounted to \$1,048 million, compared to \$482 million in the third quarter of 2011. Cash flow in the third quarter of 2011 was significantly lower than usual.

Cash flow generated from operating activities in the third quarter of 2012, net of cash used for capital investments and dividends paid, amounted to approximately \$577 million, an increase of \$575 million from the third quarter of 2011. The increase resulted mainly from higher cash flow generated from operating activities and lower capital expenditures this quarter, partially offset by higher dividend payments.

In Israel, we are exposed to the risk of appreciation of the NIS against the U.S. dollar. Accordingly, in the first quarter of 2012, we entered into hedging transactions to reduce the exposure resulting from excess costs related to payroll denominated in NIS.

In Europe, a significant portion of our profits is at risk due to the continuing depreciation of the euro. In the first quarter of 2012, we entered into hedging transactions to protect our European subsidiaries from exposure resulting from the strengthening of the U.S. dollar against the euro. In addition, in the third quarter of 2012, we entered into additional hedging transactions to partially protect our exposure to exchange rate fluctuations in 2013.

In addition to financing obligations under short-term debt and long-term senior notes and loans, debentures and convertible debentures, our major contractual obligations and commercial commitments include leases, royalty payments and participation in joint ventures associated with research and development activities.



## **Table of Contents**

We are committed to pay royalties to owners of know-how, partners in alliances and certain other arrangements and to parties that financed research and development, at a wide range of rates as a percentage of sales of certain products, as defined in the agreements. In some cases, the royalty period is not defined; in other cases, royalties will be paid over various periods not exceeding 20 years, commencing on the date of the first royalty payment.

In connection with certain development, supply and marketing, and research and collaboration or services agreements, we are required to indemnify, in unspecified amounts, the parties to such agreements against third-party claims relating to (1) infringement or violation of intellectual property or other rights of such third party; or (2) damages to users of the related products. Except as described in our financial statements we are not aware of any material pending action that may result in the counterparties to these agreements claiming such indemnification.

Certain of our loan agreements and debentures contain restrictive covenants, mainly the requirement to maintain certain financial ratios. We are currently in compliance with all applicable financial ratios.

Our principal sources of short-term liquidity are our existing cash investments, liquid securities, and available credit facilities; primarily our \$2.5 billion syndicated revolving line of credit, as well as internally generated funds, which we believe are sufficient to meet our on-going operating needs. Our cash in hand is generally invested in bank deposits as well as liquid securities that bear fixed and floating rates.

## **RISK FACTORS**

There are no material changes to the risk factors previously disclosed in our Annual Report on Form 20-F for the year ended December 31, 2011.

## **QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Reference is made to **Quantitative and Qualitative Disclosures About Market Risk** (Item 11) in our Annual Report on Form 20-F for the year ended December 31, 2011.

## **LEGAL PROCEEDINGS**

We are subject to various litigation and other legal proceedings. For a discussion of certain of these matters that we deem to be material to Teva, see **Contingencies**, Note 13 to the consolidated financial statements included in this report.

**Table of Contents**

**SIGNATURE**

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

TEVA PHARMACEUTICAL INDUSTRIES LIMITED  
(Registrant)

Date: November 1, 2012

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