

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

October 29, 2015

[Table of Contents](#)

**UNITED STATES**  
**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 October 2015**

**Commission File Number 001-16174**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**(Translation of registrant's name into English)**

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

**Petach Tikva 4951033 Israel**

**(Address of principal executive offices)**

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

Form 20-F  Form 40-F

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

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

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

	<b>Page</b>
<u>Consolidated Balance Sheets</u>	2
<u>Consolidated Statements of Income</u>	3
<u>Condensed Consolidated Statements of Comprehensive Income</u>	4
<u>Consolidated Statements of Cash Flows</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Operating and Financial Review and Prospects</u>	30
<u>Risk Factors</u>	59
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	59
<u>Legal Proceedings</u>	59

**Exhibits**

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

**USE OF CERTAIN TERMS**

Unless otherwise indicated, all references to the Company, we, our and Teva refer to Teva Pharmaceutical Industries Limited and its subsidiaries, and references to revenues refer to net revenues. 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. References to MS are to multiple sclerosis. Market data, including both sales and share data, are based on information provided by IMS Health Inc., a provider of market research to the pharmaceutical industry (IMS), unless otherwise stated. References to ROW are to our 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. References to R&D are to Research and Development, to S&M are to Selling and Marketing and to G&A are to General and Administrative.

Table of Contents

## TEVA PHARMACEUTICAL INDUSTRIES LIMITED

## CONSOLIDATED BALANCE SHEETS

(U.S. dollars in millions)

(Unaudited)

	September 30, 2015	December 31, 2014
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 928	\$ 2,226
Accounts receivable	5,275	5,408
Inventories	4,092	4,371
Deferred income taxes	915	993
Other current assets	1,290	1,398
<b>Total current assets</b>	<b>12,500</b>	<b>14,396</b>
<b>Other non-current assets</b>	<b>2,469</b>	<b>1,569</b>
<b>Property, plant and equipment, net</b>	<b>6,422</b>	<b>6,535</b>
<b>Identifiable intangible assets, net</b>	<b>8,060</b>	<b>5,512</b>
<b>Goodwill</b>	<b>19,174</b>	<b>18,408</b>
<b>Total assets</b>	<b>\$ 48,625</b>	<b>\$ 46,420</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities:</b>		
Short-term debt	\$ 2,148	\$ 1,761
Sales reserves and allowances	6,759	5,849
Accounts payable and accruals	2,964	3,171
Other current liabilities	1,107	1,508
<b>Total current liabilities</b>	<b>12,978</b>	<b>12,289</b>
<b>Long-term liabilities:</b>		
Deferred income taxes	1,909	1,101
Other taxes and long-term liabilities	1,322	1,109
Senior notes and loans	9,516	8,566
<b>Total long-term liabilities</b>	<b>12,747</b>	<b>10,776</b>
<b>Contingencies, see note 12</b>		
<b>Total liabilities</b>	<b>25,725</b>	<b>23,065</b>
<b>Equity:</b>		
<b>Teva shareholders equity:</b>		

Ordinary shares of NIS 0.10 par value per share; September 30, 2015 and December 31, 2014: authorized 2,500 million shares; issued 961 million shares and 957 million shares, respectively	50	50
Additional paid-in capital	14,425	14,121
Retained earnings	14,657	14,436
Accumulated other comprehensive loss	(2,141)	(1,343)
Treasury shares as of September 30, 2015 and December 31, 2014 109 million ordinary shares and 105 million ordinary shares, respectively	(4,252)	(3,951)
	22,739	23,313
<b>Non-controlling interests</b>	161	42
<b>Total equity</b>	22,900	23,355
<b>Total liabilities and equity</b>	\$ 48,625	\$ 46,420

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

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONSOLIDATED STATEMENTS OF INCOME****(U.S. dollars in millions, except share and per share data)****(Unaudited)**

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Net revenues	\$ 4,823	\$ 5,058	\$ 14,771	\$ 15,104
Cost of sales	2,052	2,249	6,262	6,937
Gross profit	2,771	2,809	8,509	8,167
Research and development expenses	361	412	1,079	1,109
Selling and marketing expenses	780	950	2,562	2,855
General and administrative expenses	316	293	948	897
Impairments, restructuring and others	384	164	968	364
Legal settlements and loss contingencies	(80)	(122)	531	(67)
Operating income	1,010	1,112	2,421	3,009
Financial expenses net	697	84	930	243
Income before income taxes	313	1,028	1,491	2,766
Income taxes	193	160	385	405
Share in losses of associated companies net	4	5	7	13
Net income	116	863	1,099	2,348
Net gain (loss) attributable to non-controlling interests	13	(13)	11	(20)
Net income attributable to Teva	\$ 103	\$ 876	\$ 1,088	\$ 2,368
Earnings per share attributable to Teva:				
Basic	\$ 0.12	\$ 1.02	\$ 1.28	\$ 2.78
Diluted	\$ 0.12	\$ 1.02	\$ 1.26	\$ 2.76
Weighted average number of shares (in millions):				
Basic	851	855	851	852
Diluted	862	861	860	857

**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**

(U.S. dollars in millions)

(Unaudited)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net income	\$ 116	\$ 863	\$ 1,099	\$ 2,348
Other comprehensive income (loss), net of tax:				
Currency translation adjustment	(212)	(717)	(897)	(889)
Unrealized gain (loss) from derivative financial instruments, net	(7)	156	102	151
Unrealized loss from available-for-sale securities, net	(27)	(23)	(2)	(17)
Unrealized gain (loss) on defined benefit plans	(5)	*	(1)	6
Total other comprehensive loss	(251)	(584)	(798)	(749)
Total comprehensive income (loss)	(135)	279	301	1,599
Comprehensive gain (loss) attributable to the non-controlling interests	(11)	17	(11)	24
Comprehensive income (loss) attributable to Teva	\$ (146)	\$ 296	\$ 290	\$ 1,623

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

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



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

(U.S. dollars in millions)

(Unaudited)

	<b>Nine months ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Operating activities:</b>		
Net income	\$ 1,099	\$ 2,348
Adjustments to reconcile net income to net cash provided by operations:		
Depreciation and amortization	973	1,139
Other than temporary loss on investment in securities	736	6
Net change in operating assets and liabilities	703	(217)
Impairment of long-lived assets	334	208
Other items	157	23
Deferred income taxes net and uncertain tax positions	(97)	(223)
Stock-based compensation	86	61
Net (gain) loss from sale of long-lived assets and investments	(88)	30
Purchase of research and development in process	24	
<b>Net cash provided by operating activities</b>	<b>3,927</b>	<b>3,375</b>
<b>Investing activities:</b>		
Acquisitions of subsidiaries, net of cash acquired	(3,304)	(363)
Purchases of investments and other assets	(1,926)	(242)
Purchases of property, plant and equipment	(524)	(629)
Proceeds from sales of long-lived assets and investments	508	157
Other investing activities	(26)	(26)
<b>Net cash used in investing activities</b>	<b>(5,272)</b>	<b>(1,103)</b>
<b>Financing activities:</b>		
Repayment of long-term loans and other long-term liabilities	(2,477)	(797)
Proceeds from long-term loans and other long-term liabilities	2,148	
Net change in short-term debt	1,548	(372)
Dividends paid	(865)	(884)
Purchases of treasury shares	(439)	
Proceeds from exercise of options by employees	339	290
Other financing activities	(164)	(19)
<b>Net cash provided by (used in) financing activities</b>	<b>90</b>	<b>(1,782)</b>

<b>Translation adjustment on cash and cash equivalents</b>	(43)	(55)
<b>Net change in cash and cash equivalents</b>	(1,298)	435
<b>Balance of cash and cash equivalents at beginning of period</b>	2,226	1,038
<b>Balance of cash and cash equivalents at end of period</b>	\$ 928	\$ 1,473

**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 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, 2014, as filed with the Securities and Exchange Commission (SEC). Amounts at December 31, 2014 were derived from the audited balance sheet at that date, but not all disclosures required by accounting principles generally accepted in the United States are included. The results of operations for the nine months ended September 30, 2015 are not necessarily indicative of results that could be expected for the entire fiscal year.

**NOTE 2 Recently adopted and issued accounting pronouncements:**

In July 2015, the Financial Accounting Standards Board (the FASB) issued guidance on current accounting for inventory measurement. The new guidance requires entities to measure inventory at the lower of cost or net realizable value. Net realizable value is defined by the guidance as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The guidance is effective for the interim and annual periods beginning on or after December 15, 2016 (early adoption is permitted). Teva adopted the new guidance in the third quarter of 2015, and it had an immaterial impact on its consolidated financial statements.

In February 2015, the FASB issued amended guidance on current accounting for consolidation of certain entities. Pursuant to this guidance, reporting enterprises should evaluate whether (a) they should consolidate limited partnerships and similar entities, (b) fees paid to a decision maker or service provider are variable interests in a variable interest entity (VIE), and (c) variable interests in a VIE held by related parties of the reporting enterprise require the reporting enterprise to consolidate the VIE. The guidance is effective for the interim and annual periods beginning on or after December 15, 2015 (early adoption is permitted). Teva is currently evaluating the impact of the amended guidance on its consolidated financial statements.

In May 2014, the FASB issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The guidance is effective for the interim and annual periods beginning on or after December 15, 2017 (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016). The guidance permits the use of either a retrospective or cumulative effect transition method. Teva is currently evaluating the impact of the guidance on its consolidated financial statements.

**NOTE 3 Certain transactions:**

***Rimsa acquisition:***

On October 1, 2015, Teva entered into a definitive agreement to acquire Representaciones e Investigaciones Médicas, S.A. de C.V. ( Rimsa ), a leading pharmaceutical manufacturing and distribution company in Mexico, along with a portfolio of products and companies, intellectual property, assets and pharmaceutical patents in Latin America and Europe, for an aggregate of \$2.3 billion, in a cash free, debt free set of transactions. This acquisition is expected to add a portfolio of patent-protected drugs to our business in Latin America. The transaction is expected to be funded through a combination of available cash and lines of credit. Subject to satisfaction of the closing conditions, Teva expects the acquisition to close in the first quarter of 2016.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)*****Acquisition of Allergan's generics business:***

On July 27, 2015, Teva announced that it entered into a definitive agreement with Allergan plc to acquire Allergan's worldwide generic pharmaceuticals business. Teva will pay total consideration of \$40.5 billion, consisting of \$33.75 billion in cash and approximately 100 million Teva shares, which represent \$6.75 billion in value, based on the mutually-agreed price of \$67.30 per share. Closing of the transaction is subject to certain conditions, including relevant regulatory approvals. Subject to satisfaction of the closing conditions, Teva expects the acquisition to close in the first quarter of 2016.

On September 25, 2015, Teva entered into a bridge loan credit agreement with various banks, under which the banks agreed to provide up to \$27 billion of loans to finance a portion of the Allergan acquisition. Any loan under the bridge facility would bear an interest rate of LIBOR plus a margin ranging from 0.30 to 1.65%, so long as Teva maintains an investment-grade credit rating, depending on Teva's specific credit rating and the time elapsed since funding of the bridge loans. In addition, Teva has entered into commitment letters with various banks, under which the banks committed to provide Teva with up to \$6.75 billion in loans under a separate bridge loan credit facility to finance a portion of the Allergan acquisition.

***Other transactions:***

Teva acquired stakes in Gecko Health Innovations, Inc., Immuneering Corporation and Microchips Biotech, Inc. for an aggregate of approximately \$102 million and certain contingent payments.

***Auspex acquisition:***

On March 29, 2015, Teva entered into a merger agreement with Auspex Pharmaceuticals, Inc., an innovative biopharmaceutical company specializing in applying deuterium chemistry to known molecules to create novel therapies with improved safety and efficacy profiles. On May 5, 2015, Teva completed a tender offer for all of the outstanding shares of Auspex at \$101 per share in cash, or an aggregate of \$3.5 billion, in accordance with the agreement. Net cash consideration paid by Teva amounted to \$3.3 billion.

The table below summarizes the preliminary estimates of the fair value of the assets acquired and liabilities assumed and resulting goodwill. These preliminary estimates are subject to revision, which may result in adjustments to the preliminary values presented below, when the appraisals are finalized.

	<b>U.S.\$ in millions</b>
Cash and cash equivalents	\$ 201
Other current assets	5

<b>Identifiable intangible assets:</b>	
Research and development in-process	3,143
Goodwill	1,227
Total assets acquired	4,576
<b>Current liabilities</b>	
Deferred taxes	29
	1,085
<b>Total liabilities assumed</b>	<b>1,114</b>
Net assets acquired	\$ 3,462

***Eagle license agreement:***

On February 13, 2015, Teva entered into an exclusive license agreement with Eagle Pharmaceuticals, Inc., pursuant to which Teva licensed EP-3102, Eagle's bendamustine hydrochloride (HCl) rapid infusion product for the treatment of chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin lymphoma (NHL).

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

Under the terms of the agreement, Eagle received an upfront cash payment of \$30 million and may receive up to \$90 million in additional milestone payments as well as royalties on net sales.

As the transaction was accounted as a business combination, the acquisition consideration was attributed to net assets on the basis of fair value of assets acquired and liabilities assumed based on a preliminary appraisal performed by management.

***Debt tender offer:***

In February 2015, Teva consummated a cash tender offer for certain of its outstanding senior notes as follows (principal amount):

<b>Senior notes series</b>	<b>Previously outstanding</b>	<b>Purchased</b>
	<b>U.S. \$ in millions</b>	
6.15% Senior Notes due 2036	\$ 987	\$ 197
3.65% Senior Notes due 2021	875	263
3.65% Senior Notes due 2021	875	287
2.95% Senior Notes due 2022	1,300	456
		<b>\$ 1,203</b>

As a result of the debt tender offer, Teva paid \$1.3 billion in aggregate consideration (applicable purchase price including premium and accrued interest) to redeem \$1.2 billion aggregate principal amount of senior notes.

Concurrently, Teva terminated an interest swap agreement designated as fair value hedge relating to its 2.95% senior notes due 2022 with respect to \$456 million notional amount. In addition, Teva terminated a cross-currency swap agreement designated as cash flow hedge relating to its 3.65% senior notes due 2021 with respect to \$287 million notional amount.

The Company recorded \$143 million expense in connection with the debt tender offer and the termination of the related swap agreements, recognized under financial expenses net.

***Other debt related movements:***

During the third quarter of 2015, we repaid \$0.9 billion of short term borrowings under our revolving credit facility as well as short term liquidity lines.

In June 2015, the Company repaid at maturity \$1.0 billion principal amount of its 3% fixed rate senior notes due June 2015 and settled the related \$1.0 billion notional amount cross-currency swap agreement designated as cash flow hedge of these notes.

In March 2015, Teva Pharmaceutical Finance Netherlands II B.V., a Teva finance subsidiary, issued senior notes in an aggregate principal amount of 2.0 billion, comprised of: 1.3 billion due in March 2023 bearing interest of 1.25% and 0.7 billion due in March 2027 bearing interest of 1.875%. All such notes are guaranteed by Teva.

**NOTE 4 Inventories:**

Inventories consisted of the following:

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
	<b>U.S. \$ in millions</b>	
Finished products	\$ 2,096	\$ 2,268
Raw and packaging materials	1,248	1,279
Products in process	605	638
Materials in transit and payments on account	143	186
	<b>\$ 4,092</b>	<b>\$ 4,371</b>



**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

**NOTE 5 Earnings per share:**

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

In computing diluted earnings per share for the three and nine months ended September 30, 2015 and 2014, basic earnings per share was adjusted to take into account the potential dilution that could occur upon 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.

The basic earnings per share for the three and nine months ended September 30, 2014 were adjusted to take into account, in addition to the above, the potential dilution that could occur upon the conversion of the remaining convertible senior debentures using the if-converted method, by adding interest expense on the debentures and amortization of issuance costs, net of tax benefits to net income, and by adding the weighted average number of shares issuable upon assumed conversion of the debentures to the weighted average number of ordinary shares outstanding during the period.

**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, prompt pay discounts and other deductions, such as shelf stock adjustments, which can be reasonably estimated. When sales provisions are not considered reasonably estimable by Teva, the revenue is deferred to a future period when more information is available to evaluate the impact.

Provisions for chargebacks, rebates including Medicaid and other governmental program discounts and other promotional items, such as shelf stock adjustments, are included in SR&A under current liabilities. These provisions are recognized concurrently with the sales of products. Prompt payment discounts are netted against accounts receivable.

Calculations for these deductions from sales are based on historical experience and the specific terms in the individual agreements. Chargebacks and rebates are the largest components of sales reserves and allowances. Provisions for chargebacks are determined using historical chargeback experience and expected chargeback levels and wholesaler sales information for new products, which are compared to externally obtained distribution channel reports for reasonableness. Rebates are recognized based on contractual obligations in place at the time of sales with consideration given to relevant factors that may affect the payment as well as historical experience for estimated

market activity. Shelf-stock adjustments are granted to customers based on the existing inventory of a customer following decreases in the invoice or contract price of the related product and are estimated based on expected market performance. Teva records a reserve for estimated sales returns by applying historical experience of customer returns to the amounts invoiced and the amount of returned products to be destroyed versus products that can be placed back in inventory for resale.

Revenue resulting from the achievement of milestone events stipulated in 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 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, 2015	December 31, 2014
	U.S. \$ in millions	
Rebates	\$ 3,447	\$ 2,842
Medicaid	1,370	1,099
Chargebacks	1,124	1,129
Returns	634	593
Other	184	186
	\$ 6,759	\$ 5,849

**NOTE 7 Equity:***Accumulated other comprehensive loss*

The following tables present the changes in the components of accumulated other comprehensive loss for the three months ended September 30, 2015 and 2014:

Components of accumulated other comprehensive loss	Description of the reclassification to the statement of income	Three months ended September 30, 2015				
		Other comprehensive income (loss) before reclassifications	Amounts reclassified to the statement of income	Net other comprehensive income (loss) before tax	Corresponding income tax	Net other comprehensive income (loss) after tax
		U.S.\$ in millions				
Currency translation adjustment		\$ (212)	\$	\$ (212)	\$	\$ (212)
Unrealized gain (loss) from available-for-sale securities	Loss on marketable securities, reclassified to financial expenses - net	(664)	630	(34)	7	(27)
Unrealized gain (loss) from derivative financial	Gain on derivative financial instruments	(4)	(3)	(7)	*	(7)

instruments	reclassified to net revenue						
Unrealized gain (loss) on defined benefit plans	Loss on defined benefit plans, reclassified to various statement of income items**	(6)	1	(5)	*	(5)	
Total accumulated other comprehensive income (loss)		\$ (886)	\$ 628	\$ (258)	\$ 7	\$ (251)	

Table of Contents

## TEVA PHARMACEUTICAL INDUSTRIES LIMITED

## Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

Three months ended September 30, 2014

Components of accumulated other comprehensive loss	Description of the reclassification to the statement of income	Other	Amounts	Net other		
		comprehensive income (loss) before reclassifications	reclassified to the statement of income	comprehensive income (loss) before tax	Corresponding income tax	Net other comprehensive income (loss) after tax
U.S.\$ in millions						
Currency translation adjustment		\$ (717)	\$	\$ (717)	\$	\$ (717)
Unrealized gain (loss) from available-for-sale securities	Loss on marketable securities, reclassified to financial expenses - net	(29)	6	(23)	*	(23)
Unrealized gain (loss) from derivative financial instruments	Loss on derivative financial instruments, reclassified to net revenues	155	1	156		156
Unrealized gain (loss) on defined benefit plans	Loss on defined benefit plans, reclassified to various statement of income items**	*	*	*	*	*
Total accumulated other comprehensive income (loss)		\$ (591)	\$ 7	\$ (584)	\$ *	\$ (584)

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

\*\* Reclassified to cost of sales, research and development expenses, selling and marketing expenses and general and administrative expenses.

The following tables present the changes in the components of accumulated other comprehensive loss for the nine months ended September 30, 2015 and 2014:

## Nine months ended September 30, 2015

Components of accumulated other comprehensive loss	Description of the reclassification to the statement of income	Other	Amounts	Net other		
		comprehensive income (loss) before reclassifications	reclassified to the statement of income	comprehensive income (loss) before tax	Corresponding income tax	Net other comprehensive income (loss) after tax
U.S.\$ in millions						
Currency translation adjustment		\$ (897)	\$	\$ (897)	\$	\$ (897)
Unrealized gain (loss) from available-for-sale securities	Loss on marketable securities**	(737)	735	(2)	*	(2)
Unrealized gain (loss) from derivative financial instruments	Gain on derivative financial instruments***	104	(2)	102		102
Unrealized gain (loss) on defined benefit plans	Loss on defined benefit plans, reclassified to various statement of income items****	(6)	3	(3)	2	(1)
Total accumulated other comprehensive income (loss)		\$ (1,536)	\$ 736	\$ (800)	\$ 2	\$ (798)

Table of Contents

## TEVA PHARMACEUTICAL INDUSTRIES LIMITED

## Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

Components of accumulated other comprehensive loss	Description of the reclassification to the statement of income	Nine months ended September 30, 2014				
		Other income (loss) before reclassification	Amounts to the statement of income	Net other comprehensive income (loss) before tax	Corresponding income tax	Net other comprehensive income (loss) after tax
U.S.\$ in millions						
Currency translation adjustment	Currency translation adjustment, reclassified to general and administrative expenses	\$ (884)	\$ (5)	\$ (889)	\$	\$ (889)
Unrealized gain (loss) from available-for-sale securities	Loss on marketable securities, reclassified to financial expenses - net	(20)	3	(17)	*	(17)
Unrealized gain (loss) from derivative financial instruments	Loss on derivative financial instruments, reclassified to net revenues	148	3	151		151
Unrealized gain (loss) on defined benefit plans	Loss on defined benefit plans, reclassified to various statement of income items****	*	1	1	5	6
Total accumulated other comprehensive income (loss)		\$ (756)	\$ 2	\$ (754)	\$ 5	\$ (749)

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

\*\* \$630 million loss reclassified to financial expenses net and \$105 million loss reclassified to impairments, restructuring and others.

\*\*\* \$26 million loss reclassified to financial expenses net and \$28 million gain reclassified to net revenues.

\*\*\*\* Reclassified to cost of sales, research and development expenses, selling and marketing expenses and general and administrative expenses.

**Share repurchase program**

In October 2014, Teva's board of directors authorized the Company to increase its share repurchase program up to \$3 billion of its ordinary shares and American Depositary Shares. As of September 30, 2015, \$2.1 billion remained available for repurchases. This repurchase authorization has no time limit. Repurchases may be commenced or suspended at any time.

Teva did not repurchase any of its shares during the second or third quarter of 2015.

As of September 30, 2015, Teva's treasury share balance amounted to 109 million shares compared to 105 million shares as of December 31, 2014.

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

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>in millions</b>	
Amount spent on shares repurchased	\$ 439	\$
Number of shares repurchased	7.7	



**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****NOTE 8 Fair value measurement:**

Teva's financial instruments consist mainly of cash and cash equivalents, investment in 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.

***Financial instruments measured at fair value***

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

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

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

Level 2: Observable inputs 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.

Financial items carried at fair value as of September 30, 2015 and December 31, 2014 are classified in the tables below in one of the three categories described above:

	<b>September 30, 2015</b>			
<b>Level</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>	
<b>1</b>	<b>U.S. \$ in millions</b>			

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

Cash and cash equivalents:						
Money markets	\$	4	\$	\$	4	
Cash deposits and other		924			924	
Investment in securities:						
Auction rate securities				13	13	
Equity securities		994			994	
Structured investment vehicles			98		98	
Other		9		1	10	
Derivatives:						
Asset derivatives - options and forward contracts			25		25	
Asset derivatives - interest rate and cross-currency swaps			91		91	
Liabilities derivatives - options and forward contracts			(15)		(15)	
Liabilities derivatives - forward starting interest rate swaps			(14)		(14)	
Contingent consideration*				(786)	(786)	
<b>Total</b>	<b>\$</b>	<b>1,931</b>	<b>\$</b>	<b>185</b>	<b>\$ (772)</b>	<b>\$ 1,344</b>

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

	<b>December 31, 2014</b>			<b>Total</b>
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	
	<b>U.S. \$ in millions</b>			
<b>Cash and cash equivalents:</b>				
Money markets	\$ 10	\$	\$	\$ 10
Cash deposits and other	2,216			2,216
Escrow fund	125			125
<b>Investment in securities:</b>				
Auction rate securities			13	13
Equity securities	66			66
Structured investment vehicles		96		96
Other, mainly debt securities	73		1	74
<b>Derivatives:</b>				
Asset derivatives - options and forward contracts		82		82
Asset derivatives - cross-currency swaps		20		20
Liability derivatives - options and forward contracts		(54)		(54)
Liability derivatives - interest rate swaps		(43)		(43)
Contingent consideration*			(630)	(630)
<b>Total</b>	<b>\$ 2,490</b>	<b>\$ 101</b>	<b>\$ (616)</b>	<b>\$ 1,975</b>

\* Contingent consideration represents either liabilities or assets recorded at fair value in connection with acquisitions and the sale of our animal health unit.

Teva determined the fair value of the liability or asset 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 is based on several factors, such as: the cash flows projected from the success of unapproved product candidates; the probability of success for product candidates including risks associated with uncertainty regarding achievement and payment of milestone events; the time and resources needed to complete the development and approval of product candidates; the life of the potential commercialized products and associated risks of obtaining regulatory approvals in the U.S. and Europe and the risk adjusted discount rate for fair value measurement.

The contingent consideration is evaluated quarterly or more frequently if circumstances dictate. Changes in the fair value of contingent consideration are 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.

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

	<b>2015</b>	<b>2014</b>
	<b>U.S. \$ in millions</b>	
Fair value at the beginning of the period	\$ (616)	\$ (347)
Amount realized		(5)
Contingent consideration resulting from:		
Eagle transaction	(128)	
Changes in contingent consideration:		
Cephalon acquisition	(2)	(35)
MicroDose acquisition	(9)	140
Sale of animal health unit		(5)
NuPathe acquisition	(6)	(112)
Labrys acquisition	(10)	(252)
Eagle transaction	(1)	
Fair value at the end of the period	\$ (772)	\$ (616)

Table of Contents

## TEVA PHARMACEUTICAL INDUSTRIES LIMITED

## Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

*Financial instruments not measured at fair value*

Financial instruments measured on a basis other than fair value are mostly comprised of senior notes and convertible senior debentures, and are presented in the below table in terms of fair value:

	Estimated fair value*	
	September 30, 2015	December 31, 2014
	U.S. \$ in millions	
Senior notes included under long-term liabilities	\$ (8,354)	\$ (7,776)
Senior notes and convertible senior debentures included under short-term liabilities	(716)	(1,731)
Fair value at the end of the period	\$ (9,070)	\$ (9,507)

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

*Investment in securities*

The fair value, amortized cost and gross unrealized holding gains and losses of such securities are presented in the below table:

	Fair value	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses
	U.S. \$ in millions			
September 30, 2015	\$ 1,118	\$ 1,127	\$ 13	\$ 22
December 31, 2014	259	266	19	26

During the second quarter of 2015, Teva acquired a less than 5% interest in Mylan N.V. (Mylan) shares. As the decline in fair value of this interest was considered to be other than temporary, on June 30, 2015 a loss of \$105 million was included in impairments, restructuring and others, reflecting the difference between the purchase price of this interest and its fair value as of June 30, 2015. On September 30, 2015, an additional loss of \$623 million was included in financial expenses-net, reflecting the difference between the book value of this interest and its fair value as of

September 30, 2015. Accordingly, the aggregate loss from the decline in fair value of the Mylan shares was \$728 million, as of September 30, 2015.

**NOTE 9 Derivative instruments and hedging activities:**

The following table summarizes the notional amounts for hedged items, when transactions are designated as hedge accounting:

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
	<b>U.S. \$ in millions</b>	
Forward starting interest rate swap - cash flow hedge	\$ 2,000	\$
Interest rate swap - fair value hedge	1,294	1,750
Cross-currency swap - cash flow hedge	588	1,875
Forecasted transactions - cash flow hedge		280

Table of Contents

## TEVA PHARMACEUTICAL INDUSTRIES LIMITED

## Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

The following table summarizes the classification and fair values of derivative instruments:

	Fair value			
	Designated as hedging instruments		Not designated as hedging instruments	
	September 30, 2015	December 31, 2014	September 30, 2015	December 31, 2014
	U.S. \$ in millions			
<b>Reported under</b>				
<b>Asset derivatives:</b>				
<b>Other current assets:</b>				
Cross-currency swaps - cash flow hedge	\$	\$	14	\$
Option and forward contracts - cash flow hedge		14		
Option and forward contracts			25	68
<b>Other non-current assets:</b>				
Cross-currency swaps - cash flow hedge	72	6		
Interest rate swaps - fair value hedge	19			
<b>Liability derivatives:</b>				
<b>Other current liabilities:</b>				
Option and forward contracts - cash flow hedge		(1)		
Option and forward contracts			(15)	(53)
Forward starting interest rate swaps - cash flow hedge	(14)			
<b>Senior notes and loans:</b>				
Interest rate swaps - fair value hedge		(43)		

Derivatives on foreign exchange contracts mainly hedge Teva's balance sheet items from currency exposure but are not designated as hedging instruments for accounting purposes. With respect to such derivatives, gains of \$52 million and losses of \$5 million were recognized under financial expenses-net for the nine months ended September 30, 2015 and 2014, respectively, and gains of \$40 million and \$34 million were recognized under financial expenses-net for the three months ended September 30, 2015 and 2014, respectively. Such gains and losses offset the revaluation of the balance sheet items also recorded under financial expenses-net.

With respect to the interest rate and cross-currency swap agreements, gains of \$22 million and \$32 million were recognized under financial expenses-net for the nine months ended September 30, 2015 and 2014, respectively, and gains of \$6 million and \$11 million were recognized under financial expenses-net for the three months ended September 30, 2015 and 2014, respectively. Such gains mainly reflect the differences between the fixed interest rate

and the floating interest rate.

In connection with the debt tender offer completed in February 2015, Teva terminated certain of its derivatives designated as hedging instruments and recognized a loss of \$36 million under financial expenses-net. See note 3.

During August and September 2015, Teva entered into forward starting interest rate swap agreements designated as cash flow hedges of anticipated future debt issuance, with respect to \$2 billion notional amount. These agreements hedge the variability in anticipated future interest payments due to changes in the benchmark interest rate between the date the swap agreements were entered into and the expected date of future debt issuances in 2016, at which time these agreements are intended to be settled. Upon completion of a debt issuance and settlement of the swap agreements, the change in fair value of these instruments recorded as part of other comprehensive income (loss) will be amortized under financial expenses-net over the life of the debt.

During October 2015, Teva entered into additional forward starting interest rate swap agreements, designated as cash flow hedge of anticipated future debt issuance, with respect to \$1 billion notional amount.



Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****NOTE 10 Impairments, restructuring and others:**

Impairments, restructuring and others consisted of the following:

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<b>U.S. \$ in millions</b>			
Impairments of long-lived assets	\$ 187	\$ 151	\$ 333	\$ 208
Contingent consideration	67	(21)	329	(26)
Acquisition expenses	61	1	194	11
Restructuring	70	30	121	166
Other	(1)	3	(9)	5
<b>Total</b>	<b>\$ 384</b>	<b>\$ 164</b>	<b>\$ 968</b>	<b>\$ 364</b>

During the nine months ended September 30, 2015, Teva incurred impairment expenses of \$333 million, mainly due to a \$133 million impairment of Synribo<sup>®</sup> following a decrease in sales projections, and contingent consideration expenses of \$329 million, mainly due to an expense of \$310 million following the positive phase 2b results of TEV-48125 in both chronic and episodic migraine prevention.

During the second quarter of 2015, Teva recorded acquisition expenses of \$105 million, reflecting the difference between the purchase price of the interest acquired in Mylan and its fair value as of June 30, 2015. On September 30, 2015, an additional loss of \$623 million was included in financial expenses-net, reflecting the difference between the book value of this interest and its fair value as of September 30, 2015. Accordingly, the aggregate loss from the decline in fair value of the Mylan shares was \$728 million, as of September 30, 2015. See note 8.

The carrying value as of September 30, 2015 of Teva's in-process R&D asset Revasco<sup>®</sup> (mesenchymal precursor cells) was \$258 million. This drug candidate is in a phase 3 trial for congestive heart failure. The trial results, which are expected in the first half of 2016, may lead us to reevaluate the fair value of the asset, which may result in an impairment charge. Such a charge may also lead Teva to reassess the current carrying value of its equity interest in Mesoblast Ltd., which is \$238 million as of September 30, 2015.

**NOTE 11 Legal settlements and loss contingencies:**

Legal settlements and loss contingencies for the nine months ended September 30, 2015 amounted to an expense of \$531 million, compared to income of \$67 million for the nine months ended September 30, 2014. The expenses in 2015 were related to \$680 million in additional reserves related to the settlement of the modafinil antitrust litigation,

partially offset by insurance proceeds relating to the settlement of the pantoprazole patent litigation.

**NOTE 12 Contingencies:**

*General*

From time to time, Teva and/or 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 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 matters disclosed in this note.

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 assessments of the likelihood of damages, and the advice of counsel, no provisions have been made regarding the matters disclosed in this note, except as noted below. Litigation outcomes and contingencies are unpredictable, and excessive verdicts can occur. Accordingly, management's assessments involve complex judgments about future events and often rely heavily on estimates and assumptions.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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 incurs significant legal fees 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.

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. Teva's agreements with third parties may require Teva to indemnify them, or require them to indemnify Teva, for the costs and damages incurred in connection with product liability claims, in specified or unspecified amounts.

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 Litigation***

From time to time, Teva seeks to develop generic versions of patent-protected pharmaceuticals for sale prior to patent expiration in various markets. In the United States, to obtain approval for most generics prior to the expiration of the originator's patents, Teva must challenge the patents under the procedures set forth in the Hatch-Waxman Act of 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 patents. Teva may also be involved in patent litigation involving the extent to which its product or manufacturing process techniques may infringe other originator or third-party patents.

Additionally, depending upon a complex analysis of a variety of legal and commercial factors, Teva may, in certain circumstances, elect to market a generic 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.

The general rule for damages in patent infringement cases in the United States is that the patentee should be compensated by no less than a reasonable royalty, and it may also be able in certain circumstances to be compensated for its lost profits. The amount of a reasonable royalty award would be calculated based on the sales of Teva's generic product. The amount of lost profits would be based on the lost sales of the branded product. The launch of an authorized generic and other generic competition may be relevant to the damages calculation. In addition, the patentee may seek consequential damages as well as enhanced damages of up to three times the profits lost by the patent holder for willful infringement, although courts have typically awarded much lower multiples.

Teva is also involved in litigation regarding patents in other countries where it does business, particularly in Europe, where Teva has in recent years increased the number of launches of its generic versions of branded pharmaceuticals

prior to the expiration of the innovator's patents. The laws concerning generic pharmaceuticals and patents differ from country to country. Damages for patent infringement in Europe may include lost profits or a reasonable royalty, but enhanced damages for willful infringement are generally not available.

In June 2013, Teva settled its pantoprazole patent litigation with Wyeth and agreed to pay \$1.6 billion, which was completed on October 1, 2014. Teva has sought insurance coverage to defray such amount, and to date, Teva has recovered approximately \$339 million from certain of its insurance carriers. Management believes it may have up to \$5 million in additional coverage, subject to recovery from one remaining insurance carrier, which has disputed its obligation to cover the Company's claim.

In September 2012, Teva launched its 10, 20, 30, 40, 50, and 60 mg methylphenidate ER products, which are the AB-rated generic versions of UCB's Metadate CD capsules, which had annual sales of approximately \$154 million for the twelve months ended September 2012. In December 2012, UCB sued Teva in the United States District Court for the Northern District of Georgia for infringement of UCB's formulation patent, which expires in October 2020. On March 18, 2015, the District Court granted Teva's motion for summary judgment of non-infringement. The case was dismissed on May 12, 2015. Teva continues to sell its methylphenidate ER products.

On April 28, 2015, Teva launched its 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg aripiprazole tablets, which are the AB-rated versions of Otsuka's Abilify®, which had annual sales according to IMS of approximately \$7.8 billion for the twelve months ending December 2014. Otsuka has sued Teva in New Jersey federal court for infringement of patents

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

that expire in March 2023 and March 2027. On April 16, 2015, the court denied Otsuka's motion for a temporary restraining order based on one of the patents in suit. No trial date has been scheduled. Were Otsuka ultimately to be successful in its allegation of patent infringement, Teva could be required to pay damages relating to past sales of its aripiprazole products and enjoined from future sales until patent expiry. Otsuka also filed suit against the FDA in Maryland federal court, seeking an injunction to block the FDA from approving generic versions of Abilify® that do not contain an indication for treatment of Tourette's Syndrome in the pediatric population. On April 29, 2015, the court denied Otsuka's motion for an injunction.

***Product Liability Litigation***

Teva's business inherently exposes it to potential product liability claims, and in recent years the number of product liability claims asserted against Teva has increased. Teva maintains a program of insurance, which may include commercial insurance, self-insurance (including direct risk retention), or a combination of both approaches, in amounts and on 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 commercial insurance it desires, or any commercial insurance on reasonable terms, in all of its markets.

Teva and/or its subsidiaries have been named as defendants in approximately 4,000 product liability lawsuits brought against them and other manufacturers by approximately 4,400 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 20 years, the FDA-approved label for metoclopramide has contained warning language about the risk of tardive dyskinesia, and that the risk of developing the disorder increases 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 resulting from long-term usage. The cases of approximately 500 of the plaintiffs have been dismissed or otherwise resolved to date. Teva expects to be dismissed from at least some of the remaining cases on the basis that some plaintiffs cannot demonstrate that they used a Teva product.

Approximately 40% of the plaintiffs are parties to cases against Teva that are part of a mass tort proceeding in the Philadelphia Court of Common Pleas. In addition, there are mass tort proceedings under way in state courts in California and New Jersey. The California litigation includes about half of the total plaintiffs. 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. The appellate court affirmed, and the New Jersey Supreme Court has agreed to hear Teva's further appeal of the decision with respect to the update claims. All of the cases in the New Jersey proceeding with respect to the generic defendants have been stayed pending resolution of the appeal.

*Competition Matters*

As part of its generic pharmaceuticals business, Teva has challenged a number of patents covering branded pharmaceuticals, some of which are among the most widely-prescribed and well-known drugs on the market. Many of Teva's patent challenges have resulted in litigation relating to Teva's attempts to market generic versions of such pharmaceuticals under the federal Hatch-Waxman Act. Some of this litigation has been resolved through settlement agreements in which Teva obtained a license to market a generic version of the drug, often years before the patents expire. Occasionally, Teva and its subsidiaries have been named as defendants in cases that allege antitrust violations arising from such settlement agreements. Teva believes that its settlement agreements are lawful and serve to increase competition, and intends to defend them vigorously. However, the plaintiffs in these cases typically allege (1) that Teva received something of value from the innovator in exchange for an agreement to delay generic entry, and (2) that they would have realized significant savings if there had been no settlement and competition had commenced earlier. These cases seek various forms of injunctive and monetary relief, including damages based on the difference between the brand price and what the generic price allegedly would have been, and disgorgement of profits, trebled under the relevant statutes, plus attorneys' fees and costs. The damages allegedly caused by the alleged delays in generic entry generally depend on the size of the branded market and the length of the alleged delay, and can be substantial, particularly where the alleged delays are lengthy or branded drugs with sales in the billions of dollars are involved. Nonetheless, as in the modafinil opt-out case described below, many such cases may be resolved through settlement for amounts considerably less than the damages initially alleged.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

On June 17, 2013, the United States Supreme Court held, in *Federal Trade Commission v. Actavis, Inc.* (the AndroGel case), that a rule of reason test should be applied in analyzing whether such settlements potentially violate the federal antitrust laws. The Supreme Court held that a trial court must analyze each agreement in its entirety in order to determine whether it violates the antitrust laws. This new test may lead to increased scrutiny of Teva's patent settlements, additional action by the Federal Trade Commission (FTC), and an increased risk of liability in Teva's currently pending antitrust litigations.

In April 2006, certain subsidiaries of Teva were named in a class action lawsuit filed in the United States District Court for the Eastern District of Pennsylvania. The case alleges that the settlement agreements entered into between Cephalon, Inc., now a Teva subsidiary (Cephalon), and various generic pharmaceutical companies in late 2005 and early 2006 to resolve patent litigation involving certain finished modafinil products (marketed as Provigil®) were unlawful because they had the effect of excluding generic competition. The case also alleges that Cephalon improperly asserted this patent against the generic pharmaceutical companies. The first lawsuit 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 (the Direct Purchaser Class). Similar allegations have been made in a number of additional complaints, including those filed on behalf of a proposed class of end payors of Provigil (the End Payor Class), by certain individual end payors, by certain retail chain pharmacies and by Apotex, Inc. In February 2008, following an investigation, the FTC sued Cephalon only, 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. Annual sales of Provigil® were approximately \$500 million at the time of the settlement agreements, and approximately \$1 billion when the first generic modafinil product was launched in March 2012.

In October 2011, the District Court hearing the antitrust cases described above, as well as patent claims brought by plaintiff Apotex, issued a decision regarding Apotex's invalidity claims, finding the Cephalon patent to be invalid based on obviousness, among other things, and unenforceable based on inequitable conduct. In March 2012, the District Court ruled that Apotex's product does not infringe the Cephalon patent. On April 8, 2013, the United States Court of Appeals for the Federal Circuit affirmed the District Court's rulings of invalidity and inequitable conduct. The plaintiffs in the antitrust cases sought to apply the inequitable conduct and invalidity findings to the antitrust cases in an effort to establish antitrust liability. The District Court denied, in part, plaintiffs' motion for summary judgment on this ground. In a separate ruling, the District Court granted defendants' summary judgment motion that there was no overarching conspiracy between Cephalon and the generic defendants. In addition, the District Court denied Apotex's motion for partial summary judgment seeking a ruling that Cephalon possessed monopoly power, holding that the motion raised fact issues that must be resolved at trial. Defendants' summary judgment motions arguing that none of the settlement agreements contained an impermissible reverse payment as a matter of law were denied on January 28, 2015. On June 1, 2015, the court denied class certification for the End Payor Class, and the End Payor Class has filed a petition for appellate review of that decision.

Teva settled with certain of the retail chain pharmacies (representing approximately half of the direct purchases of Provigil® from Cephalon) in 2013, and, given the significant similarities in the claims asserted and damages claimed

by certain other purchaser plaintiffs, recorded a charge of \$495 million in 2013 covering the settlement and the litigations with the remaining direct purchasers as well as the end payor purchasers. In March 2015, Teva reached a settlement with the Direct Purchaser Class for \$512 million. The Direct Purchaser Class settlement was preliminarily approved by the Court on July 27, 2015. Management recorded an additional charge of \$282 million in the first quarter of 2015 as a result of this settlement.

On May 28, 2015, Cephalon entered into a consent decree with the FTC whereby the FTC agreed to dismiss its claims against Cephalon in exchange for Cephalon and Teva making a payment into a settlement fund of \$1.2 billion, less set-offs for prior settlements, including the settlements with the Direct Purchaser Class and the retail chain pharmacy plaintiffs described above. Pursuant to the consent decree, the net amount paid into the settlement fund may be used to settle certain other related cases, including the claims still pending in the litigation described above, as well as other government investigations. Under the consent decree, Teva also agreed to certain injunctive relief with respect to the types of settlement agreements Teva may enter into to resolve patent litigation in the United States for a period of ten years. If, at the end of the ten years, the entire settlement fund has not been fully disbursed, any amount remaining will be paid to



**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

the Treasurer of the United States. On July 16, 2015, Teva made a payment into the settlement fund for the difference of \$1.2 billion less the amount of the agreed-upon settlements reached as of that date. Management recorded an additional charge of \$398 million in the second quarter of 2015 as a result of the settlement with the FTC.

A trial to determine liability only has been scheduled to begin on February 2, 2016. The only remaining plaintiffs in the trial against Teva are the named end payors and Apotex.

In addition to the pending claims, the City of Providence, Rhode Island and the State of Louisiana have also filed lawsuits against Cephalon and other Teva subsidiaries, and Cephalon and other Teva subsidiaries have received notices of potential claims related to the Provigil® settlement agreements by certain other claimants.

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 might 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 Laboratories, Inc., a subsidiary of Teva ( Barr ), is a defendant in actions in California, Florida and Kansas alleging that a January 1997 patent litigation settlement agreement between Barr and Bayer Corporation was anticompetitive and violated state antitrust and consumer protection laws. In the California case, the trial court granted defendants' summary judgment motions, and the California Court of Appeal affirmed in October 2011. The trial court approved a \$74 million class settlement with Bayer, and the California Supreme Court has received supplemental briefs addressing the effect of the AndroGel case on plaintiffs' appeal of the grant of summary judgment for the remaining defendants in this case. On May 7, 2015, the California Supreme Court reversed and remanded the case back to the trial court for a Rule of Reason inquiry. No trial date has been set. Based on the plaintiffs' expert testimony in a prior federal multidistrict litigation, estimated sales of ciprofloxacin in California were approximately \$500 million during the alleged damages period. In the Kansas action, the court granted preliminary approval of the settlement Bayer entered into with plaintiffs on June 5, 2015. On July 22, 2015, Barr and its remaining co-defendants agreed to settle with plaintiffs. The terms of the settlement are confidential until plaintiffs file their motion for preliminary approval of the settlement.

In December 2011, three groups of plaintiffs sued Wyeth and Teva for alleged violations of the antitrust laws in connection with their settlement of patent litigation involving extended release venlafaxine (generic Effexor® XR) entered into in November 2005. The cases were filed by a purported class of direct purchasers, by a purported class of indirect purchasers and by certain chain pharmacies. The plaintiffs claim that the settlement agreement between Wyeth and Teva unlawfully delayed generic entry. On October 7, 2014, the court granted Teva's motion to dismiss in the direct purchaser cases, after which the parties agreed that the court's reasoning applied equally to the indirect purchaser cases. Plaintiffs filed notices of appeal, and the Third Circuit has consolidated the appeal with a separate antitrust case in which Teva is not a party, *In re Lipitor Antitrust Litigation*, solely for purposes of disposition by the same appellate panel. Annual sales of Effexor® XR were approximately \$2.6 billion at the time of settlement and at the time generic versions were launched in July 2010.

In February 2012, two purported classes of direct-purchaser plaintiffs sued GlaxoSmithKline ( GSK ) and Teva for alleged violations of the antitrust laws in connection with their settlement of patent litigation involving lamotrigine (generic Lamictal®) entered into in February 2005. In August 2012, a purported class of indirect purchaser plaintiffs filed a nearly identical complaint against GSK and Teva. The plaintiffs claim that the settlement agreement unlawfully delayed generic entry and seek unspecified damages. In December 2012, the District Court dismissed the cases. On January 24, 2014, the District Court denied the direct purchaser plaintiffs' motion for reconsideration and affirmed its original dismissal of the cases. On June 26, 2015, the Third Circuit reversed and remanded for further proceedings. The defendants' petitions for review by the full court were denied on September 23, 2015. Annual sales of Lamictal® were approximately \$950 million at the time of the settlement, and approximately \$2.3 billion at the time generic competition commenced in July 2008.

Starting in September 2012, plaintiffs in numerous cases, including overlapping purported class actions, sued AstraZeneca and Teva, as well as Ranbaxy and Dr. Reddy's, for violating the antitrust laws by entering into settlement agreements to resolve the esomeprazole (generic Nexium®) patent litigation. Teva entered into its settlement agreement in January 2010. These cases were consolidated and transferred to the United States District Court for the District of Massachusetts. On November 24, 2014, Teva agreed to settle with all plaintiffs on all claims for \$24 million, and a charge in this amount was recorded in the financial statements. On December 5, 2014, the jury returned a verdict in favor of AstraZeneca and Ranbaxy, finding that their settlement agreement was not the cause of delay for the entry of generic Nexium®. Final approval of Teva's settlements with the classes has been granted.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

On June 18, 2014, two groups of end payors who opted out of the action in the District of Massachusetts filed complaints in the Philadelphia Court of Common Pleas (the Philadelphia Actions ) with allegations nearly identical to those in the District of Massachusetts action. Proceedings in the Philadelphia Actions are stayed pending resolution of the action in the District of Massachusetts. Annual sales of Nexium® were approximately \$6.3 billion at the time the Teva settlement agreement was entered into, and sales in 2014 were approximately \$6 billion. Teva launched its generic version of Nexium® in the first quarter of 2015.

In April 2013, purported classes of direct purchasers of and end payors for Niaspan® (extended release niacin) sued Teva and Abbott for violating the antitrust laws by entering into a settlement agreement in April 2005 to resolve patent litigation over the product. A multidistrict litigation has been established in the United States District Court for the Eastern District of Pennsylvania. Teva and Abbott's motion to dismiss was denied on September 8, 2014. In March and April 2015, several individual direct purchaser opt-out plaintiffs filed complaints with allegations nearly identical to those of the direct purchaser class. Annual sales of Niaspan® were approximately \$416 million at the time of the settlement and approximately \$1.1 billion at the time generic competition commenced in September 2013.

Since July 2013, numerous lawsuits have been filed in several federal courts by purported classes of end payors for, and direct purchasers of, Solodyn® ER (minocycline hydrochloride) against Medicis, the innovator, and several generic manufacturers, including Teva. The lawsuits allege, among other things, that the settlement agreements between Medicis and the generic manufacturers violated the antitrust laws. Teva entered into its agreement with Medicis in March 2009. A multidistrict litigation has been established in the United States District Court for the District of Massachusetts. On September 12, 2014, plaintiffs filed an amended complaint that did not name Teva as a defendant. Annual sales of Solodyn® ER were approximately \$380 million at the time Teva settled, and approximately \$765 million at the time generic competition entered the market on a permanent basis in November 2011.

Since November 2013, numerous lawsuits have been filed in several federal courts by purported classes of end payors for, and direct purchasers of, Aggrenox® (dipyridamole/aspirin tablets) against Boehringer Ingelheim ( BI ), the innovator, and several Teva entities. The lawsuits allege, among other things, that the settlement agreement between BI and Barr entered into in August 2008 violated the antitrust laws. A multidistrict litigation has been established in the United States District Court for the District of Connecticut. Teva and BI's motion to dismiss was denied on March 23, 2015. Defendants' motion for certification for an immediate appeal of that decision was granted on July 21, 2015, but the Second Circuit denied hearing the appeal. Annual sales of Aggrenox® were approximately \$340 million at the time of the settlement, and were approximately \$455 million at the time generic competition began in July 2015. Teva launched a generic version of Aggrenox® in July 2015.

Since January 2014, numerous lawsuits have been filed in the United States District Court for the Southern District of New York by purported classes of end payors for and direct purchasers of ACTOS® and ACTOplus Met® (pioglitazone and pioglitazone plus metformin) against Takeda, the innovator, and several generic manufacturers, including Teva. The lawsuits allege, among other things, that the settlement agreements between Takeda and the generic manufacturers violated the antitrust laws. Teva entered into its agreement with Takeda in December 2010. Defendants' motions to dismiss with respect to the end payor lawsuits were granted on September 23,

2015. On October 22, 2015, the end payors filed a notice of appeal of this ruling. The lawsuits brought by the direct purchasers were stayed pending a ruling on the motions to dismiss the end payor lawsuits. Following the ruling on the motions to dismiss in the end payor lawsuits, direct purchaser plaintiffs announced that they would seek to amend their complaint. At the time of the settlement, annual sales of ACTOS<sup>®</sup> were approximately \$3.7 billion and annual sales of ACTOplus Met<sup>®</sup> were approximately \$500 million. At the time generic competition commenced in August 2012, annual sales of ACTOS<sup>®</sup> were approximately \$2.8 billion and annual sales of ACTOplus Met<sup>®</sup> were approximately \$430 million.

On September 8, 2014, the FTC sued AbbVie Inc. and certain of its affiliates ( AbbVie ) and Teva in the United States District Court for the Eastern District of Pennsylvania alleging that they violated the antitrust laws when they entered into a settlement agreement to resolve the AndroGel<sup>®</sup> patent litigation and a supply agreement under which AbbVie would supply authorized generic product for TriCor<sup>®</sup> to Teva. The FTC alleges that Teva agreed to delay the entry of its generic testosterone gel product in exchange for entering into the TriCor supply agreement. On May 6, 2015, the court granted Teva's motion to dismiss the FTC's claim as to Teva. The FTC's motions for reconsideration and for entry of partial final judgment to permit an immediate appeal were denied.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

Since May 29, 2015, two lawsuits have been filed in the United States District Court for the Southern District of New York by a purported class of direct purchasers of, and a purported class of end payors for, Namenda IR<sup>®</sup> (memantine hydrochloride) against Forest Laboratories, LLC and Actavis PLC, the innovator, and several generic manufacturers, including Teva. The direct purchasers withdrew their complaint and filed an amended complaint that did not name Teva as a defendant. The lawsuits allege, among other things, that the settlement agreements between Forest and the generic manufacturers violated the antitrust laws. Teva entered into its agreement with Forest in November 2009. Annual sales of Namenda IR<sup>®</sup> at the time of the settlement were approximately \$1.1 billion, and are currently approximately \$1.4 billion.

***Government Investigations and Litigation Relating to Pricing and Marketing***

Teva is involved in government investigations and litigation arising from the marketing and promotion of its specialty pharmaceutical products in the United States. Many of these investigations originate through what are known as *qui tam* complaints, in which the government reviews a complaint filed under seal by a whistleblower (a relator) that alleges violations of the federal False Claims Act. The government considers whether to investigate the allegations and will, in many cases, issue subpoenas requesting documents and other information, including conducting witness interviews. The government must decide whether to intervene and pursue the claims as the plaintiff. Once a decision is made by the government, the complaint is unsealed. If the government decides not to intervene, then the relator may decide to pursue the lawsuit on his own without the active participation of the government.

Under the federal False Claims Act, the government (or relators who pursue the claims without the participation of the government in the case) may seek to recover up to three times the amount of damages in addition to a civil penalty of \$5,500 to \$11,000 for each allegedly false claim submitted to the government for payment. Generally speaking, these cases take several years for the investigation to be completed and, ultimately, to be resolved (either through litigation or settlement) after the complaint is unsealed. In addition, some states have pursued investigations under state false claims statutes or consumer protection laws, either in conjunction with a government investigation or separately. There is often collateral litigation that arises from public disclosures of government investigations, including the filing of class action lawsuits by third party payors alleging fraud-based claims or by shareholders alleging violations of the securities laws.

A number of state attorneys general and others have filed various actions against Teva and/or certain of its subsidiaries in the United States relating to reimbursements or drug price reporting under Medicaid or other programs. Such price reporting is alleged to have caused governments and others to pay inflated reimbursements for covered drugs. Teva and its subsidiaries have reached settlements in most of these cases, and remain parties to litigation in Illinois. A provision for the cases has been included in the financial statements. Trial in the Illinois case concluded in the fourth quarter of 2013, and post-trial briefing has been submitted and is under consideration. The State of Illinois is seeking approximately \$100 million in compensatory damages. Any such damages ultimately awarded by the court are subject to automatic trebling. In addition, the state is seeking unspecified statutory penalties that could range, depending on the method used for calculation, from a de minimis amount to well over \$100 million. Teva denies any liability, and will argue that even if the court finds liability, compensatory damages and penalties should be

significantly less than the amount sought by the state.

Several *qui tam* complaints have been unsealed in recent years as a result of government decisions not to participate in the cases. The following is a summary of certain government investigations, *qui tam* actions and related matters.

In December 2009, the United States District Court for the District of Massachusetts unsealed a complaint alleging that numerous drug manufacturers, including certain Teva 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, filed a motion to dismiss, which was granted on February 25, 2013. The plaintiffs' deadline to appeal the dismissal has not yet expired.

In September 2013, the State of Louisiana filed a complaint seeking unspecified damages against 54 pharmaceutical companies, including several Teva subsidiaries. The complaint asserts that each of the defendants allegedly defrauded the state by falsely representing that its products were FDA-approved drugs, which allegedly caused the state Medicaid program to pay millions of dollars in reimbursement claims for products that it would not otherwise have covered. The case was recently dismissed without prejudice, with the court finding that the state was not a proper plaintiff. The state is appealing this decision.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

Cephalon has received and responded to subpoenas related to Treanda<sup>®</sup>, Nuvigil<sup>®</sup> and Fentora<sup>®</sup>. In March 2013, a federal False Claims Act complaint filed against Cephalon in the United States District Court for the Southern District of New York was unsealed. The case was transferred to the Eastern District of Pennsylvania. The complaint alleges off-label promotion of Treanda<sup>®</sup> and Fentora<sup>®</sup>. The District Court granted Cephalon's motion to dismiss the Fentora claims and denied Cephalon's motion to dismiss the Treanda claims. In January 2014, a separate federal False Claims Act complaint that had been filed in the United States District Court for the Eastern District of Pennsylvania was served on Cephalon. The complaint alleges off-label promotion of Fentora<sup>®</sup>, Nuvigil<sup>®</sup> and Provigil<sup>®</sup>. The District Court dismissed the Fentora<sup>®</sup> claims and denied Cephalon's motion to dismiss the Provigil<sup>®</sup> and Nuvigil<sup>®</sup> claims. On August 13, 2015, Cephalon submitted a motion to modify the Court's order denying its motion to dismiss the relators Provigil<sup>®</sup> claims.

Cephalon is a defendant in a putative class action filed in the United States District Court for the Eastern District of Pennsylvania in which plaintiffs, third party payors, allege approximately \$700 million in losses resulting from the promotion and prescription of Actiq<sup>®</sup> for uses not approved by the FDA despite the availability of allegedly less expensive pain management drugs that were more appropriate for patients' conditions. In March 2015, the court denied the plaintiffs' motion for class certification. Cephalon is defending a separate putative class action law suit with similar off-label claims involving Provigil<sup>®</sup> and Gabitril<sup>®</sup> brought by the American Federation of State, County and Municipal Employees, District Council 47 Health and Welfare Fund. In October 2015, Cephalon reached an agreement in principle to resolve this case without admitting any liability, and the case will be dismissed.

In July 2014, the court granted Cephalon and Teva's motion to dismiss an action brought by certain Travelers entities that was filed in the Eastern District of Pennsylvania alleging off-label marketing of Actiq<sup>®</sup> and Fentora<sup>®</sup>. The plaintiffs' motion to amend the judgment and file a second amended complaint was denied on September 24, 2014, and the plaintiffs have appealed. On August 10, 2015, the Third Circuit Court of Appeals entered an order affirming the district court's order dismissing the case with prejudice. Cephalon is also a defendant in a lawsuit filed by the State of South Carolina alleging violations of the state's unfair trade practices law and common law in connection with the alleged off-label promotion of Actiq<sup>®</sup>, Provigil<sup>®</sup> and Gabitril<sup>®</sup>. In September 2015, Cephalon reached an agreement in principle to resolve this case without admitting any liability, and the case will be dismissed.

On May 21, 2014, counsel for Santa Clara County and Orange County, purportedly on behalf of the People of California, filed a complaint in the Superior Court for Orange County, California against Teva and Cephalon, along with several other pharmaceutical companies, contending that defendants allegedly engaged in off-label promotion in the sale of opioids, including Actiq<sup>®</sup> and Fentora<sup>®</sup>. On June 2, 2014, the City of Chicago filed a similar complaint against Teva and Cephalon in the Circuit Court of Cook County, Illinois, which has been removed to the Northern District of Illinois. Both complaints assert claims under state law based upon alleged off-label promotion in the sale of opioids, and both seek a variety of damages, including restitution, civil penalties, disgorgement of profits, treble damages, attorneys' fees and injunctive relief. Neither complaint specifies the exact amount of damages at issue. Teva and Cephalon filed motions to dismiss in both the California and Chicago actions. All claims against Teva and Cephalon in the Chicago action were dismissed without prejudice by the District Court. On August 26, 2015, the City of Chicago filed a second amended complaint. In the California action, on August 27, 2015, the Court granted the

defendants' demurrer, or motion to dismiss, on primary jurisdiction grounds and the case has been stayed.

On January 8, 2014, Teva received a civil investigative demand from the United States Attorney for the Southern District of New York seeking documents and information from January 1, 2006 related to sales, marketing and promotion of Copaxone® and Azilect®. The demand states that the government is investigating possible civil violations of the federal False Claims Act. On March 12, 2015, the docket in this matter and a False Claims Act civil *qui tam* complaint concerning this matter were unsealed by the court, which revealed that the United States Attorney had notified the court on November 18, 2014 that it had declined to intervene in and proceed with the lawsuit. The *qui tam* relators, however, are moving forward with the lawsuit. On June 5, 2015, Teva filed motions to dismiss the complaint, which remains pending.

For several years, Teva has been conducting a voluntary worldwide investigation into business practices that may have implications under the U.S. Foreign Corrupt Practices Act (FCPA). Teva has engaged outside counsel to assist in its investigation, which was prompted by the receipt, beginning in 2012, of subpoenas and informal document requests from the SEC and the Department of Justice (DOJ) to produce documents with respect to compliance with the FCPA in certain countries. Teva has provided and will continue to provide documents and other information to the SEC and the DOJ, and is cooperating with these agencies in their investigations of these matters. In the course of its investigation, which is continuing, Teva has identified certain business practices and transactions in Russia, certain European countries,



**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

certain Latin American countries and other countries in which it conducts business, which likely constitute violations of the FCPA and/or local law. In connection with its investigation, Teva has also become aware that Teva affiliates in certain countries under investigation provided to local authorities inaccurate or altered information relating to marketing or promotional practices. Teva has brought and continues to bring these issues to the attention of the SEC and the DOJ. Teva cannot predict at this time the impact on the Company as a result of these matters, which may include material fines in amounts that are not currently estimable, limitations on the Company's conduct, the imposition of a compliance monitor and/or other civil and criminal penalties.

***Shareholder Litigation***

On December 18, 2013, a putative class action securities lawsuit was filed in the United States District Court for the Southern District of New York on behalf of purchasers of Teva's securities between January 1, 2012 and October 29, 2013. The complaint alleges that Teva and certain directors and officers violated Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder, and that the individual defendants violated Section 20 of the Exchange Act, by making false and misleading statements that failed to disclose the existence of significant internal discord between Teva's board of directors and senior management concerning execution of Teva's strategies, including implementation of a cost reduction program. On March 2, 2015, prior to any ruling by the court on the motion, and without any payment by Teva, the plaintiff voluntarily dismissed the lawsuit.

***Other Litigation***

In January 2013, GSK filed a lawsuit against Teva for violations of the Lanham Act in the marketing of its Budeprion XL 300 mg product. The lawsuit alleges that Teva made false representations in claiming that Budeprion XL 300 mg was bioequivalent to GSK's Wellbutrin<sup>®</sup> XL 300 mg and implicitly communicated that the product was as safe and efficacious as GSK's product. At the time Teva began selling Budeprion XL 300 mg, annual sales of Wellbutrin<sup>®</sup> XL 300 mg were approximately \$1 billion. In April 2013, Teva filed a motion to dismiss the complaint on the grounds that GSK cannot retroactively challenge through the Lanham Act a determination of bioequivalence made by the FDA, and that Teva's alleged statements, which merely repeated the FDA approval status of Wellbutrin<sup>®</sup>, were not false or misleading as a matter of law. On March 10, 2014, the motion was denied, and Teva's motion for reconsideration was denied on July 18, 2014.

***Environmental Matters***

Teva is party to a number of environmental proceedings, or has received claims, 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 noncompliance 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 and claims 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 site or to pay for such activities,

including for oversight by governmental authorities, the response costs associated with such oversight and any related damages to natural resources. Teva has received claims, or has been made a party to these proceedings, along with other potentially responsible parties, as an alleged generator of wastes that were disposed of or treated at third-party waste disposal sites, or as a result of an alleged release from one of Teva's 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, under certain circumstances, 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 or for which claims have been asserted; 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, enforcement proceedings relating to alleged federal, state, commonwealth or local regulatory violations at some of Teva's facilities have resulted, or may result, in the imposition of significant penalties (in

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

amounts not expected to materially adversely affect Teva's results of operations) and the recovery of certain state or commonwealth costs and natural resource damages, and have required, or may require, that corrective measures and enhanced compliance measures be implemented.

**NOTE 13 Segments:**

Teva has two reportable segments: generic and specialty medicines. The generics segment develops, manufactures, sells and distributes generic or branded generic medicines as well as active pharmaceutical ingredients ( API ). The specialty segment engages in the development, manufacture, sale and distribution of branded specialty medicines such as those for central nervous system and respiratory indications, as well as those marketed in the women's health, oncology and other specialty businesses.

Teva's other activities include the over-the-counter ( OTC ) medicines business, distribution activity mainly in Israel and Hungary and medical devices. The OTC activity is primarily conducted through a joint venture with P&G, which combines Teva's production capabilities and market reach with P&G's marketing expertise and expansive global platform.

Teva's chief executive officer, who is the chief operating decision maker ( CODM ), reviews financial information prepared on a consolidated basis, accompanied by disaggregated information about revenues and contributed profit by the two identified reportable segments, namely generic and specialty medicines, and revenues by geographical markets.

The accounting policies of the individual segments are the same as those described in the summary of significant accounting policies in Note 1 to the annual consolidated financial statements included in Teva's Annual Report on Form 20-F for the year ended December 31, 2014.

Segment profit consists of gross profit, less S&M and R&D expenses related to the segment. Segment profit does not include G&A expenses, amortization and certain other items. Beginning in 2015, expenses related to our equity compensation are excluded from our segment results. The data presented has been conformed to reflect the exclusion of equity compensation expenses for all periods.

Teva manages its assets on a total company basis, not by segments, as many of its assets are shared or commingled. Teva's CODM does not regularly review asset information by reportable segment, and therefore Teva does not report asset information by reportable segment.

Teva's chief executive officer reviews the Company's strategy and organizational structure on a continuing basis. Any changes in strategy may lead to a reevaluation of Teva's current segments and goodwill assignment. Going forward, Teva will consider the impact of such changes on its segment reporting.



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

The following tables present profit by segments and a reconciliation of Teva's segment profit to Teva's consolidated income before income taxes, for the three and nine months ended September 30, 2015 and 2014:

	<b>Generics</b>		<b>Specialty</b>	
	<b>Three months ended September 30,</b>		<b>Three months ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<b>U.S.\$ in millions</b>		<b>U.S.\$ in millions</b>	
Revenues	\$ 2,202	\$ 2,432	\$ 2,178	\$ 2,176
Gross profit	1,005	1,078	1,859	1,890
R&D expenses	132	133	220	221
S&M expenses	295	387	417	470
Segment profit	\$ 578	\$ 558	\$ 1,222	\$ 1,199

	<b>Generics</b>		<b>Specialty</b>	
	<b>Nine months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<b>U.S.\$ in millions</b>		<b>U.S.\$ in millions</b>	
Revenues	\$ 7,289	\$ 7,345	\$ 6,224	\$ 6,317
Gross profit	3,487	3,170	5,345	5,501
R&D expenses	377	381	655	658
S&M expenses	1,004	1,192	1,360	1,448
Segment profit	\$ 2,106	\$ 1,597	\$ 3,330	\$ 3,395

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<b>U.S.\$ in millions</b>			
Generic medicines profit	\$ 578	\$ 558	\$ 2,106	\$ 1,597
Specialty medicines profit	1,222	1,199	3,330	3,395
Total segment profit	1,800	1,757	5,436	4,992

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

Profit of other activities	58	48	164	165
<b>Total profit</b>	<b>1,858</b>	<b>1,805</b>	<b>5,600</b>	<b>5,157</b>
Amounts not allocated to segments:				
Amortization	203	242	637	783
General and administrative expenses	316	293	948	897
Legal settlements and loss contingencies	(80)	(122)	531	(67)
Impairments, restructuring and others	384	164	968	364
Other unallocated amounts	25	116	95	171
Consolidated operating income	1,010	1,112	2,421	3,009
<b>Financial expenses - net</b>	<b>697</b>	<b>84</b>	<b>930</b>	<b>243</b>
Consolidated income before income taxes	\$ 313	\$ 1,028	\$ 1,491	\$ 2,766

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****Segment revenues by geographic area:**

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<b>U.S.\$ in millions</b>			
<b>Generic Medicines</b>				
United States	\$ 1,032	\$ 1,124	\$ 3,797	\$ 3,240
Europe*	661	757	2,006	2,389
Rest of the World	509	551	1,486	1,716
<b>Total Generic Medicines</b>	<b>2,202</b>	<b>2,432</b>	<b>7,289</b>	<b>7,345</b>
<b>Specialty Medicines</b>				
United States	1,701	1,533	4,802	4,482
Europe*	369	467	1,152	1,450
Rest of the World	108	176	270	385
<b>Total Specialty Medicines</b>	<b>2,178</b>	<b>2,176</b>	<b>6,224</b>	<b>6,317</b>
<b>Other Revenues</b>				
United States	1	3	8	104
Europe*	169	184	508	597
Rest of the World	273	263	742	741
<b>Total Other Revenues</b>	<b>443</b>	<b>450</b>	<b>1,258</b>	<b>1,442</b>
<b>Total Revenues</b>	<b>\$ 4,823</b>	<b>\$ 5,058</b>	<b>\$ 14,771</b>	<b>\$ 15,104</b>

\* All members of the European Union, Switzerland, Norway, Albania and the countries of former Yugoslavia.  
**Net revenues from specialty medicines:**

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>

	<b>U.S. \$ in millions</b>			
CNS	\$ 1,366	\$ 1,440	\$ 3,939	\$ 4,124
Copaxone®	1,085	1,107	3,063	3,116
Azilect®	92	103	304	320
Nuvigil®	97	94	273	283
Respiratory	285	218	803	705
ProAir®	149	111	401	358
QVAR®	92	64	273	209
Oncology	326	299	883	845
Treanda®	207	180	543	541
Women s health	115	137	354	389
Other Specialty	86	82	245	254
<b>Total Specialty Medicines</b>	<b>\$ 2,178</b>	<b>\$ 2,176</b>	<b>\$ 6,224</b>	<b>\$ 6,317</b>

A significant portion of our revenues, and a higher proportion of our profits, come from the manufacture and sale of patent-protected pharmaceuticals. Many of our specialty medicines are covered by several patents that expire at different times. Nevertheless, once patent protection has expired, or has been lost prior to the expiration date as a result of a legal challenge, we no longer have patent exclusivity on these products, and subject to regulatory approval, generic pharmaceutical manufacturers are able to produce similar (or purportedly similar) products and sell them for a lower price. The commencement of generic competition, even in the form of non-equivalent products, can result in a substantial decrease in revenues for a particular specialty medicine in a very short time. Any such expiration or loss of intellectual property rights could therefore significantly adversely affect our results of operations and financial condition.



**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

In particular, we rely heavily on sales of Copaxone<sup>®</sup>, our leading specialty medicine. A key element of our business strategy for Copaxone<sup>®</sup> is the continued migration of current daily Copaxone<sup>®</sup> 20 mg/mL patients to the three-times-a-week 40 mg/mL version introduced in 2014, and the maintenance of patients on that new version. Any substantial reduction in the number of patients taking Copaxone<sup>®</sup>, whether due to the introduction of generic competition or to the increased use of oral medicines or other competing products, would likely have a material adverse effect on our financial results and cash flow.

Sandoz obtained FDA approval of a generic version of Copaxone<sup>®</sup> 20 mg/mL in April 2015 and started selling its generic product Glatopa<sup>™</sup> in June 2015 in the United States.

Copaxone<sup>®</sup> 40 mg/mL is protected by three U.S. Orange Book patents that expire in 2030, which are being challenged in paragraph IV litigation and in patent office proceedings in the United States and a fourth U.S. Orange Book patent expiring in 2030 that was issued in October 2015. It is also protected by one European patent, which is being contested.

For the nine months ended September 30, 2015, Copaxone<sup>®</sup> revenues in the United States, which include revenues from both Copaxone<sup>®</sup> 20 mg/mL and Copaxone<sup>®</sup> 40 mg/mL product, amounted to \$2.5 billion (approximately 29% of U.S. revenues) and Copaxone<sup>®</sup> revenues outside the United States amounted to \$583 million (approximately 9% of non-U.S. revenues).

The profit of the multiple sclerosis franchise, which is comprised of Copaxone<sup>®</sup> products and laquinimod (a developmental compound for the treatment of multiple sclerosis), was \$2.4 billion for the nine months ended September 30, 2015, compared to \$2.3 billion for the nine months ended September 30, 2014. The profitability of the multiple sclerosis franchise as a percentage of Copaxone<sup>®</sup> revenues was 77.4% for the nine months ended September 30, 2015 and 75.0% for the nine months ended September 30, 2014.

---

**Table of Contents****OPERATING AND FINANCIAL REVIEW AND PROSPECTS*****Forward-Looking Statements***

The following discussion and analysis contains forward-looking statements, which are based on management's current beliefs and expectations and 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 for our specialty products, especially Copaxone® (including competition from orally-administered alternatives, as well as from generic equivalents such as the recently launched Sandoz product) and our ability to continue to migrate users to our 40 mg/mL version and maintain patients on that version; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions (such as our pending acquisitions of Allergan's generic business and Rimsa); the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters; our ability to achieve expected results from the research and development efforts invested in our pipeline of specialty and other products; our ability to reduce operating expenses to the extent and during the timeframe intended by our cost reduction program; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents, confidentiality agreements and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; adverse effects of political or economic instability, major hostilities or acts of terrorism on our significant worldwide operations; interruptions in our supply chain or problems with internal or third-party information technology systems that adversely affect our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; competition for our specialty pharmaceutical businesses from companies with greater resources and capabilities; the impact of continuing consolidation of our distributors and customers; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability in the U.S., Europe and other markets for sales of generic products prior to a final resolution of outstanding patent litigation; our potential exposure to product liability claims that are not covered by insurance; any failure to recruit or retain key personnel, or to attract additional executive and managerial talent; any failures to comply with complex Medicare and Medicaid reporting and payment obligations; significant impairment charges relating to intangible assets, goodwill and property, plant and equipment; the effects of increased leverage and our resulting reliance on access to the capital markets; potentially significant increases in tax liabilities; the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner; environmental risks; and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2014 and in our other filings with the U.S. Securities and Exchange Commission (the "SEC").

Forward-looking statements speak only as of the date on which they are made and we assume no obligation to update or revise 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, 2014, as updated by our report on Form 6-K filed on July 30, 2015. 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**

### *Overview*

We are a global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic medicines and a focused portfolio of specialty medicines. We operate in pharmaceutical markets worldwide, with major operations in the United States, Europe and other markets. As the world's leading generic medicines company with a strong specialty medicines portfolio, we are strategically positioned to benefit from ongoing changes in the global healthcare environment.

We seek to address unmet patient needs while capitalizing on evolving market, economic and legislative dynamics in global healthcare. These dynamics include the aging population, increased spending on pharmaceuticals in emerging markets, economic pressure on governments and private payors to provide accessible healthcare solutions, legislative and regulatory reforms, an increase in patient awareness and the growing importance of OTC medicines.

## **Table of Contents**

We believe that our dedicated leadership and employees, world-leading generics expertise and portfolio, focused specialty portfolio, OTC joint venture with P&G, API production capability, integrated R&D capabilities and global infrastructure and scale position us to take advantage of opportunities created by these dynamics.

## ***Segments***

We operate our business in two segments:

**Generic medicines**, which include chemical and therapeutic equivalents of originator medicines in a variety of dosage forms, including tablets, capsules, injectables, inhalants, liquids, ointments and creams. We are the leading generic drug company in the United States and Europe, and we have a significant or growing presence in our ROW markets. We are also one of the world's leading manufacturers of Active Pharmaceutical Ingredients ( APIs ).

**Specialty medicines**, which include several franchises, most significantly our core therapeutic areas of central nervous system ( CNS ) medicines such as Copaxone<sup>®</sup>, Azilect<sup>®</sup> and Nuvigil<sup>®</sup> and of respiratory medicines such as ProAir<sup>®</sup> HFA and QVAR<sup>®</sup>. Our specialty medicines segment includes other therapeutic areas, such as oncology, women's health and selected other areas.

In addition to these two segments, we have other activities, primarily PGT Healthcare, our over-the-counter ( OTC ) joint venture with P&G.

## **Highlights**

Significant highlights of the third quarter of 2015 included:

Our revenues amounted to \$4.8 billion, compared to \$5.1 billion in the third quarter of 2014, down 5% , but up 3% in local currency terms.

Our generic medicines segment generated revenues of \$2.2 billion and profit of \$578 million. Revenues decreased 9%, or 1% in local currency terms. Profit increased 4% compared to the third quarter of 2014. The increase in profit was mainly due to lower selling and marketing expenses.

Our specialty medicines segment generated revenues of \$2.2 billion and profit of \$1.2 billion. Revenues were flat, while profit was up 2%, compared to the third quarter of 2014. The increase in profit was mainly due to lower selling and marketing expenses.

Expenses related to impairments, restructuring and others amounted to \$384 million in the third quarter of 2015, compared to \$164 million in the third quarter of 2014.

Operating income amounted to \$1.0 billion, compared to \$1.1 billion in the third quarter of 2014.

Financial expenses amounted to \$697 million, compared to \$84 million in the third quarter of 2014. The increase was mainly due to a \$623 million loss on our Mylan shares.

Net income attributable to Teva was \$103 million in the third quarter of 2015, compared to \$876 million in the third quarter of 2014.

Exchange rate differences between the third quarter of 2015 and the third quarter of 2014 had a negative impact of \$371 million on revenues and a net negative impact of \$56 million on operating income.

Cash flow generated from operating activities during the third quarter of 2015 amounted to \$1.1 billion, compared to \$1.4 billion in the third quarter of 2014.

**Acquisition of Allergan's generics business:**

On July 27, 2015, we announced that we entered into a definitive agreement with Allergan plc to acquire Allergan's worldwide generic pharmaceuticals business. We will pay total consideration of \$40.5 billion, consisting of \$33.75 billion in cash and approximately 100 million Teva shares, which represent \$6.75 billion in value, based on the mutually-agreed price of \$67.30 per share. Closing of the transaction is subject to certain conditions, including relevant regulatory approvals. Subject to satisfaction of the closing conditions, we expect the acquisition to close in the first quarter of 2016. Following consummation of the acquisition, our generics segment is expected to make up a much larger percentage of our revenues.

**Table of Contents**

On September 25, 2015, we entered into a bridge loan credit agreement with various banks, under which the banks agreed to provide up to \$27 billion of loans to finance a portion of the Allergan acquisition. Any loan under the bridge facility would bear an interest rate of LIBOR plus a margin ranging from 0.30 to 1.65%, so long as we maintain an investment-grade credit rating, depending on our specific credit rating and the time elapsed since funding of the bridge loans. In addition, we have entered into commitment letters with various banks, under which the banks committed to provide us with up to \$6.75 billion in loans under a separate bridge loan credit facility to finance a portion of the Allergan acquisition.

**Rimsa acquisition:**

On October 1, 2015, we entered into a definitive agreement to acquire Rimsa, a leading pharmaceutical manufacturing and distribution company in Mexico, along with a portfolio of products and companies, intellectual property, assets and pharmaceutical patents in Latin America and Europe, for an aggregate of \$2.3 billion, in a cash free, debt free set of transactions. This acquisition is expected to add a portfolio of patent-protected drugs to our business in Latin America. The transaction is expected to be funded through a combination of available cash and lines of credit. Subject to satisfaction of the closing conditions, we expect the acquisition to close in the first quarter of 2016.

**Other transactions:**

We acquired stakes in Gecko Health Innovations, Inc., Immuneering Corporation and Microchips Biotech, Inc. for an aggregate of approximately \$102 million and certain contingent payments.

**Results of Operations****Comparison of Three Months Ended September 30, 2015 to Three Months Ended September 30, 2014**

The following table sets forth, for the periods indicated, certain financial data derived from our U.S. GAAP financial statements, presented as percentages of net revenues, and the percentage change for each item as compared to the previous period.

	<b>Percentage of Net Revenues</b>		
	<b>Three Months Ended September 30,</b>		<b>Percentage Change</b>
	<b>2015</b>	<b>2014</b>	<b>2015-2014</b>
	<i>%</i>	<i>%</i>	<i>%</i>
Net revenues	100.0	100.0	(5)
Gross profit	57.5	55.5	(1)
Research and development expenses	7.5	8.1	(12)
Selling and marketing expenses	16.2	18.8	(18)
General and administrative expenses	6.6	5.8	8
Impairments, restructuring and others	8.0	3.2	134
Legal settlements and loss contingencies	(1.7)	(2.4)	(34)
Operating income	20.9	22.0	(9)
Financial expenses - net	14.4	1.7	730
Income before income taxes	6.5	20.3	(70)

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

Income taxes	4.0	3.2	21
Share in losses of associated companies - net	0.1	0.1	(20)
Net gain (loss) attributable to non-controlling interests	0.3	(0.3)	n/a
Net income attributable to Teva	2.1	17.3	(88)

**Table of Contents****Segment Information****Generic Medicines Segment**

The following table presents revenues, expenses and profit for our generic medicines segment for the three months ended September 30, 2015 and 2014:

	<b>Three Months Ended September 30,</b>			
	<b>2015</b>		<b>2014</b>	
	<b>U.S.\$ in millions / % of Segment</b>			
	<b>Revenues</b>			
Revenues	\$ 2,202	100.0%	\$ 2,432	100.0%
Gross profit	1,005	45.6%	1,078	44.3%
R&D expenses	132	6.0%	133	5.5%
S&M expenses	295	13.4%	387	15.9%
Segment profit*	\$ 578	26.2%	\$ 558	22.9%

\* Segment profit is comprised of gross profit for the segment, less R&D and S&M expenses related to the segment. Segment profit does not include G&A expenses, amortization and certain other items. See note 13 to our consolidated financial statements and Operating Income below for additional information. Beginning in 2015, expenses related to equity compensation are excluded from our segment results. The data presented have been conformed to reflect the exclusion of equity compensation expenses for all periods.

***Generic Medicines Revenues***

Our generic medicines segment includes sales of generic medicines as well as API sales to third parties. In the third quarter of 2015, revenues from our generic medicines segment amounted to \$2.2 billion, a decrease of \$230 million, or 9%, compared to the third quarter of 2014. In local currency terms, revenues decreased 1%.

Revenues of generic medicines in the United States, our largest generic market, amounted to \$1.0 billion in the third quarter of 2015, a decrease of 8% compared to the third quarter of 2014. Revenues of generic medicines in Europe amounted to \$661 million, a decrease of 13% compared to the third quarter of 2014. In local currency terms, our European revenues were flat compared to the third quarter of 2014. In our ROW markets, revenues from generic medicines in the third quarter of 2015 amounted to \$509 million, a decrease of 8% compared to the third quarter of 2014. In local currency terms, ROW sales increased 10%.

API sales to third parties in the third quarter of 2015 amounted to \$206 million, an increase of 11%, or 13% in local currency terms, compared to the third quarter of 2014.

The following table presents generic segment revenues by geographic area for the three months ended September 30, 2015 and 2014:



	<b>Three Months Ended September 30,</b>		<b>Percentage Change</b>
	<b>2015</b>	<b>2014</b>	<b>2015 - 2014</b>
	<b>U.S. \$ in millions</b>		
United States	\$ 1,032	\$ 1,124	(8%)
Europe*	661	757	(13%)
Rest of the World	509	551	(8%)
 Total Generic Medicines	 \$ 2,202	 \$ 2,432	 (9%)

\* All members of the European Union, Switzerland, Norway, Albania and the countries of former Yugoslavia.

**Table of Contents****United States Generic Medicines Revenues**

In the third quarter of 2015, we continued to lead the U.S. generic market in total prescriptions and new prescriptions, with approximately 481 million total prescriptions, representing 13.4% of total U.S. generic prescriptions. We seek to continue our U.S. market leadership by introducing new generic equivalents for brand-name products on a timely basis, with a focus on complex generics and other high-barrier products that we believe will create more value for patients and customers, our strong emphasis on customer service, our broad product line, our commitment to quality and regulatory compliance and our cost-effective production.

Revenues from generic medicines in the United States during the third quarter of 2015 amounted to \$1.0 billion, a decrease of 8% compared to the third quarter of 2014. The decrease resulted mainly from a decline in sales of budesonide (the generic equivalent of Pulmicort®), niacin ER (the generic equivalent of Niaspan®), capecitabine (the generic equivalent of Xeloda®) and omega-3-acid ethyl esters (the generic equivalent of Lovaza®) due to price declines resulting from increased competition. These decreases were partially offset by sales of products sold in the third quarter of 2015 that were not sold in the third quarter of 2014, the most significant of which were esomeprazole (the generic equivalent of Nexium®), aspirin/extended-release dipyridamole (the generic equivalent of Aggrenox®) and aripiprazole (the generic equivalent of Abilify®).

Among the most significant generic products we sold in the United States in the third quarter of 2015 were generic versions of Pulmicort® (budesonide inhalation), Nexium® (esomeprazole magnesium DR capsules), Adderall XR® (mixed amphetamine salts ER), Aggrenox® (aspirin/extended-release dipyridamole), Xeloda® (capecitabine) and Abilify® (aripiprazole tablets).

**Launches.** In the third quarter of 2015, we launched generic versions of the following branded products in the United States (listed by month of launch):

<b>Generic Name</b>	<b>Brand Name</b>	<b>Month of Launch</b>	<b>Total Annual U.S. Market at Time of Launch \$ millions (IMS)*</b>
Aspirin/extended-release dipyridamole capsules 25 mg/200 mg	Aggrenox®	July	\$ 436
Almotriptan malate tablets 6.25 & 12.5mg	Axert®	July	\$ 30
Ifosfamide injection 50 mg/mL, 1 gm & 50 mg/mL, 3 gm**		August	\$ 1

\* The figures given are for the twelve months ended in the calendar quarter closest to our launch or re-launch.

\*\* Product was re-launched.

We expect that our generic medicines revenues in the U.S. will continue to benefit from our strong generic pipeline, which, as of October 16, 2015, had 107 product registrations awaiting FDA approval, including 26 tentative approvals. Collectively, these 107 products had U.S. sales in the twelve months ended June 30, 2015 exceeding \$71 billion. Of these applications, 77 were Paragraph IV applications challenging patents of branded products. We believe we are first to file with respect to 35 of these products, the branded versions of which had U.S. sales of more than \$24 billion in the twelve months ended June 30, 2015. 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. The potential advantages of being the first filer with respect to some of these products may be subject to forfeiture, shared exclusivity or competition from so-called authorized generics, which may ultimately affect the value derived.

In the third quarter of 2015, we received tentative approval for a generic equivalent of the products listed below. 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.

<b>Generic Name</b>	<b>Brand Name</b>	<b>Total U.S. Annual Branded Market</b>	<b>\$ millions (IMS)*</b>
Fluvastatin ER tablets 80 mg	Lescol <sup>®</sup> XL	\$	38
Erlotinib tablets 25 mg	Tarceva <sup>®</sup>	\$	54
Sitagliptin & Metformin ER tablets 50/500, 50/1000 & 100/1000 mg	Janumet <sup>®</sup> XR	\$	373

\* For the twelve months ended June 30, 2015.

**Table of Contents**

***Europe Generic Medicines Revenues***

Teva defines its European region as the 28 countries in the European Union, Norway, Switzerland, Albania and the countries of the former Yugoslavia. It is a diverse region that has a population of over 500 million people.

Revenues from generic medicines in Europe in the third quarter of 2015 amounted to \$661 million, a decrease of 13% compared to the third quarter of 2014. In local currency terms, revenues were flat compared to the third quarter of 2014, mainly as a result of our continued focus on sustainable and profitable business, with increases in Spain, Italy and Germany, offset by significant decreases in France, Switzerland and the United Kingdom.

As in previous years, European regulatory measures aimed at reducing healthcare and drug expenditures have led to slower growth in the generic medicines market, and have adversely affected our revenues in some markets. In Germany, Italy, France, Spain and Poland, governmental measures (such as tenders and price-referencing) have reduced prices. We have adjusted our strategy to address these changes, shifting from a market share-driven approach to a model emphasizing profitable and sustainable growth. The selective approach to our portfolio, as well as our strong focus on cost reduction, have contributed to significantly improved profit in the region.

Since the beginning of the year, Teva received 740 generic approvals in Europe relating to 80 compounds in 183 formulations, including one European Medicines Agency ( EMA ) approval valid in all EU member states. In addition, Teva had 1,780 marketing authorization applications pending approval in 31 European countries, relating to 157 compounds in 319 formulations.

Listed below are generic revenues highlights for the third quarter of 2015 in our most significant European operations in terms of size:

**Germany:** Generic revenues in the third quarter of 2015 decreased 12%, but increased 4% in local currency terms, compared to the third quarter of 2014. The increase in local currency terms was primarily due to new product launches in the first quarter of 2015. We maintained our position as one of Germany's leading suppliers of medicines and maintained our position as the second largest generic pharmaceutical company.

**United Kingdom:** Generic revenues in the third quarter of 2015 decreased 11%, or 4% in local currency terms, compared to the third quarter of 2014. The decrease in local currency terms was mainly due to reduced prices. We maintained our position as one of the largest generic pharmaceutical companies in the U.K.

**Italy:** Generic revenues in the third quarter of 2015 decreased 10%, but increased 6% in local currency terms, compared to the third quarter of 2014. The increase in local currency terms was due to improved commercial performance, improved supply chain management and new product launches.

**France:** Generic revenues in the third quarter of 2015 decreased 38%, or 26% in local currency terms, compared to the third quarter of 2014, due primarily to increasing competition and our continued focus on profitable business.

**Switzerland:** Generic revenues in the third quarter of 2015 decreased 9%, or 5% in local currency terms, compared to the third quarter of 2014, mainly due to a decrease in API sales.

**Spain:** Generic revenues in the third quarter of 2015 decreased 5%, but increased 12% in local currency terms, compared to the third quarter of 2014. The increase was mainly due to improved product mix following successful commercial activities.

***ROW Generic Medicines Revenues***

Our ROW markets include all countries other than the United States and those in our European region. Our key ROW markets are Japan, Canada and Russia. The countries in this category range from highly regulated, pure generic markets such as Canada, to hybrid markets such as Japan and Brazil, to branded generics markets such as Russia, certain Commonwealth of Independent States markets and Latin American markets.

In our ROW markets, generic revenues in the third quarter of 2015 amounted to \$509 million, a decrease of 8% compared to the third quarter of 2014. In local currency terms, revenues increased 10% mainly due to higher revenues in Latin America and Russia, which were partially offset by lower revenues in Canada and Japan.

## Table of Contents

Listed below are generic revenues highlights for the third quarter of 2015 in our main ROW markets:

**Japan:** Our generic medicines revenues in the third quarter of 2015 decreased 17%, or 4% in local currency terms, compared to the third quarter of 2014. The decrease in local currency terms is mainly due to a reduction in revenues from the contract manufacturing business as well as lower API sales. The Japanese generics market as a whole is expected to continue to grow, bolstered by government incentives to increase generic penetration.

**Russia:** Our generic medicines revenues in the third quarter of 2015 decreased 25%, but increased 31% in local currency terms, compared to the third quarter of 2014. The increase in local currency terms was mainly due to inflation related price increases. We maintained our leading position in the Russian generic pharmaceutical market.

**Canada:** Our generic medicines revenues in the third quarter of 2015 decreased 24%, or 9% in local currency terms, compared to the third quarter of 2014. The decrease was mainly due to volume and price decreases. We maintained our position as one of the two leading generic pharmaceutical companies in Canada.

### ***Generic Medicines Gross Profit***

In the third quarter of 2015, gross profit from our generic medicines segment amounted to \$1.0 billion, a decrease of \$73 million, or 7%, compared to the third quarter of 2014. The lower gross profit was mainly a result of lower sales of budesonide (the generic equivalent of Pulmicort®) and niacin ER (the generic equivalent of Niaspan®) in the United States, which are both high gross profit products. In addition, exchange rate movements in our ROW and European markets further decreased gross profit. This decrease was partially offset by higher gross profit of our API business. In local currency terms, gross profit increased 1%.

Gross profit margin for our generic medicines segment in the third quarter of 2015 increased to 45.6%, from 44.3% in the third quarter of 2014. This increase of 1.3 points in gross margin was mainly a result of higher profitability of our business in Europe (1.9 points) and higher profitability of our ROW markets (0.3 points), partially offset by lower profitability of our U.S. business (0.8 points) as well as lower profitability of our API business (0.2 points).

### ***Generic Medicines R&D Expenses***

Research and development expenses relating to our generic medicines for the third quarter of 2015 amounted to \$132 million, compared to \$133 million in the third quarter of 2014. In local currency terms, expenses increased 3%, mainly due to increased development activities for the U.S. market. As a percentage of segment revenues, R&D expenses were 6.0% in the third quarter of 2015, compared to 5.5% in the third quarter of 2014.

Our R&D activities for the generic medicines segment include both (a) direct expenses relating to product formulation, analytical method development, stability testing, management of bioequivalence and other clinical studies, regulatory filings and other expenses relating to patent review and challenges prior to obtaining tentative approval, and (b) indirect expenses such as costs of internal administration, infrastructure and personnel involved in generic R&D.

***Generic Medicines S&M Expenses***

Selling and marketing expenses related to our generic medicines in the third quarter of 2015 amounted to \$295 million, a decrease of 24% compared to \$387 million in the third quarter of 2014. In local currency terms, S&M expenses decreased 13%, mainly due to reduced royalties related to our sales of budesonide (the generic equivalent of Pulmicort®) in the United States.

As a percentage of segment revenues, selling and marketing expenses decreased to 13.4% in the third quarter of 2015 compared to 15.9% in the third quarter of 2014.

***Generic Medicines Profit***

The profit of our generic medicines segment is comprised of the gross profit for the segment less selling and marketing expenses and research and development expenses related to this segment. Segment profit does not include general and administrative expenses, amortization and certain other items. See note 13 to our consolidated financial statements and **Operating Income** below for additional information.

**Table of Contents**

Profit of our generic medicines segment amounted to \$578 million in the third quarter of 2015, compared to \$558 million in the third quarter of 2014. The increase was mainly due to factors previously discussed, primarily lower selling and marketing expenses, partially offset by lower gross profit.

Generic medicines profit as a percentage of generic medicines revenues was 26.2% in the third quarter of 2015, up from 22.9% in the third quarter of 2014. This increase of 3.3 points was due to lower S&M expenses as a percentage of revenues (2.5 points) and higher gross margin (1.3 points), partially offset by higher R&D expenses as a percentage of revenues (0.5 points).

**Specialty Medicines Segment**

Our specialty medicines business includes our core therapeutic areas of CNS (with a strong emphasis on MS, neurodegenerative disorders and pain care) and respiratory medicines (with a focus on asthma and chronic obstructive pulmonary disease). We also have specialty medicines in oncology, women's health and selected other areas. Our specialty medicines segment also includes our New Therapeutic Entity ( NTE ) development program.

The following table presents revenues, expenses and profit for our specialty medicines segment for the three months ended September 30, 2015 and 2014:

	<b>Three Months Ended September 30,</b>			
	<b>2015</b>		<b>2014</b>	
	<b>U.S.\$ in millions / % of Segment</b>			
	<b>Revenues</b>			
Revenues	\$ 2,178	100.0%	\$ 2,176	100.0%
Gross profit	1,859	85.4%	1,890	86.9%
R&D expenses	220	10.1%	221	10.2%
S&M expenses	417	19.1%	470	21.6%
Segment profit*	\$ 1,222	56.1%	\$ 1,199	55.1%

\* Segment profit is comprised of gross profit for the segment, less R&D and S&M expenses related to the segment. Segment profit does not include G&A expenses, amortization and certain other items. See note 13 to our consolidated financial statements and Operating Income below for additional information.

Beginning in 2015, expenses related to equity compensation are excluded from our segment results. The data presented have been conformed to reflect the exclusion of equity compensation expenses for all periods.

**Specialty Medicines Revenues**

Specialty medicines revenues in the third quarter of 2015 amounted to \$2.2 billion, flat compared to the third quarter of 2014. In local currency terms, revenues increased 5%. In the United States, our specialty medicines revenues amounted to \$1.7 billion, an increase of 11% from the third quarter of 2014. Specialty medicines revenues in Europe amounted to \$369 million, a decrease of 21% from the third quarter of 2014. In local currency terms, specialty medicines revenues in Europe decreased 7%. ROW revenues were \$108 million, a decrease of 39%, or 18% in local currency terms, compared to the third quarter of 2014.





**Table of Contents****Specialty Medicines Revenues Breakdown**

The following table presents revenues by therapeutic area and key products for our specialty medicines segment for the three months ended September 30, 2015 and 2014:

	<b>Three Months Ended</b>		<b>Percentage Change 2015 - 2014</b>
	<b>September 30, 2015</b>	<b>2014</b>	
	<b>U.S. \$ in millions</b>		
CNS	\$ 1,366	\$ 1,440	(5%)
Copaxone®	1,085	1,107	(2%)
Azilect®	92	103	(11%)
Nuvigil®	97	94	3%
Respiratory	285	218	31%
ProAir®	149	111	34%
QVAR®	92	64	44%
Oncology	326	299	9%
Treanda®	207	180	15%
Women s Health	115	137	(16%)
Other Specialty	86	82	5%
<b>Total Specialty Medicines</b>	<b>\$ 2,178</b>	<b>\$ 2,176</b>	<b>*</b>

\* Less than 0.5%.

**Central Nervous System**

Our CNS specialty product line includes Copaxone®, Azilect®, Nuvigil® and several other medicines. In the third quarter of 2015, our CNS sales amounted to \$1.4 billion, a decrease of 5% compared to the third quarter of 2014, due to lower sales of Copaxone® in Europe and ROW and Azilect® in Europe.

**Copaxone®.** In the third quarter of 2015, Copaxone® (glatiramer acetate injection 20 mg/mL and 40 mg/mL), our leading specialty medicine, continued to be the leading multiple sclerosis therapy in the United States and globally. Our sales of Copaxone® amounted to \$1.1 billion, a decrease of 2% compared to the third quarter of 2014.

Copaxone® revenues in the United States in the third quarter of 2015 were \$878 million, an increase of 10% compared to the third quarter of 2014. The increase was mainly due to higher sales volume in the third quarter of 2015, partially offset by net pricing declines. The Copaxone® family s U.S. market shares in terms of new and total prescriptions were 27.1% and 29.3%, respectively, according to September 2015 IMS data.

At the end of September 2015, Copaxone® 40 mg/mL three times a week in the United States accounted for approximately 76% of total Copaxone® prescriptions. This was driven by patient and physician choice of the 40 mg/mL version, supported by payor access and patient support activities.

In June 2015, Sandoz launched its generic version of Copaxone® 20 mg/mL, Glatopa™, in the United States.

Copaxone<sup>®</sup> revenues in the United States accounted for 81% of global Copaxone<sup>®</sup> revenues in the third quarter of 2015, compared to 72% in the third quarter of 2014.

Our Copaxone<sup>®</sup> revenues outside the United States were \$207 million in the third quarter of 2015, a decrease of 33%, or 15% in local currency terms, compared to the third quarter of 2014. The decrease in local currency terms is mainly due to increased competition in our European markets resulting in lower volumes and lower tender volumes in Russia.

## **Table of Contents**

Copaxone<sup>®</sup> was responsible for approximately 22% of our revenues in the third quarter of 2015, and contributed a significantly higher percentage to our profits and cash flow from operations during such period.

Our U.S. Orange Book patents covering Copaxone<sup>®</sup> 20 mg/mL expired in May 2014. Following remand from the United States Supreme Court, the United States Court of Appeals for the Federal Circuit decided that our non-Orange Book patent that covers a process for the production of glatiramer acetate that was meant to expire in September 2015 is invalid. We did not pursue any further appeals of that decision. Our patents on Copaxone<sup>®</sup> 20 mg/mL expired in May 2015 in most of the rest of the world. In 2013, we entered into an agreement with Takeda to market this product in Japan in December 2014. Copaxone<sup>®</sup> 20 mg/mL was approved in September 2015 for marketing in Japan.

In January 2014, we launched Copaxone<sup>®</sup> 40 mg/mL, a higher dose of Copaxone<sup>®</sup> with a three times a week dosing regimen for patients with relapsing-remitting multiple sclerosis, in the United States. This formulation allows for a less frequent dosing regimen administered subcutaneously for patients with relapsing forms of MS. In December 2014, we received European Medicines Agency (EMA) approval in a decentralized procedure for Copaxone<sup>®</sup> 40 mg/mL in Europe. We continued to launch Copaxone<sup>®</sup> 40 mg/mL in certain European countries during the third quarter of 2015 and expect to launch Copaxone<sup>®</sup> 40 mg/mL in additional European countries during the remainder of 2015.

We received regulatory approval for Copaxone<sup>®</sup> 40 mg/mL in Russia in October 2015 and expect to launch by the end of 2015. We expect to receive marketing approvals in other ROW markets during the remainder of 2015.

Copaxone<sup>®</sup> 40 mg/mL is protected by three U.S. Orange Book patents that expire in 2030, which are being challenged in paragraph IV litigation and in patent office proceedings in the United States and a fourth U.S. Orange Book patent expiring in 2030 that was issued in October 2015. It is also protected by one European patent, which is being contested.

**Azilect<sup>®</sup>** (rasagiline tablets) is indicated as an initial monotherapy and as an adjunct to levodopa for the treatment of the signs and symptoms of Parkinson's disease, the second most common neurodegenerative disorder. We market Azilect<sup>®</sup> jointly with Lundbeck in certain key European countries. We exclusively market Azilect<sup>®</sup> in the United States, Germany and certain other markets, while Lundbeck exclusively markets Azilect<sup>®</sup> in the remaining European countries and certain other international markets. By the end of 2015, the initial period of our agreement with Lundbeck ends for all European markets and all marketing rights will revert to us. In 2014, we signed an agreement with Takeda to market this product in Japan.

Global in-market sales in the third quarter of 2015, which represent sales by Teva and Lundbeck to third parties, amounted to \$129 million, flat compared to the third quarter of 2014. Our sales of Azilect<sup>®</sup> in the third quarter of 2015 amounted to \$92 million, a decrease of 11% compared to the third quarter of 2014. In local currency terms, our sales decreased 5%.

**Nuvigil<sup>®</sup>** (armodafinil), the R-isomer of modafinil, is indicated for the treatment of excessive sleepiness associated with narcolepsy and certain other disorders. Global sales of Nuvigil<sup>®</sup> in the third quarter of 2015 amounted to \$97 million, compared to \$94 million in the third quarter of 2014.

In September 2015, we launched **Zecuity<sup>®</sup>** in the United States. Zecuity<sup>®</sup>, designed to provide relief from migraine, is a single-use, disposable patch system that delivers sumatriptan through the skin.

## ***Respiratory***

Our respiratory portfolio includes ProAir<sup>®</sup>, QVAR<sup>®</sup>, DuoResp Spiromax<sup>®</sup> and Qnasl<sup>®</sup>. Revenues from our specialty respiratory products in the third quarter of 2015 amounted to \$285 million, an increase of 31% compared to the third quarter of 2014.

**ProAir<sup>®</sup>** hydrofluoroalkane ( HFA ) inhalation aerosol with dose counter (albuterol sulfate), which we sell only in the United States, is indicated for patients four years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm. ProAir<sup>®</sup> revenues in the third quarter of 2015 amounted to \$149 million, an increase of 34% compared to the third quarter of 2014, mainly due to positive price effects. ProAir<sup>®</sup> maintained its leadership in the short-acting beta-agonist market, with a market share of 55.8% in terms of total number of prescriptions during the third quarter of 2015, an increase of 0.3 points compared to the third quarter of 2014.

**Table of Contents**

In May 2015, we launched ProAir<sup>®</sup> RespiClick (albuterol sulfate) inhalation powder, a breath-actuated, multi-dose, dry-powder, short-acting beta-agonist inhaler for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 12 years of age and older.

**QVAR<sup>®</sup>** (beclomethasone dipropionate HFA) is indicated as a maintenance treatment for asthma as a prophylactic therapy in patients five years of age or older. QVAR<sup>®</sup> is also indicated for asthma patients who require systemic corticosteroid administration, where adding QVAR<sup>®</sup> may reduce or eliminate the need for systemic corticosteroids. QVAR<sup>®</sup> global revenues in the third quarter of 2015 amounted to \$92 million, an increase of 44% compared to the third quarter of 2014, mainly due to positive price effects. QVAR<sup>®</sup> maintained its second-place position in the inhaled corticosteroids category in the United States, with a market share of 37.7% in terms of total number of prescriptions during the third quarter of 2015, an increase of 2.5 points compared to the third quarter of 2014.

***Oncology***

Our oncology portfolio includes Treanda<sup>®</sup>, Trisenox<sup>®</sup>, Granix<sup>®</sup> and Synribo<sup>®</sup> in the United States and Lonquex<sup>®</sup>, Tevagrastim<sup>®</sup>/Ratiograstim<sup>®</sup>, Myocet<sup>®</sup>, Trisenox<sup>®</sup> and Eporatio<sup>®</sup> outside the United States. Sales of our oncology products amounted to \$326 million in the third quarter of 2015, compared to \$299 million in the third quarter of 2014. The increase resulted primarily from higher sales of Treanda<sup>®</sup> and our G-CSF products, Lonquex<sup>®</sup> and Granix<sup>®</sup>, partially offset by lower sales of certain other products.

**Treanda<sup>®</sup>** (bendamustine hydrochloride for injection) is approved in the United States for the treatment of patients with chronic lymphocytic leukemia and patients with indolent B-cell non-Hodgkin's lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Sales of Treanda<sup>®</sup> in the third quarter of 2015 amounted to \$207 million, compared to \$180 million in the third quarter of 2014, an increase of 15%, which was mainly due to supply chain management. In April 2015, Eagle's NDA for a liquid bendamustine hydrochloride rapid infusion product, for which Teva has an exclusive license, was accepted for filing by the FDA. This product candidate has received Orphan Drug Designations for both chronic lymphocytic leukemia and indolent B-cell non-Hodgkin's lymphoma, and therefore may be eligible for seven years of exclusivity upon approval.

***Women's Health***

Our women's health portfolio includes ParaGard<sup>®</sup>, Plan B One-Step<sup>®</sup> OTC/Rx (levonorgestrel), Quartette<sup>®</sup> and Zoely<sup>®</sup>, along with a number of other local products that are marketed in the United States, Europe and ROW. Revenues from our global women's health products amounted to \$115 million in the third quarter of 2015, a decrease of 16% compared to the third quarter of 2014. In local currency terms, the decrease was 11%, mainly due to a decrease in Europe.

***Specialty Medicines Gross Profit***

In the third quarter of 2015, gross profit from our specialty medicines segment amounted to \$1.9 billion, a decrease of \$31 million compared to the third quarter of 2014.

Gross profit margin for our specialty medicines segment in the third quarter of 2015 was 85.4%, compared to 86.9% in the third quarter of 2014.

***Specialty Medicines R&D Expenses***

Our specialty R&D activities focus primarily on product candidates in the CNS and respiratory therapeutic areas, with additional activities in specific areas. Research and development expenses relating to our specialty medicines segment, including NTEs, in the third quarter of 2015 amounted to \$220 million, compared to \$221 million in the third quarter of 2014. In local currency terms, R&D expenses increased 1%, mainly due to development costs related to assets acquired through the Auspex and Labrys transactions. As a percentage of segment revenues, R&D spending was 10.1% in the third quarter of 2015, compared to 10.2% in the third quarter of 2014.

Our specialty R&D spending takes place throughout the development process, including (a) early-stage projects in both discovery and preclinical phases; (b) middle-stage projects in clinical programs up to phase 3; (c) late-stage projects in phase 3 programs, including where an NDA is currently pending approval; and (d) life cycle management and other studies for marketed products. Furthermore, our NTE R&D activities are managed and reported as part of our specialty R&D expenses.

## **Table of Contents**

### ***Specialty Medicines S&M Expenses***

Selling and marketing expenses related to our specialty medicines segment in the third quarter of 2015 amounted to \$417 million, a decrease of 11% compared to \$470 million in the third quarter of 2014. In local currency terms, S&M expenses decreased 6%, mainly due to a decline in S&M expenses in the United States and Europe.

As a percentage of segment revenues, selling and marketing expenses decreased to 19.1% in the third quarter of 2015 from 21.6% in the third quarter of 2014.

### ***Specialty Medicines Profit***

The profit of our specialty medicines segment equals gross profit for the segment, less selling and marketing expenses and research and development expenses related to this segment. Segment profit does not include general and administrative expenses, amortization and certain other items. See note 13 to our consolidated financial statements and Operating Income below for additional information.

Profit of our specialty medicines segment amounted to \$1.2 billion in the third quarter of 2015, an increase of 2% compared to the third quarter of 2014. This is a result of the factors discussed above, mainly lower S&M expenses, largely offset by lower gross profit.

Specialty medicines profit as a percentage of segment revenues was 56.1% in the third quarter of 2015, up 1.0 point from 55.1% in the third quarter of 2014. The increase was mainly attributable to lower S&M expenses as a percentage of specialty medicines revenues (2.5 points), partially offset by lower gross profit as a percentage of specialty medicines revenues (1.5 points).

Our multiple sclerosis franchise includes our Copaxone<sup>®</sup> products and laquinimod (a developmental compound for the treatment of MS). The profit of our multiple sclerosis franchise is comprised of Copaxone<sup>®</sup> revenues net of cost of goods sold and S&M and R&D expenses related to our MS franchise. It does not include G&A expenses, amortization and certain other items. Our MS franchise profit in the third quarter of 2015 amounted to \$876 million, compared to \$864 million in the third quarter of 2014. Profit of our multiple sclerosis franchise as a percentage of Copaxone<sup>®</sup> revenues was 80.7% in the third quarter of 2015, compared to 78.0% in the third quarter of 2014.

### **Other Activities**

In addition to our generic and specialty medicines segments, we have other activities, primarily PGT Healthcare, our OTC joint venture with P&G, distribution services, primarily in Israel and Hungary, and sales of medical devices.

### ***OTC***

Our revenues related to PGT in the third quarter of 2015 amounted to \$255 million, an increase of 13% compared to \$225 million in the third quarter of 2014. In local currency terms, revenues increased 37%, mainly due to higher sales in Latin America.

PGT's in-market sales in the third quarter of 2015 amounted to \$381 million, an increase of \$9 million compared to the third quarter of 2014. The increase was mainly due to volume and price increases in most regions, partially offset by foreign currency exchange fluctuations. PGT's in-market sales consist of sales of the combined OTC portfolios of Teva and P&G outside North America.



***Others***

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

Revenues in the third quarter of 2015 amounted to \$188 million, a decrease of 16%, compared to the third quarter of 2014, or 9% in local currency terms. The decrease in local currency terms was mainly due to the discontinuation of the distribution agreement with Sanofi in Israel.

**Teva Consolidated Results**

**Revenues**

Revenues in the third quarter of 2015 amounted to \$4.8 billion, a decrease of 5% compared to the third quarter of 2014, primarily due to lower revenues of our generic medicines. Specialty revenues were flat compared to the third quarter of 2014. See Generic Medicines Revenues, Specialty Medicines Revenues, and Other Activities above. During the third quarter of 2015, exchange rate movements, including the impact of certain hedging transactions, negatively impacted overall revenues by \$371 million, compared to the third quarter of 2014. In local currency terms, revenues increased 3%.

## **Table of Contents**

### **Gross Profit**

In the third quarter of 2015, gross profit amounted to \$2.8 billion, a decrease of 1% compared to the third quarter of 2014.

The lower gross profit was mainly the result of the lower gross profit of our generic medicines segment and our specialty medicines segment, partially offset by lower amortization of purchased intangible assets. See [Generic Medicines Gross Profit](#) and [Specialty Medicines Gross Profit](#) above and the reconciliation of our segment profit to our consolidated operating income under [Operating Income](#) below.

Gross profit as a percentage of revenues was 57.5% in the third quarter of 2015, compared to 55.5% in the third quarter of 2014. The increase in gross profit as a percentage of revenues primarily reflects the higher profitability of our generic medicines segment (up 1.2 points) and the lower amortization of purchased intangible assets, costs related to regulatory actions taken in facilities and accelerated depreciation (up 1.0 point) as well as the lower revenues of other activities, mainly distribution (up 0.5 point), partially offset by lower profitability of our specialty medicines segment (down 0.6 points) as well as lower profitability of OTC products (down 0.1 points).

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

Net R&D expenses for the third quarter of 2015 amounted to \$361 million, a decrease of 12% compared to the third quarter of 2014. The decrease mainly resulted from higher R&D expenses in the third quarter of 2014 due to an impairment expense related to the cancellation of the balugrastim R&D project. See also [Generic Medicines R&D Expenses](#) and [Specialty Medicines R&D Expenses](#) above.

As a percentage of revenues, R&D spending was 7.5% in the third quarter of 2015, compared to 8.1% in the third quarter of 2014.

R&D expenditures include upfront and milestone payments for products in the development phase, the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, clinical trials, product registration costs and other costs, and are reported net of contributions received from collaboration partners.

### **Selling and Marketing (S&M) Expenses**

S&M expenses in the third quarter of 2015 amounted to \$780 million, a decrease of 18% compared to the third quarter of 2014. The decrease was mainly due to lower S&M expenses related to our generic and specialty medicines segments. See [Generic Medicines S&M Expenses](#) and [Specialty Medicines S&M Expenses](#) above.

As a percentage of revenues, S&M expenses were 16.2% in the third quarter of 2015, compared to 18.8% in the third quarter of 2014.

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

G&A expenses in the third quarter of 2015 amounted to \$316 million, compared to \$293 million in the third quarter of 2014. As a percentage of revenues, G&A expenses were 6.6% in the third quarter of 2015, compared to 5.8% in the third quarter of 2014. The increase was mainly due to higher expenses related to our joint venture with P&G and higher legal costs, which were partially offset by income from divestiture of certain products in the third quarter of 2015.

### **Legal Settlements and Loss Contingencies**

In the third quarter of 2015, we recorded income of \$80 million for legal settlements and loss contingencies, compared to income of \$122 million in the third quarter of 2014. Income in the third quarter of 2015 was mainly related to insurance proceeds relating to the settlement of the pantoprazole patent litigation.

### **Impairments, Restructuring and Others**

In the third quarter of 2015, we recorded expenses of \$384 million for impairments, restructuring and others, compared to \$164 million in the third quarter of 2014. These expenses were mainly due to a \$133 million impairment of Synribo<sup>®</sup> following a decrease in sales projections, contingent consideration expenses of \$64 million following the positive phase 2b results of TEV-48125 in both chronic and episodic migraine prevention and acquisition expenses of \$61 million.

**Table of Contents**

The carrying value of our in-process R&D asset Revascor® (mesenchymal precursor cells) was \$258 million as of September 30, 2015. This drug candidate is in a phase 3 trial for congestive heart failure. The interim trial results, which are expected in the first half of 2016, may lead us to reevaluate the fair value of the asset, which may lead to an impairment charge. Such a loss may also lead us to reassess the current carrying value of our equity interest in Mesoblast Ltd., which is \$238 million, as of September 30, 2015.

**Operating Income**

Operating income was \$1.0 billion in the third quarter of 2015, compared to \$1.1 billion in the third quarter of 2014. As a percentage of revenues, operating income was 20.9% in the third quarter of 2015 compared to 22.0% in the third quarter of 2014.

The decrease in operating income was due to factors previously discussed, primarily higher impairments, restructuring and others, lower income from legal settlements and loss contingencies and higher G&A expenses, partially offset by lower other unallocated amounts, lower amortization, higher profit of our specialty medicines segment, higher profit of our generic medicines segment as well as higher profit of other activities.

The decrease in operating income as a percentage of revenues (1.0 points) was due to higher impairments, restructuring and others (4.7 points), higher general and administrative expenses (0.8 points) and lower income from legal settlements and loss contingencies (0.8 points), partially offset by lower other unallocated amounts (1.8 points), higher profit of our specialty medicines segment (1.6 points), higher profit of our generic medicines segment (1.0 point) and lower amortization expenses (0.6 points) as well as lower profit of other activities (0.3 points).

The following table presents a reconciliation of our segment profit to our consolidated operating income for the three months ended September 30, 2015 and 2014:

	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>U.S.\$ in millions</b>	
Generic medicines profit	\$ 578	\$ 558
Specialty medicines profit	1,222	1,199
<b>Total segment profit</b>	<b>1,800</b>	<b>1,757</b>
Profit of other activities	58	48
<b>Total profit</b>	<b>1,858</b>	<b>1,805</b>
Amounts not allocated to segments:		
Amortization	203	242
General and administrative expenses	316	293
Legal settlements and loss contingencies	(80)	(122)
Impairments, restructuring and others	384	164
Other unallocated amounts	25	116
<b>Consolidated operating income</b>	<b>1,010</b>	<b>1,112</b>

Financial expenses net	697	84
Consolidated income before income taxes	\$ 313	\$ 1,028

Beginning in 2015, expenses related to equity compensation are excluded from our segment results. The data presented have been conformed to reflect the exclusion of equity compensation expenses for all periods.

### **Financial Expenses-Net**

In the third quarter of 2015, financial expenses amounted to \$697 million, compared to \$84 million in the third quarter of 2014. The increase was mainly due to a \$623 million loss on our Mylan shares, partially offset by lower interest expenses due to lower cost of debt.

## **Table of Contents**

We operate in certain territories that have more than one official exchange rate, which deviate significantly among themselves as well as from unofficial market rates, and remittance of cash outside the country is limited. We currently prepare our financial statements using the official preferential industry exchange rate. As a result, we are exposed to a potential devaluation loss on our total monetary net assets in these territories, which, as of September 30, 2015, amounted to approximately \$398 million.

## **Tax Rate**

In the third quarter of 2015, the provision for taxes amounted to \$193 million, or 62%, on pre-tax income of \$313 million. In the third quarter of 2014, the provision for taxes amounted to \$160 million, or 16%, on pre-tax income of \$1.0 billion.

We expect our annual tax rate for 2015 to be higher than the tax rate for 2014, mainly due to our product mix in the different geographies and the effect of the loss on our Mylan shares.

The statutory Israeli corporate tax rate is 26.5% in 2015. However, our effective consolidated tax rates have historically been, and continue to be this year, considerably lower than the statutory rate because of tax incentives we benefit from in Israel and other countries.

## **Net Income**

Net income attributable to Teva in the third quarter of 2015 was \$103 million, compared to \$876 million in the third quarter of 2014. This decrease was due to the factors previously discussed, primarily our higher financial expenses and lower operating income.

## **Diluted Shares Outstanding and Earnings Per Share**

The average weighted diluted shares outstanding used for the fully diluted share calculation for the third quarter of 2015 and 2014 were 862 million and 861 million shares, respectively. The increase in the number of the average weighted diluted shares outstanding was mainly due to the issuance of shares for employee stock option exercises and vesting of RSUs, in addition to higher amounts of dilutive options, RSUs and convertible senior debentures following an increase in the share price. The increase was partially offset by the impact of the shares repurchased pursuant to our share repurchase program during the fourth quarter of 2014 and the first quarter of 2015.

As of September 30, 2015 and 2014, the share count for calculating Teva's market capitalization was approximately 852 million and 855 million, respectively.

Diluted earnings per share amounted to \$0.12 in the third quarter of 2015, compared to \$1.02 in the third quarter of 2014.

## **Impact of Currency Fluctuations on Results of Operations**

Because our results are reported in U.S. dollars, changes in the rate of exchange between the U.S. dollar and the local currencies in the markets in which we operate (primarily the euro, Israeli shekel, Russian ruble, Canadian dollar, British pound and Japanese yen) impact our results. In the third quarter of 2015, compared to the third quarter of 2014, the main currencies relevant to our operations decreased in value against the U.S. dollar: the euro by 16%, the Russian ruble by 43%, the Israeli shekel by 9%, the Canadian dollar by 17%, the British pound by 7% and the Japanese yen by 15% (all compared on a quarterly average basis). Latin American currencies had an overall negative change of 9%

compared to last year.

As a result, exchange rate movements during the third quarter of 2015 in comparison with the third quarter of 2014 negatively impacted overall revenues by \$371 million and negatively impacted our operating income by \$56 million, both of which are net of profits from certain hedging transactions.

**Table of Contents****Comparison of Nine Months Ended September 30, 2015 to Nine Months Ended September 30, 2014****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, 2015 and 2014. Additional factors affecting the nine months month 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, 2014:

	Percentage of Net Revenues Nine Months Ended September 30,		Percentage Change 2015 from 2014
	2015 %	2014 %	2014 %
Net revenues	100.0	100.0	(2)
Gross profit	57.6	54.1	4
Research and development expenses	7.3	7.3	(3)
Selling and marketing expenses	17.3	18.9	(10)
General and administrative expenses	6.4	6.0	6
Impairments, restructuring and others	6.6	2.4	166
Legal settlements and loss contingencies	3.6	(0.4)	n/a
Operating income	16.4	19.9	(20)
Financial expenses net	6.3	1.6	283
Income before income taxes	10.1	18.3	(46)
Income taxes	2.6	2.7	(5)
Share in losses of associated companies net	*	0.1	(46)
Net gain (loss) attributable to non-controlling interests	0.1	(0.2)	n/a
Net income attributable to Teva	7.4	15.7	(54)

\* Represents an amount less than 0.05%.

**Segment Information****Generic Medicines Segment**

The following table presents revenues and profit of our generic medicines segment for the nine months ended September 30, 2015 and 2014:

**Generics**  
**Nine months ended September 30,**



	<b>2015</b>		<b>2014</b>	
	<b>U.S.\$ in millions / % of Segment</b>			
	<b>Revenues</b>			
Revenues	\$ 7,289	100.0%	\$ 7,345	100.0%
Gross profit	3,487	47.8%	3,170	43.2%
R&D expenses	377	5.2%	381	5.2%
S&M expenses	1,004	13.8%	1,192	16.2%
Segment profit*	\$ 2,106	28.9%	\$ 1,597	21.7%

\* Segment profit consists of gross profit, less S&M and R&D expenses related to the segment. Segment profit does not include G&A expenses, amortization and certain other items. See note 13 to our consolidated financial statements and Operating Income below for additional information.

Beginning in 2015, expenses related to equity compensation are excluded from our segment results. The data presented have been conformed to reflect the exclusion of equity compensation expenses for all periods.

**Table of Contents*****Generic Medicine Revenues***

Our generic medicines segment includes sales of generic medicines as well as API sales to third parties. In the first nine months of 2015, revenues from our generic medicines segment amounted to \$7.3 billion, a decrease of \$56 million, or 1%, compared to the first nine months of 2014. In local currency terms, revenues increased 7%.

API sales to third parties in the first nine months of 2015 amounted to \$546 million, flat compared to the first nine months of 2014. In local currency terms, sales increased 2%.

The following table presents generic segment revenues by geographic area for the nine months ended September 30, 2015 and 2014:

	<b>Nine Months Ended September 30, 2015      2014</b>		<b>Percentage Change 2015 - 2014</b>
	<b>U.S. \$ in millions</b>		
United States	\$ 3,797	\$ 3,240	17%
Europe*	2,006	2,389	(16%)
Rest of the World	1,486	1,716	(13%)
<b>Total Generic Medicines</b>	<b>\$ 7,289</b>	<b>\$ 7,345</b>	<b>(1%)</b>

\* All members of the European Union, Switzerland, Norway, Albania and the countries of former Yugoslavia.

***United States Generic Medicines Revenues***

Revenues from generic medicines in the United States in the first nine months of 2015 amounted to \$3.8 billion, an increase of 17% compared to \$3.2 billion in the first nine months of 2014.

Among the most significant generic products we sold in the United States in the first nine months of 2015 were generic versions of Nexium® (esomeprazole), Pulmicort® (budesonide inhalation), Abilify® (aripiprazole), Xeloda® (capecitabine), Lovaza® (omega-3-acid ethyl esters), Adderall XR® (mixed amphetamine salts ER), Detrol® (tolterodine ER), Accutane® (isotretinoin), Pravachol® (pravastatin), Evista® (raloxifene), and Celebrex® (celecoxib).

***Europe Generic Medicines Revenues***

Revenues from generic medicines in Europe in the first nine months of 2015 amounted to \$2.0 billion, a decrease of 16% compared to \$2.4 billion in the first nine months of 2014. In local currency terms, revenues decreased 2%.

***ROW Generic Medicines Revenues***

Revenues from generic medicines in our ROW markets in the first nine months of 2015 amounted to \$1.5 billion, a decrease of 13% compared to \$1.7 billion in the first nine months of 2014. In local currency terms, revenues increased 2%.

***Generic Medicines Gross Profit***

In the first nine months of 2015, gross profit from our generic medicines segment amounted to \$3.5 billion, an increase of \$317 million, or 10%, compared to \$3.2 billion in the first nine months of 2014.

Gross profit margin for our generic medicines segment in the first nine months of 2015 increased to 47.8%, from 43.2% in the first nine months of 2014.

**Table of Contents*****Generic Medicines R&D Expenses***

Research and development expenses relating to our generic medicines segment for the first nine months of 2015 amounted to \$377 million, a decrease of 1% compared to \$381 million in the first nine months of 2014. As a percentage of segment revenues, R&D expenses were 5.2% in the first nine months of 2015, flat compared to the first nine months of 2014.

***Generic Medicines S&M Expenses***

Selling and marketing expenses related to our generic medicines segment in the first nine months of 2015 amounted to \$1.0 billion, a decrease of 16% compared to \$1.2 billion in the first nine months of 2014.

As a percentage of segment revenues, selling and marketing expenses decreased to 13.8% in the first nine months of 2015 from 16.2% in the first nine months of 2014.

***Generic Medicines Profit***

Profit of our generic medicines segment amounted to \$2.1 billion in the first nine months of 2015, compared to \$1.6 billion in the first nine months of 2014.

**Specialty Medicines Segment**

The following table presents revenues and profit of our specialty medicines segment for the nine months ended September 30, 2015 and 2014:

	<b>Specialty</b>			
	<b>Nine months ended September 30,</b>			
	<b>2015</b>		<b>2014</b>	
	<b>U.S.\$ in millions / % of Segment</b>			
	<b>Revenues</b>			
Revenues	\$ 6,224	100.0%	\$ 6,317	100.0%
Gross profit	5,345	85.9%	5,501	87.1%
R&D expenses	655	10.5%	658	10.4%
S&M expenses	1,360	21.9%	1,448	22.9%
Segment profit*	\$ 3,330	53.5%	\$ 3,395	53.7%

\* Segment profit consists of gross profit, less S&M and R&D expenses related to the segment. Segment profit does not include G&A expenses, amortization and certain other items. See note 13 to our consolidated financial statements and Operating Income below for additional information.

Beginning in 2015, expenses related to equity compensation are excluded from our segment results. The data presented have been conformed to reflect the exclusion of equity compensation expenses for all periods.

***Specialty Medicines Revenues***

Our revenues from specialty medicines in the first nine months of 2015 amounted to \$6.2 billion, a decrease of 1% compared to the first nine months of 2014. In the United States, our specialty medicines revenues amounted to \$4.8 billion, an increase of 7% compared to the first nine months of 2014. Specialty medicines revenues in Europe amounted to \$1.2 billion, a decrease of 21% from the first nine months of 2014. In local currency terms, specialty medicines revenues in Europe decreased 5%. ROW revenues were \$270 million, a decrease of 30%, or 14% in local currency terms, compared to the first nine months of 2014.

**Table of Contents****Specialty Medicines Revenues Breakdown**

The following table presents revenues by therapeutic area and key products for our specialty medicines segment for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,		Percentage
	2015	2014	Change 2015 - 2014
	U.S. \$ in millions		
CNS	\$ 3,939	\$ 4,124	(4%)
Copaxone®	3,063	3,116	(2%)
Azilect®	304	320	(5%)
Nuvigil®	273	283	(4%)
Respiratory	803	705	14%
ProAir®	401	358	12%
QVAR®	273	209	31%
Oncology	883	845	4%
Treanda®	543	541	0%
Women's Health	354	389	(9%)
Other Specialty	245	254	(4%)
<b>Total Specialty Medicines</b>	<b>\$ 6,224</b>	<b>\$ 6,317</b>	<b>(1%)</b>

**Central Nervous System**

In the first nine months of 2015, our CNS sales amounted to \$3.9 billion, a decrease of 4% compared to the first nine months of 2014.

**Copaxone®.** In the first nine months of 2015, sales of Copaxone® amounted to \$3.1 billion, a decrease of 2% compared to the first nine months of 2014.

Copaxone® revenues in the United States, which include our revenues from both Copaxone® 20 mg/mL and Copaxone® 40 mg/mL products, amounted to \$2.5 billion, an increase of 9% compared to the first nine months of 2014.

Our Copaxone® revenues outside the United States amounted to \$583 million during the first nine months of 2015, a decrease of 30% compared to the first nine months of 2014, or a decrease of 15% in local currency terms.

**Azilect®.** Our sales of Azilect® amounted to \$304 million, a decrease of 5% compared to the first nine months of 2014.

Global in-market sales of Azilect® amounted to \$385 million in the first nine months of 2015 compared to \$408 million in the first nine months of 2014, a decrease of 6%.

**Nuvigil®.** Our sales of Nuvigil® in the first nine months of 2015 amounted to \$273 million, compared to \$283 million in the first nine months of 2014.

***Respiratory Products***

In the first nine months of 2015, revenues from our specialty respiratory products increased 14% to \$803 million, compared to the first nine months of 2014.

## **Table of Contents**

**ProAir**<sup>®</sup> revenues in the first nine months of 2015 amounted to \$401 million, an increase of 12% compared to the first nine months of 2014.

**QVAR**<sup>®</sup> global sales in the first nine months of 2015 amounted to \$273 million, an increase of 31% compared to the first nine months of 2014.

### ***Oncology Products***

Sales of our oncology products amounted to \$883 million in the first nine months of 2015, compared to \$845 million in the first nine months of 2014.

Sales of **Treanda**<sup>®</sup> amounted to \$543 million in the first nine months of 2015, compared to \$541 million in the first nine months of 2014.

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

Revenues from our global women's health products amounted to \$354 million in the first nine months of 2015, a decrease of 9% compared to the first nine months of 2014.

### ***Specialty Medicines Gross Profit***

In the first nine months of 2015, gross profit from our specialty medicines segment amounted to \$5.3 billion, a decrease of 3% compared to the first nine months of 2014.

Gross profit margin for our specialty medicines segment in the first nine months of 2015 was 85.9%, compared to 87.1% in the first nine months of 2014.

### ***Specialty Medicines R&D Expenses***

Research and development expenses relating to our specialty medicines segment, including NTEs, in the first nine months of 2015 amounted to \$655 million, compared to \$658 million in the first nine months of 2014. As a percentage of segment revenues, R&D spending was 10.5% in the first nine months of 2015, compared to 10.4% in the first nine months of 2014.

### ***Specialty Medicines S&M Expenses***

Selling and marketing expenses related to our specialty medicines segment in the first nine months of 2015 amounted to \$1.4 billion, a decrease of 6% compared to the first nine months of 2014.

As a percentage of segment revenues, selling and marketing expenses were 21.9% in the first nine months of 2015, compared to 22.9% in the first nine months of 2014.

### ***Specialty Medicines Profit***

The profit of our specialty medicines segment consists of the gross profit, less selling and marketing expenses and research and development expenses related to this segment. Segment profit does not include general and administrative expenses, amortization and certain other items. See note 13 to our consolidated financial statements and Operating Income below for additional information.



Profit of our specialty medicines segment amounted to \$3.3 billion in the first nine months of 2015, a decrease of 2% compared to the first nine months of 2014.

Specialty medicines profit as a percentage of segment revenues was 53.5% in the first nine months of 2015, compared to 53.7% in the first nine months of 2014, a decrease of 0.2 points.

Our multiple sclerosis franchise includes our Copaxone<sup>®</sup> products and laquinimod (a developmental compound for the treatment of MS). The profit of our multiple sclerosis franchise consists of Copaxone<sup>®</sup> revenues less cost of goods sold and S&M and R&D expenses related to our MS franchise. It does not include G&A expenses, amortization and certain other items. Profit of our multiple sclerosis franchise in the first nine months of 2015 was \$2.4 billion, an increase of 1% compared to the first nine months of 2014. Profit of our multiple sclerosis franchise as a percentage of Copaxone<sup>®</sup> revenues was 77.4% in the first nine months of 2015 compared to 75.0% in the first nine months of 2014.

## **Table of Contents**

### **Other Activities**

#### ***OTC***

Our revenues from OTC products in the first nine months of 2015 amounted to \$678 million, a decrease of 12% compared to \$768 million in the first nine months of 2014. The decrease was mainly due to the sale of our U.S. OTC plants, previously purchased from P&G, back to P&G in July 2014. Our revenues related to PGT in the first nine months of 2015 amounted to \$678 million, an increase of 1%, compared to \$670 million in the first nine months of 2014. In local currency terms, revenues increased 22%.

PGT's in-market sales in the first nine months of 2015 amounted to \$1.1 billion, in line with in-market sales in the first nine months of 2014.

#### ***Others***

In the first nine months of 2015, we recorded revenues of \$580 million from our other activities, a decrease of 14% compared to sales of \$674 million in the first nine months of 2014.

### **Teva Consolidated Results**

#### **Revenues**

Revenues in the first nine months of 2015 amounted to \$14.8 billion, a decrease of 2% compared to the first nine months of 2014. Exchange rate movements during the first nine months of 2015 in comparison with the first nine months of 2014 negatively impacted revenues by \$1.1 billion. In local currency terms, revenues increased 5%. See [Generic Medicines Revenues](#), [Specialty Medicines Revenues](#) and [Other Activities](#) above.

#### **Gross Profit**

In the first nine months of 2015, gross profit amounted to \$8.5 billion, an increase of 4% compared to the first nine months of 2014.

The higher gross profit was mainly a result of the higher gross profit of our generic medicines segment and lower amortization expenses, partially offset by the lower gross profit of our specialty medicines segment. See [Generic Medicines Gross Profit](#) and [Specialty Medicines Gross Profit](#) above and the reconciliation of our segment profit to our consolidated operating income under [Operating Income](#) below.

Gross profit as a percentage of revenues was 57.6% in the first nine months of 2015, compared to 54.1% in the first nine months of 2014.

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

Net research and development expenses for the first nine months of 2015 amounted to \$1.1 billion, a decrease of 3% compared to the first nine months of 2014. See [Generic Medicines R&D Expenses](#) and [Specialty Medicines R&D Expenses](#) above.

As a percentage of revenues, R&D spending was 7.3% in the first nine months of 2015, flat compared to the first nine months of 2014.

**Selling and Marketing (S&M) Expenses**

Selling and marketing expenses in the first nine months of 2015 amounted to \$2.6 billion, a decrease of 10% compared to the first nine months of 2014. See [Generic Medicines S&M Expenses](#) and [Specialty Medicines S&M Expenses](#) above.

As a percentage of revenues, S&M expenses were 17.3% in the first nine months of 2015 compared to 18.9% in the first nine months of 2014.

**Table of Contents****General and Administrative (G&A) Expenses**

G&A expenses in the first nine months of 2015 amounted to \$948 million, compared to \$897 million in the first nine months of 2014. As a percentage of revenues, G&A expenses increased to 6.4% in the first nine months of 2015, from 6.0% in the first nine months of 2014.

**Legal Settlements and Loss Contingencies**

Legal settlements and loss contingencies for the first nine months of 2015 amounted to an expense of \$531 million, compared to income of \$67 million in the first nine months of 2014.

The expenses in the first nine months of 2015 were mainly due to an additional reserve for the settlement of the modafinil antitrust litigation, which was partially offset by insurance proceeds relating to the settlement of the pantoprazole patent litigation.

**Impairments, Restructuring and Others**

In the first nine months of 2015, we recorded \$968 million in impairments, restructuring and others, compared to \$364 million in the first nine months of 2014.

The expenses in the first nine months of 2015 were mainly due to a \$310 million increase of liability for contingent consideration following the positive phase 2b results of TEV-48125 in both chronic and episodic migraine prevention, impairment of Synribo<sup>®</sup> of \$133 million following a decrease in sales projections.

During the second quarter of 2015, Teva recorded acquisition expenses of \$105 million, reflecting the difference between the purchase price of the interest acquired in Mylan and its fair value as of June 30, 2015. On September 30, 2015, an additional loss of \$623 million was included in financial expenses-net, reflecting the difference between the book value of this interest and its fair value as of September 30, 2015. Accordingly, the aggregate loss from the decline in fair value of our Mylan shares was \$728 million as of September 30, 2015. See note 8 to the consolidated financial statements.

**Operating Income**

Operating income amounted to \$2.4 billion in the first nine months of 2015, compared to \$3.0 billion in the first nine months of 2014. As a percentage of revenues, operating income was 16.4% in the first nine months of 2015, compared to 19.9% in the first nine months of 2014.

The following table presents a reconciliation of our segment profit to our consolidated operating income for the nine months ended September 30, 2015 and 2014:

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>U.S.\$ in millions</b>	
Generic medicines profit	\$ 2,106	\$ 1,597
Specialty medicines profit	3,330	3,395

Total segment profit	5,436	4,992
Profit of other activities	164	165
Total profit	5,600	5,157
Amounts not allocated to segments:		
Amortization	637	783
General and administrative expenses	948	897
Legal settlements and loss contingencies	531	(67)
Impairments, restructuring and others	968	364
Other unallocated amounts	95	171
Consolidated operating income	2,421	3,009
Financial expenses net	930	243
Consolidated income before income taxes	\$ 1,491	\$ 2,766

Beginning in 2015, expenses related to equity compensation are excluded from our segment results. The data presented have been conformed to reflect the exclusion of equity compensation expenses for all periods.

## **Table of Contents**

### **Financial Expenses-Net**

In the first nine months of 2015, financial expenses amounted to \$930 million, compared to \$243 million in the first nine months of 2014. The increase was mainly due to a \$623 million loss on our Mylan shares, as well as expenses of \$143 million in connection with the debt tender offer and the termination of related swap agreements during the first quarter of 2015, partially offset by income from derivative financial instruments, lower interest expenses resulting from lower cost of debt, lower debt balance and higher financial income from deposits.

### **Tax Rate**

In the first nine months of 2015, the provision for taxes amounted to \$385 million, or 26%, on pre-tax income of \$1.5 billion. In the first nine months of 2014, the provision for taxes amounted to \$405 million, or 15%, on pre-tax income of \$2.8 billion.

We expect our annual tax rate for 2015 to be higher than the tax rate for 2014, mainly due to product mix in the different geographies and the effect of the loss on our Mylan shares.

### **Net Income**

Net income attributable to Teva in the first nine months of 2015 amounted to \$1.1 billion, compared to \$2.4 billion in the first nine months of 2014.

### **Diluted Shares Outstanding and Earnings per Share**

The average weighted diluted shares outstanding used for the fully diluted share calculation for the first nine months of 2015 and 2014 were 860 million and 857 million shares, respectively.

During 2014, we repurchased approximately nine million shares at a weighted average price of \$57.43 per share, for an aggregate purchase price of \$0.5 billion. In the first quarter of 2015, we repurchased approximately eight million shares at a weighted average price of \$57.09 per share, for an aggregate purchase price of \$0.4 billion. During the second and third quarters of 2015, we did not repurchase any shares.

Diluted earnings per share amounted to \$1.26 in the first nine months of 2015, compared to \$2.76 in the first nine months of 2014.

### **Impact of Currency Fluctuations on Results of Operations**

Because our results are reported in U.S. dollars, changes in the rate of exchange between the U.S. dollar and the local currencies in the markets in which we operate (primarily the euro, Israeli shekel, Russian ruble, Canadian dollar, British pound and Japanese yen) affect our results. During the first nine months of 2015, all the main currencies relevant to our operations decreased in value against the U.S. dollar: the euro by 18%, the Russian ruble by 41%, the Israeli shekel by 10%, the Canadian dollar by 13%, the British pound by 8% and the Japanese yen by 15% (all compared on a nine-monthly average basis). Latin American currencies showed an overall negative change of 8% compared to last year.

As a result, exchange rate movements during the first nine months of 2015 in comparison with the first nine months of 2014 negatively impacted overall revenues by \$1.1 billion and reduced our operating income by \$62 million.

### **Liquidity and Capital Resources**

Total balance sheet assets amounted to \$48.6 billion as of September 30, 2015, compared to \$50.4 billion as of June 30, 2015. The decrease is mainly due to a \$0.6 billion decline in the fair market value of our Mylan shares, a decrease of \$0.4 billion in deferred income taxes and a decrease of \$0.3 billion in accounts receivables.

Inventory balances as of September 30, 2015 amounted to \$4.1 billion, a decrease of \$0.1 billion compared to June 30, 2015.

## **Table of Contents**

Accounts receivable as of September 30, 2015, net of sales reserves and allowances ( SR&A ), amounted to negative \$1.5 billion, compared to negative \$0.9 billion as of June 30, 2015. This lower balance is due to higher provisions for SR&A.

We monitor macro-economic risks in certain emerging markets that are experiencing economic stress, focusing on Eastern Europe and Latin America, and have taken action to limit our exposure in these regions.

Accounts payable and accruals amounted to \$3.0 billion as of September 30, 2015, flat compared to June 30, 2015.

Our working capital balance, which includes accounts receivable, inventories, deferred income taxes and other current assets net of SR&A, accounts payable and accruals and other current liabilities, was \$0.7 billion as of September 30, 2015, a decrease of \$0.1 billion compared to June 30, 2015.

Investment in property, plant and equipment in the third quarter of 2015 was approximately \$170 million, compared to \$212 million in the third quarter of 2014. Depreciation amounted to \$111 million in the third quarter of 2015, compared to \$117 million in the third quarter of 2014.

Cash and cash equivalents and short term and long term investments as of September 30, 2015 amounted to \$2.0 billion, compared to \$2.8 billion as of June 30, 2015. The decrease was mainly due to payments of approximately \$1 billion related to the modafinil settlement and a decline in the fair market value of our Mylan shares, as well as repayments of short term borrowings, partially offset by cash generated during the quarter.

See - Commitments below regarding our funding of the Allergan generics and Rimsa acquisitions.

## **2015 Debt Movements**

During the third quarter of 2015, we repaid \$0.9 billion of short term borrowings under our revolving credit facility as well as short term liquidity lines.

## **Aggregate Debt**

As of September 30, 2015, our outstanding debt amounted to \$11.7 billion, compared to \$12.5 billion as of June 30, 2015. Our debt as of September 30, 2015 was effectively denominated in the following currencies: U.S. dollar 47%, euro 38%, Japanese yen 11% and Swiss franc 4%.

The portion of total debt classified as short term as of September 30, 2015 was 18%, compared to 24% as of June 30, 2015. The decrease was mainly due to repayments of short term borrowings.

Our financial leverage decreased to 34% as of September 30, 2015, compared to 35% as of June 30, 2015.

Our average debt maturity was approximately 5.9 years as of September 30, 2015.

During August and September 2015, we entered into forward starting interest rate swap agreements designated as cash flow hedges of anticipated future debt issuance, with respect to \$2 billion notional amount. These agreements hedge the variability in anticipated future interest payments due to changes in the benchmark interest rate between the date the swap agreements were entered into and the expected date of future debt issuances in 2016, at which time these agreements are intended to be settled.



During October 2015, we entered into additional forward starting interest rate swap agreements, designated as cash flow hedge of anticipated future debt issuance, with respect to \$1 billion notional amount.

### **Shareholders Equity**

Total shareholders equity was \$22.9 billion as of September 30, 2015, compared to \$23.1 billion as of June 30, 2015. The decrease was mainly due to \$0.3 billion in dividend payments and \$0.2 billion in exchange rate differences, partially offset by \$0.1 billion of net income, \$0.1 billion in proceeds from employee stock option exercises and a \$0.1 billion increase in non-controlling interests.

Exchange rate fluctuations affected our balance sheet, as approximately 24% of our net assets in the third quarter of 2015 (including both non-monetary and monetary assets) were in currencies other than the U.S. dollar. When compared to June 30, 2015, changes in currency rates had a negative impact of \$0.2 billion on our equity as of September 30, 2015, mainly due to the change in value against the U.S. dollar of: the Russian ruble by (16%), the euro by 0.12%, the Canadian dollar by (8%) and certain Latin American currencies by (8%). All comparisons are on a quarter-end to quarter-end basis.

## **Table of Contents**

### **Cash Flow**

Cash flow generated from operating activities during the third quarter of 2015 amounted to \$1.1 billion, compared to \$1.4 billion in the third quarter of 2014. The decrease was mainly due to payments of approximately \$1 billion related to the modafinil settlement, partially offset by a decrease in account receivables.

Cash flow generated from operating activities in the third quarter of 2015, net of cash used for capital investments, amounted to \$1.0 billion, a decrease of \$236 million compared to the third quarter of 2014. The decrease resulted mainly from lower cash flow generated from operating activities.

### **Dividends**

We announced a dividend for the third quarter of 2015 of \$0.34 per share. The dividend payment is expected to take place on December 3, 2015 to holders of record as of November 17, 2015.

### **Commitments**

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 acquisitions, leases, royalty payments, contingent payments pursuant to acquisition agreements and participation in joint ventures associated with research and development activities.

On July 27, 2015, we announced that we entered into a definitive agreement with Allergan plc to acquire Allergan's worldwide generic pharmaceuticals business. We will pay total consideration of \$40.5 billion, consisting of \$33.75 billion in cash and approximately 100 million Teva shares, which represent \$6.75 billion in value, based on the mutually-agreed price of \$67.30 per share. Closing of the transaction is subject to certain conditions, including relevant regulatory approvals. Subject to satisfaction of the closing conditions, we expect the acquisition to close in the first quarter of 2016.

On September 25, 2015, we entered into a bridge loan credit agreement with various banks, under which the banks agreed to provide up to \$27 billion of loans to finance a portion of the Allergan acquisition. Any loan under the bridge facility would bear an interest rate of LIBOR plus a margin ranging from 0.30 to 1.65%, so long as we maintain an investment-grade credit rating, depending on our specific credit rating and the time elapsed since funding of the bridge loans. In addition, we have entered into commitment letters with various banks, under which the banks committed to provide us with up to \$6.75 billion in loans under a separate bridge loan credit facility to finance a portion of the Allergan acquisition.

On October 1, 2015, we entered into a definitive agreement to acquire Rimsa, a leading pharmaceutical manufacturing and distribution company in Mexico, along with a portfolio of products and companies, intellectual property, assets and pharmaceutical patents in Latin America and Europe, for an aggregate of \$2.3 billion, in a cash free, debt free set of transactions. The transaction is expected to be funded through a combination of available cash and lines of credit. Subject to satisfaction of the closing conditions, Teva expects the acquisition to close in the first quarter of 2016.

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.

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.

**Table of Contents**

Our principal sources of short-term liquidity are our existing cash investments, liquid securities, and available credit facilities; primarily our \$3 billion syndicated revolving line of credit of which \$1.5 billion remained unutilized as of September 30, 2015 as well as internally generated funds, which we believe are sufficient to meet our on-going operating needs. Our cash on hand is generally invested in bank deposits as well as liquid securities that bear fixed and floating rates.

**Supplemental Non-GAAP Income Data**

The tables on the following pages present supplemental non-GAAP data, in U.S. dollar terms and as a percentage of revenues, which we believe facilitates an understanding of the factors affecting our business.

In these tables, we exclude the following amounts:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2015</b>	<b>2014</b>	<b>September 30, 2015</b>	<b>2014</b>
	<b>U.S. \$ in millions</b>			
Amortization of purchased intangible assets	\$ 203	\$ 242	\$ 637	\$ 783
Impairment of long-lived assets	187	151	333	208
Legal settlements and loss contingencies	(80)	(122)	531	(67)
Restructuring expenses and other non-GAAP items	69	36	114	181
Contingent consideration	67	(21)	329	(26)
Acquisition expenses	61	1	194	11
Equity compensation	24	18	82	54
Costs related to regulatory actions taken in facilities	9	13	28	45
Purchase of research and development in process			24	
Costs associated with cancellation of R&D projects		52		52
Branded prescription drug fee		40		40
Financial expense	632	7	775	6
Corresponding tax benefit*	(126)	(144)	(591)	(386)
Minority interest changes	16		16	

\* The tax rate reflected by the corresponding tax benefit in the third quarter of 2015 is significantly lower than our expected annual tax rate due to the effect of the loss on our Mylan shares.

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 a detailed work plan for the next fiscal year. This work plan is used to manage the business and is the plan 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 tables 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.

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

**Table of Contents**

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. Beginning in 2015, expenses related to our equity compensation are excluded from our non-GAAP results. The data presented have been conformed to reflect the exclusion of equity compensation expenses for all periods.

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

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

**Table of Contents**

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

	Three Months Ended September 30, 2015				Three Months Ended September 30, 2014			
	GAAP	Non-GAAP Adjustments	Non-GAAP Revenues	% of Net Revenues	GAAP	Non-GAAP Adjustments	Non-GAAP Revenues	% of Net Revenues
Gross profit (1)	2,771	208	2,979	62%	2,809	256	3,065	61%
Operating income (1)(2)	1,010	540	1,550	32%	1,112	410	1,522	30%
Net income attributable to Teva (1)(2)(3)	103	1,062	1,165	24%	876	273	1,149	23%
Earnings per share attributable to Teva Diluted (4)	0.12	1.23	1.35		1.02	0.31	1.33	
(1) Amortization of purchased intangible assets		196				239		
Costs related to regulatory actions taken in facilities		9				13		
Equity compensation		3				1		
Other COGS related adjustments						3		
Gross profit adjustments		208				256		
(2) Impairment of long-lived assets		187				151		
Legal settlements and loss contingencies		(80)				(122)		
Restructuring expenses and other non-GAAP items		69				125		
Contingent consideration		67				(21)		
Acquisition expenses		61				1		
Equity compensation		21				17		
Amortization of purchased intangible assets		7				3		
		332				154		
Operating income adjustments		540				410		
(3) Financial expense		632				7		
Tax benefit and other items		(110)				(144)		
Net income adjustments		1,062				273		

(4)

The weighted average number of shares was 862 million and 861 million for the three months ended September 30, 2015 and 2014, 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.



**Table of Contents**

**Nine Months Ended September 30, 2015** **Nine Months Ended September 30, 2014**  
**U.S. dollars and shares in millions (except per share amounts)**

	Non- GAAP	Non- GAAP	% of Net Revenues	Non- GAAP	Non- GAAP	Non- GAAP	% of Net Revenues	
	GAAP	Adjustments	GAAP	GAAP	Adjustments	GAAP	Revenues	
Gross profit (1)	8,509	652	9,161	62%	8,167	815	8,982	59%
Operating income (1)(2)	2,421	2,272	4,693	32%	3,009	1,281	4,290	28%
Net income attributable to Teva (1)(2)(3)	1,088	2,472	3,560	24%	2,368	901	3,269	22%
Earnings per share attributable to Teva Diluted (4)	1.26	2.88	4.14		2.76	1.05	3.81	

(1) Amortization of purchased intangible assets	614	756
Costs related to regulatory actions taken in facilities	28	45
Equity compensation	8	4
Other COGS related adjustments	2	10
Gross profit adjustments	652	815
(2) Legal settlements and loss contingencies	531	(67)
Impairment of long-lived assets	333	208
Contingent consideration	329	(26)
Acquisition expenses	194	11
Restructuring expenses and other non-GAAP items	136	263
Equity compensation	74	50
Amortization of purchased intangible assets	23	27
	1,620	466
Operating income adjustments	2,272	1,281
(3) Financial expense	775	6
Tax benefit and other items	(575)	(386)
Net income adjustments	2,472	901

(4) The weighted average number of shares was 860 and 857 million for the nine months ended September 30, 2015 and 2014, 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 Rate**

The provision for non-GAAP taxes for the third quarter of 2015 amounted to \$319 million, or 21%, on pre-tax non-GAAP income of \$1.5 billion. The provision for non-GAAP taxes in the comparable quarter of 2014 was \$304 million, or 21%, on pre-tax non-GAAP income of \$1.4 billion.

The provision for non-GAAP taxes for the first nine months of 2015 amounted to \$976 million, or 21%, on pre-tax non-GAAP income of \$4.5 billion. The provision for non-GAAP taxes in the comparable period of 2014 was \$791 million, or 20% on pre-tax income of \$4.1 billion.

We expect our annual non-GAAP tax rate for 2015 to be higher than the annual non-GAAP tax rate for 2014, mainly due to our product mix in the different geographies.

## **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, 2014. 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, 2014 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.

### **RISK FACTORS**

Except as set forth below, 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, 2014, as updated by our report on Form 6-K filed on July 30, 2015.

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

Reference is made to Item 11 Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 20-F for the year ended December 31, 2014.

### **LEGAL PROCEEDINGS**

We are subject to various litigation and other legal proceedings. For a discussion of these matters, see Contingencies included in note 12 to the condensed consolidated financial statements included in this report.

Table of Contents

**SIGNATURES**

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

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

Date: October 29, 2015

By: /S/ EYAL DESHEH  
Name: **Eyal Desheh**  
Title: **Group Executive Vice President,**  
**Chief Financial Officer**

60