

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

August 04, 2016

[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 August 2016**

**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>Consolidated Statements of Comprehensive Income (Loss)</u>	4
<u>Consolidated Statements of Cash Flows</u>	5
<u>Notes to Consolidated Financial Statements</u>	6
<u>Operating and Financial Review and Prospects</u>	30
<u>Risk Factors</u>	60
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	60
<u>Legal Proceedings</u>	60

**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)

	June 30, 2016	December 31, 2015
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 6,984	\$ 6,946
Accounts receivable	5,374	5,350
Inventories	3,921	3,966
Deferred income taxes	801	735
Other current assets	1,264	1,401
<b>Total current assets</b>	<b>18,344</b>	<b>18,398</b>
<b>Other non-current assets</b>	<b>2,639</b>	<b>2,591</b>
<b>Property, plant and equipment, net</b>	<b>6,693</b>	<b>6,544</b>
<b>Identifiable intangible assets, net</b>	<b>9,544</b>	<b>7,675</b>
<b>Goodwill</b>	<b>20,700</b>	<b>19,025</b>
<b>Total assets</b>	<b>\$ 57,920</b>	<b>\$ 54,233</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities:</b>		
Short-term debt	\$ 2,882	\$ 1,585
Sales reserves and allowances	6,196	6,601
Accounts payable and accruals	3,855	3,594
Other current liabilities	1,478	1,225
<b>Total current liabilities</b>	<b>14,411</b>	<b>13,005</b>
<b>Long-term liabilities:</b>		
Deferred income taxes	2,097	1,748
Other taxes and long-term liabilities	1,353	1,195
Senior notes and loans	8,036	8,358
<b>Total long-term liabilities</b>	<b>11,486</b>	<b>11,301</b>
<b>Commitments and contingencies, see note 13</b>		
<b>Total liabilities</b>	<b>25,897</b>	<b>24,306</b>

**Equity:**

**Teva shareholders equity:**

Preferred shares of NIS 0.10 par value per mandatory convertible preferred share; June 30, 2016 and December 31, 2015: authorized 5.0 million shares; issued 3.7 million shares and 3.4 million shares, respectively	3,620	3,291
Ordinary shares of NIS 0.10 par value per share; June 30, 2016 and December 31, 2015: authorized 2,500 million shares; issued 1,022 million shares and 1,016 million shares, respectively	52	52
Additional paid-in capital	18,236	17,757
Retained earnings	14,990	14,851
Accumulated other comprehensive loss	(2,544)	(1,955)
Treasury shares as of June 30, 2016 and December 31, 2015 108 million ordinary shares	(4,204)	(4,227)
	30,150	29,769
<b>Non-controlling interests</b>	1,873	158
<b>Total equity</b>	32,023	29,927
<b>Total liabilities and equity</b>	\$ 57,920	\$ 54,233

/s/ E. VIGODMAN

/s/ E. DESHEH

E. Vigodman

E. Desheh

President and Chief Executive Officer

Group Executive Vice President,

Chief Financial Officer

The accompanying notes are an integral part of the 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>Six months ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net revenues	\$ 5,038	\$ 4,966	\$ 9,848	\$ 9,948
Cost of sales	2,161	2,064	4,180	4,210
Gross profit	2,877	2,902	5,668	5,738
Research and development expenses	375	386	764	718
Selling and marketing expenses	952	860	1,791	1,782
General and administrative expenses	311	325	615	632
Impairments, restructuring and others	712	285	831	584
Legal settlements and loss contingencies	166	384	141	611
Operating income	361	662	1,526	1,411
Financial expenses net	105	41	403	233
Income before income taxes	256	621	1,123	1,178
Income taxes	29	88	257	192
Share in (profits) losses of associated companies net	(15)	(6)	(9)	3
Net income	242	539	875	983
Net loss attributable to non-controlling interests	(12)		(15)	(2)
Net income attributable to Teva	254	539	890	985
Dividends on preferred shares	66		132	
Net income attributable to ordinary shareholders	\$ 188	\$ 539	\$ 758	\$ 985
Earnings per share attributable to ordinary shareholders:				
Basic	\$ 0.21	\$ 0.64	\$ 0.83	\$ 1.16
Diluted	\$ 0.20	\$ 0.63	\$ 0.82	\$ 1.15
Weighted average number of shares (in millions):				
Basic	914	849	914	850
Diluted	920	859	922	859

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

Table of Contents

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

(U.S. dollars in millions)

(Unaudited)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Net income	\$ 242	\$ 539	\$ 875	\$ 983
Other comprehensive (income) loss, net of tax:				
Currency translation adjustment	(91)	(115)	(346)	685
Unrealized (gain) loss from derivative financial instruments, net	185	99	521	(109)
Unrealized (gain) loss from available-for-sale securities, net	66	(14)	265	(25)
Unrealized gain on defined benefit plans	*	(1)	*	(4)
Total other comprehensive (income) loss	160	(31)	440	547
Total comprehensive income	82	570	435	436
Comprehensive income attributable to the non-controlling interests	136	1	134	
Comprehensive income (loss) attributable to Teva	\$ (54)	\$ 569	\$ 301	\$ 436

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

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



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

(U.S. dollars in millions)

(Unaudited)

	<b>Six months ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Operating activities:</b>		
Net income	\$ 875	\$ 983
Adjustments to reconcile net income to net cash provided by operations:		
Depreciation and amortization	615	658
Impairment of long-lived assets	585	147
Venezuela impairment of net monetary assets	246	
Deferred income taxes net and uncertain tax positions	(202)	(404)
Other items	126	246
Stock-based compensation	52	60
Net change in operating assets and liabilities	53	1,166
Net gain from sale of long-lived assets and investments	(21)	(46)
Research and development in process	10	24
<b>Net cash provided by operating activities</b>	<b>2,339</b>	<b>2,834</b>
<b>Investing activities:</b>		
Acquisitions of subsidiaries, net of cash acquired	(2,312)	(3,261)
Purchases of property, plant and equipment	(347)	(354)
Proceeds from sales of long-lived assets and investments	39	435
Purchases of investments and other assets	(37)	(1,935)
Other investing activities	15	(21)
<b>Net cash used in investing activities</b>	<b>(2,642)</b>	<b>(5,136)</b>
<b>Financing activities:</b>		
Net change in short-term debt	758	2,414
Dividends paid on ordinary shares	(617)	(578)
Proceeds from issuance of ordinary shares, net of issuance costs	329	
Proceeds from issuance of mandatory convertible preferred shares, net of issuance costs	329	
Dividends paid on preferred shares	(126)	
Other financing activities	(102)	(154)
Repayment of long-term loans and other long-term liabilities	(43)	(2,468)
Proceeds from exercise of options by employees	20	258
Proceeds from long-term loans and other long-term liabilities	(2)	2,147
Purchases of treasury shares		(439)

<b>Net cash provided by financing activities</b>	546	1,180
<b>Translation adjustment on cash and cash equivalents</b>	(205)	(36)
<b>Net change in cash and cash equivalents</b>	38	(1,158)
<b>Balance of cash and cash equivalents at beginning of period</b>	6,946	2,226
<b>Balance of cash and cash equivalents at end of period</b>	\$ 6,984	\$ 1,068

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

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements**

**(Unaudited)**

**NOTE 1 Basis of presentation:**

The accompanying unaudited 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, 2015, as filed with the Securities and Exchange Commission (SEC). Amounts at December 31, 2015 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 six months ended June 30, 2016 are not necessarily indicative of results that could be expected for the entire fiscal year.

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

In March 2016, the Financial Accounting Standards Board (FASB) issued guidance on stock compensation. The guidance is intended to simplify several aspects of the accounting for share-based payments, including income tax consequences, classification of awards as either equity or liabilities, and classification in the statement of cash flows. The guidance will be effective for fiscal years beginning after December 15, 2016, including interim periods within that year. Teva has adopted the provisions of this update during the second quarter of 2016. The guidance did not have a material impact on Teva's consolidated financial statements for the second quarter of 2016.

In February 2016, the FASB issued guidance on leases. The guidance requires entities to record lease assets and lease liabilities on the balance sheet and disclose key information about leasing arrangements. The guidance will become effective for interim and annual periods beginning after December 15, 2018 (early adoption is permitted) and is required to be adopted at the earliest period presented using a modified retrospective approach. Teva is currently evaluating the potential effect of the guidance on its consolidated financial statements.

In January 2016, the FASB issued guidance which updates certain aspects of recognition, measurement, presentation and disclosure of equity investments. The guidance requires entities to recognize changes in fair value in net income rather than in accumulated other comprehensive income. The guidance is effective for interim and annual periods beginning after December 15, 2017 (early adoption is permitted). Teva is currently evaluating the potential effect of the guidance on its consolidated financial statements.

In November 2015, the FASB issued guidance on balance sheet classification of deferred taxes. The guidance requires entities to present all deferred tax assets and liabilities, along with any related valuation allowance, as non-current on the balance sheet. The guidance is effective for interim and annual periods beginning after December 15, 2016 (early adoption is permitted). Teva is currently evaluating the potential effect of the 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. In March, April and May 2016, the FASB issued three additional updates regarding identifying performance obligations and licensing, certain principal versus agent considerations, and various narrow scope improvements based on practical questions raised by users. 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.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

**NOTE 3 Certain transactions:**

***Anda acquisition:***

On August 3, 2016, Teva entered into a definitive agreement with Allergan plc to purchase Anda Inc., the fourth largest distributor of generic pharmaceuticals in the United States, for cash consideration of \$500 million. Closing of this transaction is expected in 2016, subject to antitrust approval and satisfaction of other customary conditions.

***Actavis Generics acquisition:***

On August 2, 2016, Teva consummated its acquisition of Allergan plc's worldwide generic pharmaceuticals business (Actavis Generics). At closing, Teva paid consideration of approximately \$33.4 billion in cash and approximately 100.3 million Teva shares issued to Allergan.

In July 2016, Teva completed debt issuances for an aggregate principal amount of \$20.4 billion, or \$20.3 billion net proceeds, consisting of senior notes with aggregate principal amount of \$15 billion, \$4 billion and CHF 1 billion and maturities of two to 30 years. The effective average interest rate of the newly issued notes is 2.32% per annum.

At the closing of the acquisition, Teva borrowed \$5 billion under its term loan facility with a syndicate of banks. The term facility is split into two tranches of \$2.5 billion each, with the first tranche maturing in full after three years and the second tranche maturing in five years with payment installments each year. In addition, Teva terminated its \$22 billion bridge loan credit agreement.

Teva financed the cash consideration with the amounts mentioned above, in addition to approximately \$8.1 billion from cash on hand, including from its December 2015 equity offerings, and borrowings under its syndicated revolving line of credit.

***Japanese business venture:***

On April 1, 2016, Teva and Takeda established Teva Takeda Yakuhin Ltd., a new business venture in Japan. The business venture combines Teva's Japanese generics business along with Takeda's portfolio of non-exclusive products. The business venture seeks to leverage Takeda's leading brand reputation and strong distribution presence in Japan with Teva's expertise in supply chain, operational network, infrastructure and R&D, to meet the wide-ranging needs of patients and growing importance of generics in Japan through the provision of off-patent medicines.

Teva assigned 49% in the business venture to Takeda in consideration of the contribution of its off-patented products business in Japan. The business venture was consolidated in Teva's financial statements commencing April 1, 2016. Takeda's interest in the business venture is accounted for under net loss attributable to non-controlling interests.

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. Under the accounting treatment for the

transaction, Teva recorded net assets acquired of \$1.8 billion and non-controlling interests of \$1.6 billion, with the difference recorded under Teva shareholders equity.

	<b>U.S.\$ in millions</b>
Inventories	\$ 139
Identifiable intangible assets:	
Product and marketing rights	1,664
Goodwill	566
<b>Total assets acquired</b>	<b>2,369</b>
Current liabilities	34
Other liabilities	510
<b>Total liabilities assumed</b>	<b>544</b>
<b>Net assets acquired</b>	<b>\$ 1,825</b>

Pro forma information giving effect to the acquisition has not been provided as the results would not be material.

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

On March 3, 2016, Teva completed the acquisition of 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 amount of \$2.3 billion, in a cash free, debt free set of transactions. Teva financed the transaction using cash on hand.

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>
Current assets	\$ 110
Deferred taxes and other assets	696
Identifiable intangible assets:	
Product rights	781
Research and development in-process	177
Trade names / customer relationships	49
Goodwill	995
 Total assets acquired	 2,808
Current liabilities	117
Other liabilities	370
 Total liabilities assumed	 487
 Net assets acquired	 \$ 2,321

Pro forma information giving effect to the acquisition has not been provided as the results would not be material.

**NOTE 4 Inventories:**

Inventories consisted of the following:

**June 30,      December 31,**

	<b>2016</b>	<b>2015</b>
	<b>U.S. \$ in millions</b>	
Finished products	\$ 2,018	\$ 2,050
Raw and packaging materials	1,243	1,195
Products in process	475	535
Materials in transit and payments on account	185	186
	<b>\$ 3,921</b>	<b>\$ 3,966</b>

**NOTE 5 Earnings per share:**

Basic earnings per share is computed by dividing net income attributable to Teva's ordinary shareholders by the weighted average number of ordinary shares outstanding (including fully vested restricted share units ( RSUs )) during the period, net of treasury shares.

In computing diluted earnings per share for the three and six months ended June 30, 2016 and 2015, basic earnings per share was adjusted to take into account the potential dilution that could occur upon the exercise of options and non-vested RSUs granted under employee stock compensation plans, and convertible senior debentures, using the treasury stock method.



**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

Additionally, for the three and six months ended June 30, 2016, no account was taken of the potential dilution of the mandatory convertible preferred shares amounting to 59 million weighted average shares, since they had an anti-dilutive effect on earnings per share.

**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 sales reserves and allowances ( 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, 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.

Sales reserves and allowances consisted of the following:

	<b>June 30, 2016</b>	<b>December 31, 2015</b>
	<b>U.S. \$ in millions</b>	
Rebates	\$ 3,037	\$ 3,382
Medicaid	1,291	1,319
Chargebacks	1,030	1,091
Returns	634	598
Other	204	211
	<b>\$ 6,196</b>	<b>\$ 6,601</b>

Table of Contents

## TEVA PHARMACEUTICAL INDUSTRIES LIMITED

## Notes to Consolidated Financial Statements (Continued)

(Unaudited)

## NOTE 7 Equity:

*Accumulated other comprehensive (income) loss*

The following tables present the changes in the components of accumulated other comprehensive (income) loss for the three months ended June 30, 2016 and 2015:

		Three months ended June 30, 2016				
Components of accumulated other comprehensive loss	Description of the reclassification to the statements of income	Other comprehensive (income) loss before reclassification	Amounts reclassified to 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		\$ (123)	\$	\$ (123)	\$ 32	\$ (91)
Unrealized (gain) loss from available-for-sale securities	Loss on marketable securities, reclassified to financial expenses - net	163	(98)	65	1	66
Unrealized (gain) loss from derivative financial instruments	Loss on derivative financial instruments reclassified to financial expenses - net	187	(2)	185		185
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		\$ 227	\$ (100)	\$ 127	\$ 33	\$ 160

		Three months ended June 30, 2015				
Components of accumulated other comprehensive loss	Description of the reclassification to the statements of income	Other comprehensive (income) loss	Amounts reclassified to the	Net other comprehensive (income)	Corresponding income tax	Net other comprehensive (income)

		before statement reclassifications of income		loss before tax		loss after tax	
		U.S.\$ in millions					
Currency translation adjustment		\$ (115)	\$	\$ (115)	\$	\$ (115)	\$ (115)
Unrealized (gain) loss from available-for-sale securities	Loss on marketable securities, reclassified to impairments, restructuring and others	83	(105)	(22)	8	(14)	
Unrealized (gain) loss from derivative financial instruments	Gain on derivative financial instruments reclassified to net revenue	84	15	99	*	99	
Unrealized (gain) loss on defined benefit plans	Loss on defined benefit plans, reclassified to various statement of income items**	*	(1)	(1)	*	(1)	
Total accumulated other comprehensive (income) loss		\$ 52	\$ (91)	\$ (39)	\$ 8	\$ (31)	

\* 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.

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

The following tables present the changes in the components of accumulated other comprehensive (income) loss for the six months ended June 30, 2016 and 2015:

Components of accumulated other comprehensive loss	Description of the reclassification to the statements of income	Six months ended June 30, 2016				
		Other comprehensive (income) loss before reclassification	Amounts reclassified to the income statement	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 share in losses of associated companies-net	\$ (376)	\$ (3)	\$ (379)	\$ 33	\$ (346)
Unrealized (gain) loss from available-for-sale securities	Loss on marketable securities, reclassified to financial expenses net	364	(98)	266	(1)	265
Unrealized (gain) loss from derivative financial instruments	Loss on derivative financial instruments reclassified to financial expenses - net	523	(2)	521		521
Unrealized (gain) loss on defined benefit plans	Loss on defined benefit plans, reclassified to various statement of income items***	*	*	*	*	*
<b>Total accumulated other comprehensive (income) loss</b>		<b>\$ 511</b>	<b>\$ (103)</b>	<b>\$ 408</b>	<b>\$ 32</b>	<b>\$ 440</b>

Components of accumulated other comprehensive loss	Description of the reclassification to the statements of income	Six months ended June 30, 2015				
		Other comprehensive (income) loss before reclassification	Amounts reclassified to the income statement	Net other comprehensive (income) loss	Corresponding income tax	Net other comprehensive (income) loss

		reclassifications of		before		after	
		income		tax		tax	
		U.S.\$ in millions					
Currency translation adjustment		\$ 685	\$	\$ 685	\$	\$ 685	\$ 685
Unrealized (gain) loss from available-for-sale securities	Loss on marketable securities, reclassified to impairments, restructuring and others	73	(105)	(32)	7	(25)	(25)
Unrealized (gain) loss from derivative financial instruments	Loss on derivative financial instruments**	(108)	(1)	(109)	*	(109)	(109)
Unrealized (gain) loss on defined benefit plans	Loss on defined benefit plans, reclassified to various statement of income items***	*	(2)	(2)	(2)	(4)	(4)
<b>Total accumulated other comprehensive (income) loss</b>		<b>\$ 650</b>	<b>\$ (108)</b>	<b>\$ 542</b>	<b>\$ 5</b>	<b>\$ 547</b>	<b>\$ 547</b>

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

\*\* \$26 million loss reclassified to financial expenses - net and \$25 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 to up to \$3 billion of its ordinary shares and American Depositary Shares. As of June 30, 2016, \$2.1 billion remained available for repurchases. This repurchase authorization has no time limit. Repurchases may be commenced or suspended at any time.

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

Teva did not repurchase any of its shares during the first half of 2016, and as of June 30, 2016 and December 31, 2015, Teva's treasury share balance amounted to 108 million shares.

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

	<b>Six months ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
	<b>in millions</b>	
Amount spent on shares repurchased	\$	\$ 439
Number of shares repurchased		7.7

**NOTE 8 Debt obligations**

Short-term debt is mainly comprised of current maturities of long term liabilities and convertible debentures.

Long-term debt includes the following:

	<b>Weighted average interest rate as of June 30, 2016</b>	<b>Maturity</b>	<b>December 31,</b>	
	<b>%</b>		<b>June 30, 2016</b>	<b>2015</b>
			<b>(U.S. \$ in millions)</b>	
Senior notes EUR 1,300 million	1.25%	2023	\$ 1,435	\$ 1,409
Senior notes EUR 1,000 million	2.88%	2019	1,111	1,092
Senior notes EUR 700 million	1.88%	2027	775	762
Senior notes USD 950 million	2.40%	2016	950	950
Senior notes USD 844 million	2.95%	2022	843	843
Senior notes USD 789 million	6.15%	2036	780	780
Senior notes USD 700 million	2.25%	2020	700	700
Senior notes USD 613 million	3.65%	2021	612	611
Senior notes USD 588 million	3.65%	2021	586	586
Senior notes CHF 450 million	1.50%	2018	459	455
Fair value hedge accounting adjustments			53	(10)
Total senior notes			8,304	8,178
Term loan JPY 65 billion	0.99%	2017	637	544

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

Term loan JPY 35 billion	1.42%	2019	340	290
Term loan JPY 35 billion	LIBOR +0.3%	2018	340	290
Other loans JPY 5 billion	1.67%	2016		39
<b>Total loans</b>			<b>1,317</b>	<b>1,163</b>
Debentures USD 15 million	7.20%	2018	15	15
Other	7.48%	2026	10	5
<b>Total debentures and others</b>			<b>25</b>	<b>20</b>
<b>Less current maturities</b>			<b>(1,587)</b>	<b>(989)</b>
Derivative instruments				11
<b>Less debt issuance cost*</b>			<b>(23)</b>	<b>(25)</b>
<b>Total long-term debt</b>			<b>\$ 8,036</b>	<b>\$ 8,358</b>

\* In accordance with FASB guidance, effective January 1, 2016, long-term debt is presented net of related debt issuance costs. Prior periods were adjusted to conform with the guidance.



**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****(Unaudited)****NOTE 9 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 June 30, 2016 and December 31, 2015 are classified in the tables below in one of the three categories described above:

	<b>June 30, 2016</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	\$ 254	\$	\$	\$ 254
Cash deposits and other	6,730			6,730
Investment in securities:				
Equity securities	1,128			1,128
Structured investment vehicles		97		97
Other	13		1	14
Derivatives:				
Asset derivatives - options and forward contracts		18		18
Asset derivatives - interest rate and cross currency		131		131
Liabilities derivatives - options and forward contracts		(33)		(33)
Liabilities derivatives - treasury locks and forward starting interest rate swaps		(174)		(174)
Contingent consideration*			(662)	(662)
Total	\$ 8,125	\$ 39	\$ (661)	\$ 7,503

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

	<b>December 31, 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>		
<b>Cash and cash equivalents:</b>				
Money markets	\$ 162	\$	\$	\$ 162
Cash deposits and other	6,784			6,784
<b>Investment in securities:</b>				
Equity securities	1,352			1,352
Structured investment vehicles		94		94
Other	11		1	12
<b>Derivatives:</b>				
Asset derivatives - options and forward contracts		25		25
Asset derivatives - interest rate, cross-currency and forward starting interest rate swaps		105		105
Liability derivatives - options and forward contracts		(11)		(11)
Liability derivatives - treasury locks, interest rate and forward starting interest rate swaps		(26)		(26)
Contingent consideration*			(812)	(812)
<b>Total</b>	<b>\$ 8,309</b>	<b>\$ 187</b>	<b>\$ (811)</b>	<b>\$ 7,685</b>

\* Contingent consideration represents either liabilities or assets recorded at fair value in connection with acquisitions. 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.



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

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

	<b>Six months ended</b>	
	<b>June 30, 2016</b>	<b>Year ended December 31, 2015</b>
	<b>U.S. \$ in millions</b>	
Fair value at the beginning of the period	\$ (811)	\$ (616)
Auction-rate securities realized		(13)
Additional contingent consideration resulting from:		
Eagle license		(128)
Gecko acquisition		(5)
Adjustments to provisions for contingent consideration:		
Labrys acquisition	(16)	(311)
Eagle license	(141)	(63)
MicroDose acquisition	(4)	(10)
Cephalon acquisition	(12)	(5)
NuPathe acquisition	122	(10)
Settlement of contingent consideration:		
Labrys acquisition	25	350
Eagle acquisition	22	
Cephalon acquisition	154	
Fair value at the end of the period	\$ (661)	\$ (811)

***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:

<b>Estimated fair value*</b>	
<b>June 30, 2016</b>	<b>December 31, 2015</b>
<b>U.S. \$ in millions</b>	

Senior notes included under long-term liabilities	\$ 7,687	\$ 7,305
Senior notes and convertible senior debentures included under short-term liabilities	1,605	1,778
<b>Total</b>	<b>\$ 9,292</b>	<b>\$ 9,083</b>

\* 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:

	<b>Fair value</b>	<b>Amortized cost</b>	<b>Gross unrealized holding gains</b>	<b>Gross unrealized holding losses</b>
	<b>U.S. \$ in millions</b>			
June 30, 2016	\$ 1,493	\$ 1,442	\$ 85	\$ 34
December 31, 2015	\$ 1,620	\$ 1,303	\$ 338	\$ 21

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

Venezuela has experienced hyperinflation in recent years. The government of Venezuela currently has two official exchange rates: the DIPRO rate of 10 bolivars per U.S. dollar (which replaced the CENCOEX rate of 6.3 in March 2016) and the DICOM rate, which fluctuates and is currently approximately 640 bolivars per U.S. dollar. In addition, remittance of cash outside of Venezuela is limited.

Following the announcement of the Venezuelan Central Bank and the Ministry for Banking and Finance of FX Regulation 35, effective March 10, 2016, the DIPRO rate was used to settle transactions involving the importation, manufacture and distribution of pharmaceutical products. Teva used the CENCOEX rate until March 2016 and then replaced it with the DIPRO rate to report its Venezuelan financial position, results of operations and cash flows, since it believes that the nature of its business operations in Venezuela, which include the importation, manufacture and distribution of pharmaceutical products, qualifies for the most preferential rates permitted by law.

As a result of the new regulation, Teva impaired its monetary balance sheet items as of March 31, 2016 using the new DIPRO rate (instead of the CENCOEX rate it previously used), with the net difference of \$246 million recorded in financial expenses net during the first quarter of 2016.

In the event of an additional devaluation or if a less favorable exchange rate is used, Teva would be exposed to further potential impairments of net monetary assets in Venezuela, which, as of June 30, 2016, amounted to approximately \$355 million.

**NOTE 10 Derivative instruments and hedging activities:**

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

	<b>June 30, 2016</b>	<b>December 31, 2015</b>
	<b>U.S. \$ in millions</b>	
Forward starting interest rate swap - cash flow hedge	\$ 3,750	\$ 3,500
Treasury lock - cash flow hedge	1,500	500
Interest rate swap - fair value hedge	1,294	1,294
Cross-currency swap - cash flow hedge	588	588

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to 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	
	June 30, 2016	December 31, 2015	June 30, 2016	December 31, 2015
	U.S. \$ in millions			
<b>Reported under</b>				
<b>Asset derivatives:</b>				
<b>Other current assets:</b>				
Forward starting interest rate swap - cash flow hedge	\$	\$ 26	\$	\$
Option and forward contracts			18	25
<b>Other non-current assets:</b>				
Cross-currency swaps - cash flow hedge	78	78		
Interest rate swaps - fair value hedge	53	1		
<b>Liability derivatives:</b>				
<b>Other current liabilities:</b>				
Forward starting interest rate swaps - cash flow hedge	(107)	(10)		
Treasury locks - cash flow hedge	(67)	(5)		
Option and forward contracts			(33)	(11)
<b>Senior notes and loans:</b>				
Interest rate swaps - fair value hedge		(11)		

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, losses of \$19 million and gains of \$12 million were recognized under financial expenses-net for the six months ended June 30, 2016 and 2015, respectively, and losses of \$33 million and \$14 million were recognized under financial expenses-net for the three months ended June 30, 2016 and 2015, 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 \$9 million and \$16 million were recognized under financial expenses-net for the six months ended June 30, 2016 and 2015, respectively and gains of \$4 million and \$7 million were recognized under financial expenses-net for the three months ended June 30, 2016 and 2015, respectively. Such gains mainly reflect the differences between the fixed interest rate and the floating interest rate.



Commencing the third quarter of 2015, Teva entered into forward starting interest rate swap and treasury lock agreements designated as cash flow hedges of the U.S. dollar debt issuance in July 2016, with respect to \$3.75 billion and \$1.5 billion notional amounts, respectively. These agreements hedged the variability in anticipated future interest payments due to possible changes in the benchmark interest rate between the date the agreements were entered into and the expected date of the U.S. dollar debt issuance in July 2016 (in connection with the closing of the Actavis Generics acquisition).

Certain of the forward starting interest rate swaps and treasury lock agreements matured during the first half of 2016, generating a loss of \$336 million due to a decline in interest rates. This loss is recorded in other comprehensive (income) loss. In July 2016, in connection with the debt issuances mentioned in note 3, Teva terminated all of the forward starting interest rate swaps and treasury lock agreements. Termination of these transactions generated a total loss of \$493 million, which includes the \$336 million loss mentioned above, and will be settled by October 7, 2016. Upon completion of the debt issuance and settlement of the swap and treasury lock agreements, the change in fair value of these instruments recorded as part of other comprehensive income will be amortized under financial expenses-net over the life of the debt.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****(Unaudited)****NOTE 11 Other expenses:**

Impairments, restructuring and others consisted of the following:

	Three months ended		Six months ended	
	June 30, 2016	2015	June 30, 2016	2015
	U.S. \$ in millions			
Impairments of long-lived assets	\$ 572	\$ 81	\$ 585	\$ 146
Acquisition expenses	34	132	58	133
Integration expenses	28		41	
Restructuring expenses	20	48	39	51
Contingent consideration		18	51	262
Other	58	6	57	(8)
<b>Total</b>	<b>\$ 712</b>	<b>\$ 285</b>	<b>\$ 831</b>	<b>\$ 584</b>

During the three months ended June 30, 2016, Teva recorded a \$258 million impairment of the full carrying value of Teva's in-process R&D asset Revasco<sup>®</sup> (mesenchymal precursor cells), following a decision to exercise a contractual right to terminate Teva's involvement with Mesoblast Ltd. in the ongoing phase 3 trial of Revasco<sup>®</sup> (mesenchymal precursor cell). In addition, Teva recorded a \$248 million impairment of the full carrying value of Zecuity<sup>®</sup>, partially offset by a reversal of \$122 million in related contingent consideration, following a decision to voluntarily suspend sales, marketing and distribution of Zecuity<sup>®</sup>. Teva also recorded an increase of \$104 million in contingent consideration related to Bendeka<sup>™</sup>, due to a change in the future sales outlook following a court decision delaying generic competition in Treanda<sup>®</sup>.

**NOTE 12 Legal settlements and loss contingencies:**

Legal settlements and loss contingencies for the six months ended June 30, 2016 amounted to \$141 million primarily due to a settlement in principle reached in connection with a patent litigation matter, compared to \$611 million for the six months ended June 30, 2015. The expenses in 2015 consisted mainly of additional reserves relating to the settlement of the modafinil antitrust litigation, partially offset by insurance proceeds relating to the settlement of the pantoprazole patent litigation.

**NOTE 13 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.

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 flows 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.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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.

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 sued Teva in New Jersey federal court for infringement of patents that

expire in March 2023 and March 2027. On January 20, 2016, the court issued an order granting summary judgment on the grounds that Teva's generic product does not infringe Otsuka's patent directed to using aripiprazole in combination with certain anti-depressants. Otsuka appealed this order. In July 2016, Teva and Otsuka agreed in principle to settle this litigation, and a provision for the settlement was recorded in the financial statements for this quarter.

***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.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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 long-term 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 this dismissal. On April 11, 2016, the New Jersey Supreme Court heard oral argument on 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. In the Philadelphia and California proceedings, the parties are working with the coordinating judges to identify potential representative cases that would go to trial initially, in order to determine the possibility of settlement of the various proceedings.

***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.

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 its Provigil® 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 ).

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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. (collectively, these cases are referred to as the Philadelphia Modafinil Action ). Separately, Apotex challenged Cephalon's Provigil patent, and in October 2011, the Court found the patent to be invalid and unenforceable based on inequitable conduct. This decision was affirmed on appeal in April 2013. Teva has either settled or reached agreements in principle to settle with all of the plaintiffs in the Philadelphia Modafinil Action.

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 (the FTC Modafinil Action ).

In addition to the Philadelphia Modafinil Action and the FTC Modafinil Action, the City of Providence, Rhode Island, the State of Louisiana and United Healthcare have also filed lawsuits against Cephalon and other Teva subsidiaries. Teva has reached an agreement in principle with the City of Providence, and won its motion to dismiss against the State of Louisiana. Cephalon and other Teva subsidiaries have also received notices of potential claims related to the Provigil® settlement agreements by certain other claimants. 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.

On May 28, 2015, Cephalon entered into a consent decree with the FTC under which the FTC dismissed its claims against Cephalon in the FTC Modafinil Action in exchange for payment of \$1.2 billion (less set-offs for prior settlements) by Cephalon and Teva into a settlement fund. 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 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.

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 Commission has indicated to Teva that it intends to issue a statement that will specify the initial findings of the investigation.

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 concerning the antibiotic Cipro 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. While an appeal was pending before the California Supreme Court, the trial court approved a \$74 million class settlement with Bayer. On May 7, 2015, the California Supreme Court reversed and remanded the case back to the trial court for a rule of reason inquiry as to the remaining defendants, including Barr. A trial has been scheduled for October 2016. Based on the plaintiffs' expert testimony in the California case, estimated sales of ciprofloxacin in California were approximately \$500 million during the alleged damages period.

In the Kansas Cipro action, the court granted preliminary approval of the settlement Bayer entered into with plaintiffs on June 5, 2015. On July 22, 2015, Barr and the remaining co-defendants also agreed to settle with the plaintiffs; the court granted final approval of the settlement on June 6, 2016. The Florida case has been administratively closed by the court.

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. The appeal has been fully briefed and oral argument is expected to be heard in the fall of 2016. 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.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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. On February 19, 2016, Teva and GSK filed a petition for a writ of certiorari in the United States Supreme Court, which remains pending. On June 6, 2016, the Supreme Court invited the Solicitor General of the United States to file a brief expressing the government's views on the pending petition. Litigation has resumed in the district court in both the direct purchaser and indirect purchaser actions. Teva and GSK filed a motion for judgment on the pleadings in the indirect purchaser action on December 28, 2015, which the District Court granted in part and denied in part on March 22, 2016. The plaintiffs moved the District Court to reconsider that ruling, but the motion was denied. 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.

On June 18, 2014, two groups of end payors sued AstraZeneca and Teva, as well as Ranbaxy and Dr. Reddy's, in the Philadelphia Court of Common Pleas for violating the antitrust laws by entering into settlement agreements to resolve the esomeprazole (generic Nexium®) patent litigation (the Philadelphia Esomeprazole Actions). These end payors had opted out of a class action that was filed in the Massachusetts federal court in September 2012 and resulted in a jury verdict in December 2014 in favor of AstraZeneca and Ranbaxy (the Massachusetts Action). Prior to the jury verdict, Teva settled with all plaintiffs for \$24 million. The allegations in the Philadelphia Esomeprazole Actions are nearly identical to those in the Massachusetts Action. The Philadelphia Esomeprazole Actions are stayed pending resolution of the Massachusetts Action, which is currently on appeal to the First Circuit with respect to the claims against the nonsettling defendants AstraZeneca and Ranbaxy.

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, April and December 2015 and in January 2016, 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<sup>®</sup> 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<sup>®</sup> (dipyridamole/aspirin tablets) against Boehringer Ingelheim ( BI ), the innovator, and several Teva subsidiaries. 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<sup>®</sup> 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<sup>®</sup> in July 2015.

---

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

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<sup>®</sup> and ACTO *plus* Met<sup>®</sup> (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, and on March 22, 2016, a stipulation was filed dismissing Teva and the other generic defendants from the appeal. 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, the direct purchaser plaintiffs amended their complaint. Defendants have moved to dismiss that complaint. The case against the direct purchasers has been stayed pending resolution of the appeal filed by the end payors. At the time of the settlement, annual sales of ACTOS<sup>®</sup> were approximately \$3.7 billion and annual sales of ACTO *plus* 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 ACTO *plus* 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.

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. Defendants have moved to dismiss the claims made by the end payors. 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.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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 court has notified the parties that it will issue an order regarding the case by August 17, 2016. 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 United States 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 dismissed without prejudice in September 2015, with the court finding that the state was not a proper plaintiff. The state has appealed this decision.

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 court granted Cephalon's motion to dismiss the Fentora claims and denied Cephalon's motion to dismiss the Treanda<sup>®</sup> claims. On May 9, 2016, Cephalon filed a motion to limit the fact discovery period to pre-December 2012 because of the lack of factual specificity regarding ongoing conduct in the relator's complaint. Discovery is ongoing in this matter. 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 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 relator's Provigil<sup>®</sup> claims. On February 2, 2016, the District Court granted Cephalon's motion for judgment on the pleadings as to Provigil<sup>®</sup> claims that allegedly occurred prior to February 28, 2008. The relator's motion for reconsideration was denied without prejudice. On May 9, 2016, the relator filed a motion seeking an extension of the claims period through the time of

trial and requesting the District Court to permit fact discovery for the period after March 2014.

In May 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 improper marketing of opioids, including Actiq® and Fentora®. In June 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 improper marketing 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. In the California action, in August 2015, the Court granted the defendants' demurrer, or motion to dismiss, on primary jurisdiction grounds and the case has been stayed. In June 2016, the counties in the California action filed a motion to lift the stay and a motion for leave to file a third amended complaint. Defendants filed oppositions to those motions on July 1, 2016. In the Chicago action, all claims against Teva and Cephalon were dismissed without prejudice. In August 2015, the City of Chicago filed a second amended complaint and defendants have filed motions to dismiss the second amended complaint. The City filed its opposition to the motion to dismiss on February 18, 2016, and the defendants replied on April 15, 2016.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

In December 2015, the Mississippi Attorney General filed a lawsuit against Teva Pharmaceuticals USA, Inc. ( Teva USA ) and Cephalon along with the same defendants named in the California and Chicago actions described above. The Mississippi complaint is similar to the California and Chicago complaints, asserts claims under Mississippi state law based upon alleged improper marketing of opioids, including Actiq® and Fentora®, and seeks a variety of damages including restitution, civil penalties, disgorgement of profits, treble damages, attorneys fees and injunctive relief. The complaint does not specify the exact amount of damages at issue. Teva USA and Cephalon, along with the co-defendants named in the action, filed joint and individual motions to dismiss on March 8, 2016. The State filed its opposition to the various motions to dismiss on June 16, 2016. The defendants filed replies in support of the motions to dismiss on July 28, 2016.

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. On February 22, 2016, the Court stayed its decision on the relators claims based on state and local laws, denied Teva s motions to dismiss the False Claims Act claims, and instructed the relators to amend their complaint with additional information. On March 23, 2016, the relators filed an amended complaint. On April 11, 2016, Teva filed an answer. The case is proceeding to discovery. No trial date has been scheduled.

On June 21, 2015, Teva USA received a subpoena from the Antitrust Division of the United States Department of Justice seeking documents and other information relating to the marketing and pricing of certain of Teva USA s generic products and communications with competitors about such products. On July 12, 2016, Teva USA received a subpoena from the Connecticut Attorney General seeking documents and other information relating to potential state antitrust law violations. Teva is cooperating fully with these requests.

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 substantially complete, Teva has identified certain business practices and transactions in Russia, certain European countries, 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.

***Environmental Matters***

Teva and some of its subsidiaries are 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.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

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 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 14 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, 2015.

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.

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.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to 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 six months ended June 30, 2016 and 2015:

	Generics		Specialty	
	Three months ended June 30,		Three months ended June 30,	
	2016	2015	2016	2015
	U.S.\$ in millions		U.S.\$ in millions	
Revenues	\$ 2,294	\$ 2,466	\$ 2,271	\$ 2,090
Gross profit	1,072	1,198	1,978	1,808
R&D expenses	125	134	245	220
S&M expenses	333	335	478	457
Segment profit	\$ 614	\$ 729	\$ 1,255	\$ 1,131

	Generics		Specialty	
	Six months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
	U.S.\$ in millions		U.S.\$ in millions	
Revenues	\$ 4,464	\$ 5,087	\$ 4,423	\$ 4,046
Gross profit	2,071	2,482	3,849	3,486
R&D expenses	261	245	474	435
S&M expenses	612	709	935	943
Segment profit	\$ 1,198	\$ 1,528	\$ 2,440	\$ 2,108

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
	U.S.\$ in millions			
Generic medicines profit	\$ 614	\$ 729	\$ 1,198	\$ 1,528
Specialty medicines profit	1,255	1,131	2,440	2,108
Total segment profit	1,869	1,860	3,638	3,636

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

Profit of other activities	13	56	64	106
<b>Total profit</b>	<b>1,882</b>	<b>1,916</b>	<b>3,702</b>	<b>3,742</b>
Amounts not allocated to segments:				
Amortization	193	214	382	434
General and administrative expenses	311	325	615	632
Impairments, restructuring and others	712	285	831	584
Legal settlements and loss contingencies	166	384	141	611
Other unallocated amounts	139	46	207	70
Consolidated operating income	361	662	1,526	1,411
<b>Financial expenses - net</b>	<b>105</b>	<b>41</b>	<b>403</b>	<b>233</b>
Consolidated income before income taxes	\$ 256	\$ 621	\$ 1,123	\$ 1,178

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**  
**Notes to Consolidated Financial Statements (Continued)**  
**(Unaudited)**

**Segment revenues by geographic area:**

	Three months ended		Six months ended	
	June 30,		June 30,	
	2016	2015	2016	2015
	U.S.\$ in millions			
<b>Generic Medicines</b>				
United States	\$ 892	\$ 1,326	\$ 1,868	\$ 2,765
Europe*	660	665	1,331	1,345
Rest of the World	742	475	1,265	977
<b>Total Generic Medicines</b>	<b>2,294</b>	<b>2,466</b>	<b>4,464</b>	<b>5,087</b>
<b>Specialty Medicines</b>				
United States	1,772	1,622	3,449	3,101
Europe*	414	378	808	783
Rest of the World	85	90	166	162
<b>Total Specialty Medicines</b>	<b>2,271</b>	<b>2,090</b>	<b>4,423</b>	<b>4,046</b>
<b>Other Revenues</b>				
United States	3	4	7	7
Europe*	165	157	335	339
Rest of the World	305	249	619	469
<b>Total Other Revenues</b>	<b>473</b>	<b>410</b>	<b>961</b>	<b>815</b>
<b>Total Revenues</b>	<b>\$ 5,038</b>	<b>\$ 4,966</b>	<b>\$ 9,848</b>	<b>\$ 9,948</b>

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

**Net revenues from specialty medicines:**

	Three months ended		Six months ended	
	June 30,		June 30,	
	2016	2015	2016	2015
	U.S. \$ in millions			

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

CNS	\$ 1,415	\$ 1,353	\$ 2,738	\$ 2,573
Copaxone®	1,141	1,054	2,147	1,978
Azilect®	108	105	221	212
Nuvigil®	51	91	154	176
Respiratory	313	253	679	518
ProAir®	135	128	308	252
QVAR®	116	83	250	181
Oncology	334	293	602	557
Treanda® and Bendeka	207	179	362	336
Women s health	117	110	227	239
Other Specialty	92	81	177	159
Total Specialty Medicines	\$ 2,271	\$ 2,090	\$ 4,423	\$ 4,046

A significant portion of Teva s revenues, and a higher proportion of the profits, come from the manufacture and sale of patent-protected pharmaceuticals. Many of Teva s 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, Teva 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 Teva s results of operations and financial condition.

**Table of Contents**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

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

**(Unaudited)**

In particular, Teva relies heavily on sales of Copaxone<sup>®</sup>, its leading specialty medicine. A key element of Teva's business strategy for Copaxone<sup>®</sup> is maintaining patients on the three-times-a-week 40 mg/mL version introduced in 2014, and protecting its patents for the 40 mg/mL version. Any substantial reduction in the number of patients taking Copaxone<sup>®</sup>, whether due to increased use of oral medicines or other competing products, including competing 20 mg/mL generic products (with one generic version introduced in the U.S. in 2015 and one approved in Europe in 2016), would likely have a material adverse effect on Teva's financial results and cash flow.

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 inter parties review proceedings in the United States, and a fourth U.S. Orange Book patent expiring in 2030 that was issued in October 2015. This fourth patent is also being challenged in paragraph IV litigation, and it is the subject of a pending petition for post grant review at the patent office. A hearing was held in the inter parties review proceedings on May 12, 2016 and decisions are expected for two of the patents no later than August 25, 2016, and the decision for the third patent is expected no later than September 1, 2016. The decision on whether the patent office will institute a post grant review of the fourth patent is expected no later than August 24, 2016. The product is also protected by one European patent expiring in 2030, the validity of which was confirmed by the European Patent Office in December 2015, which rejected all invalidity claims.

For the six months ended June 30, 2016, 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 products, amounted to \$1.8 billion (approximately 33% of U.S. revenues) and Copaxone<sup>®</sup> revenues outside the United States amounted to \$371 million (approximately 8% 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 \$1.7 billion for the six months ended June 30, 2016, compared to \$1.5 billion for the six months ended June 30, 2015. The profit of the multiple sclerosis franchise is comprised of Copaxone<sup>®</sup> revenues and cost of goods sold as well as S&M and R&D expenses related to the MS franchise. It does not include G&A expenses, amortization and non-recurring items. The profit of the multiple sclerosis franchise as a percentage of Copaxone<sup>®</sup> revenues was 80.7% for the six months ended June 30, 2016 and 75.6% for the six months ended June 30, 2015.



---

**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® (which faces competition from orally-administered alternatives and a generic version); our ability to integrate the acquisition of Actavis Generics and to realize the anticipated benefits of such acquisition (and the timing of realizing such benefits); the fact that following the consummation of the Actavis Generics acquisition, we are dependent to a much larger extent than previously on our generic pharmaceutical business; potential restrictions on our ability to engage in additional transactions or incur additional indebtedness as a result of the substantial amount of debt we incurred to finance the Actavis Generics acquisition; the fact that for a period of time following the consummation of the Actavis Generics acquisition, we will have significantly less cash on hand than previously, which could adversely affect our ability to grow; 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 investments in our pipeline of specialty and other products; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; 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; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; 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 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, 2015 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, 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 a world leading pharmaceutical company, 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 over-the-counter ( OTC ) medicines.

## **Table of Contents**

We believe that our dedicated leadership and employees, world-leading generics expertise and portfolio, focused specialty portfolio, global reach, robust 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 OTC joint venture with P&G.

## **Highlights**

Significant highlights of the second quarter of 2016 included:

Our revenues amounted to \$5.0 billion, up 1%, or 4% in local currency terms, compared to the second quarter of 2015.

Our generic medicines segment generated revenues of \$2.3 billion and profit of \$614 million. Revenues decreased 7%, or 4% in local currency terms. Profit decreased 16% compared to the second quarter of 2015. Our lower revenues and profit in the second quarter of 2016 were mainly due to loss of exclusivity on certain products as well as increased competition on other products.

Our specialty medicines segment generated revenues of \$2.3 billion and profit of \$1.3 billion. Revenues increased 9% in both U.S dollar and local currency terms. Profit was up 11%, compared to the second quarter of 2015, mainly due to higher revenues.

Expenses related to impairments, restructuring and others amounted to \$712 million in the second quarter of 2016, mainly due to impairments of Revascor<sup>®</sup> and Zecuity<sup>®</sup>, compared to \$285 million in the second quarter of 2015.

Legal settlements and loss contingencies amounted to \$166 million in the second quarter of 2016, primarily related to a settlement in principle of a patent litigation matter, compared to \$384 million in the second quarter of 2015, which primarily related to the modafinil settlement.

Operating income amounted to \$361 million, compared to \$662 million in the second quarter of 2015. The decrease was mainly due to higher impairments, restructuring and others expenses and lower profit of our generic segment, partially offset by lower legal settlements and loss contingencies and higher profit of our specialty medicines segment.

Net income attributable to Teva was \$254 million in the second quarter of 2016, compared to \$539 million in the second quarter of 2015.

Net income attributable to ordinary shareholders was \$188 million in the second quarter of 2016.

Exchange rate differences between the second quarter of 2016 and the second quarter of 2015 had a negative impact of \$141 million on revenues and a net negative impact of \$55 million on operating income.

Cash flow generated from operating activities during the second quarter of 2016 amounted to \$963 million, compared to \$1.5 billion in the second quarter of 2015.

In anticipation of the closing of the Actavis Generics acquisition, in July 2016, we completed debt issuances for an aggregate principal amount of \$20.4 billion, or \$20.3 billion net proceeds, consisting of senior notes with aggregate principal amounts of \$15 billion, 4 billion and CHF 1 billion and maturities of two to 30 years. The effective average interest rate of the newly issued notes is 2.32 % per annum.

**Table of Contents****Acquisition of Anda**

On August 3, 2016, we entered into a definitive agreement with Allergan plc to purchase Anda Inc., the fourth largest distributor of generic pharmaceuticals in the United States, for cash consideration of \$500 million. Closing of this transaction is expected in 2016, subject to antitrust approval and satisfaction of other customary conditions.

**Acquisition of Actavis Generics**

On August 2, 2016, we consummated our acquisition of Allergan plc's worldwide generic pharmaceuticals business. At closing, we paid consideration of approximately \$33.4 billion in cash and approximately 100.3 million Teva shares issued to Allergan. We financed the cash portion of the acquisition with approximately \$8.1 billion from cash on hand, including from our December 2015 equity offerings, and borrowing under our syndicated revolving line of credit, \$20.3 billion net proceeds from our senior note offerings in July 2016 and \$5 billion under our term loan facility.

We expect to divest products with aggregate revenues in 2015 of approximately \$1.1 billion in connection with the acquisition.

The acquisition significantly expands our product portfolio, R&D capabilities and product pipeline, and our operational network around the world and is expected to result in greater efficiencies and to open new possibilities in both generics and specialty medicines. As a result of the acquisition, the proportion of our revenues attributable to our generics business is expected to increase from less than half to nearly two-thirds, and accordingly we will be more reliant on that business and market, regulatory and other factors affecting that business. Following the closing, we have approximately 338 product registrations pending FDA approval and approximately 115 pending first-to-file ANDAs in the United States. In Europe, we will have a pipeline of over 5,000 expected launches. In our ROW markets, we now have approximately 600 pending product approvals.

**Results of Operations****Comparison of Three Months Ended June 30, 2016 to Three Months Ended June 30, 2015**

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.

	Percentage of Net Revenues Three Months Ended		Percentage Change 2016-2015
	June 30,		
	2016	2015	%
Net revenues	100.0	100.0	1
Gross profit	57.1	58.4	(1)
Research and development expenses	7.4	7.8	(3)
Selling and marketing expenses	18.9	17.3	11
General and administrative expenses	6.2	6.5	(4)
Impairments, restructuring and others	14.1	5.7	150
Legal settlements and loss contingencies	3.3	7.8	(57)

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

Operating income	7.2	13.3	(45)
Financial expenses - net	2.1	0.8	156
Income before income taxes	5.1	12.5	(59)
Income taxes	0.6	1.8	(67)
Share in losses of associated companies - net	(0.3)	(0.1)	150
Net loss attributable to non-controlling interests	(0.2)	*	
Net income attributable to Teva	5.0	10.8	(53)
Dividends on preferred shares	1.3		n/a
Net income attributable to ordinary shareholders	3.7	10.8	(65)

\* Represents an amount less than 0.05%.

**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 June 30, 2016 and 2015:

	<b>Three Months Ended June 30,</b>			
	<b>2016</b>		<b>2015</b>	
	<b>U.S.\$ in millions / % of Segment Revenues</b>			
Revenues	\$ 2,294	100.0%	\$ 2,466	100.0%
Gross profit	1,072	46.7%	1,198	48.6%
R&D expenses	125	5.4%	134	5.4%
S&M expenses	333	14.5%	335	13.6%
Segment profit*	\$ 614	26.8%	\$ 729	29.6%

\* 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 14 to our consolidated financial statements and **Operating Income** below for additional information.

As noted above, our generic medicines segment will expand significantly following the closing of our acquisition of Actavis Generics on August 2, 2016.

***Generic Medicines Revenues***

Our generic medicines segment includes generic medicines as well as API sales to third parties. In the second quarter of 2016, revenues from our generic medicines segment amounted to \$2.3 billion, a decrease of \$172 million, or 7%, compared to the second quarter of 2015. In local currency terms, revenues decreased 4%.

Revenues of generic medicines in the United States, our largest generic market, amounted to \$892 million in the second quarter of 2016, a decrease of 33% compared to the second quarter of 2015. Revenues of generic medicines in Europe amounted to \$660 million, a decrease of 1% compared to the second quarter of 2015 in both U.S. dollar and local currency terms. Revenues of generic medicines in our ROW markets amounted to \$742 million, an increase of 56% compared to the second quarter of 2015. In local currency terms, our ROW revenues increased 71% compared to the second quarter of 2015.

API sales to third parties in the second quarter of 2016 amounted to \$207 million, an increase of 13%, compared to the second quarter of 2015. In local currency terms, sales increased 12%, mainly due to an increase in sales in Europe and in the United States, partially offset by a decrease in our ROW markets.

The following table presents generic segment revenues by geographic area for the three months ended June 30, 2016 and 2015:

	<b>Three Months Ended June 30,</b>		<b>Percentage Change</b>
	<b>2016</b>	<b>2015</b>	<b>2016 - 2015</b>
	<b>U.S. \$ in millions</b>		
United States	\$ 892	\$ 1,326	(33%)
Europe*	660	665	(1%)
Rest of the World	742	475	56%
Total Generic Medicines	\$ 2,294	\$ 2,466	(7%)

\* 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 second quarter of 2016, we continued to lead the U.S. generic market in total prescriptions and new prescriptions, with approximately 446 million total prescriptions, representing 12.1% of total U.S. generic prescriptions. We seek to continue our U.S. market leadership based on our ability to introduce 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, the breadth of our product line, our commitment to quality and regulatory compliance and our cost-effective production, including through our recent acquisition of Actavis Generics, which will substantially expand our generics operations and pipeline.

Revenues from generic medicines in the United States during the second quarter of 2016 amounted to \$892 million, a decrease of \$434 million, or 33%, compared to the second quarter of 2015. The decrease resulted mainly from the loss of exclusivity on aripiprazole (the generic equivalent of Abilify®) and esomeprazole (the generic equivalent of Nexium®) as well as a decline in sales of budesonide (the generic equivalent of Pulmicort®), capecitabine (the generic equivalent of Xeloda®) and omega-3-acid ethyl esters (the generic equivalent of Lovaza®), due to increased competition.

Among the most significant generic products we sold in the United States in the second quarter of 2016 were generic versions of Pulmicort® (budesonide inhalation), Adderall XR® (mixed amphetamine salts ER) and Abilify® (aripiprazole tablets).

**Launches.** In the second quarter of 2016, we launched generic versions of the following branded products in the United States (listed by month of launch):

Generic Name	Brand Name	Month of Launch	Total Annual U.S. Market at Time of Launch \$ millions (IMS)*
Octreotide acetate injection 100 mcg/mL, 100 mcg, 200 mcg/mL, 1000 mcg, 500 mcg/mL, 500 mcg & 1000 mcg/mL, 5000 mcg**	Sandostatin®	May	\$ 44
Fluvastatin sodium extended-release tablets 80 mg	Lescol® XL	June	\$ 31
Budesonide capsules (enteric coated) 3 mg	Entocort® EC	June	\$ 343

\* The figures given are for the twelve months ended in the calendar quarter closest to our 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 July 12, 2016, had 102 product registrations awaiting FDA approval, including 32 tentative approvals. Collectively, these 102 products had U.S. sales in the twelve months ended March 31, 2016 exceeding \$74 billion. Of these applications, 71 were Paragraph IV applications challenging patents of branded products. We believe we are first to file with respect to 32 of these products, the branded versions of which had U.S. sales of more than \$34 billion in the twelve months ended March 31, 2016. As a result of the Actavis Generics acquisition, we have approximately 338

product registrations pending FDA approval and approximately 115 pending first-to-file ANDAs in the United States.

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 second quarter of 2016, we received tentative approval for generic equivalents 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.

**Table of Contents**

<b>Generic Name</b>	<b>Brand Name</b>	<b>Total U.S. Annual Branded Market</b>	
		<b>\$</b>	<b>millions (IMS)*</b>
Pemetrexed disodium injection 500 mg	Alimta®	\$	967
Ranolazine extended release tablets, 500 mg & 1000 mg	Ranexa®	\$	725
Olmesartan medoxomil, amlodipine besylate and hydrochlorothiazide tablets 20/5/12.5, 40/5/12.5, 40/5/25, 40/10/12.5 & 40/10/25 mg	Tribenzor®	\$	236
Ezetimibe and simvastatin tablets 10/80, 10/10, 10/20 & 10/40 mg	Vytorin®	\$	702
Vilazodone tablets 10mg, 20mg & 40mg	Viibryd®	\$	320

\* The figures given are for the twelve months ended in the calendar quarter closest to the receipt of tentative approval.

**Europe Generic Medicines Revenues**

We define our 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 second quarter of 2016 amounted to \$660 million, a decrease of 1% in both U.S. dollar and local currency terms, compared to the second quarter of 2015, mainly as a result of decreases in generic medicine sales in the United Kingdom and Germany, largely offset by higher API sales to third parties and generic medicine sales in Switzerland, Italy and Spain.

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, we received 506 generic approvals in Europe relating to 52 compounds in 113 formulations. In addition, we had 1,501 marketing authorization applications pending approval in 31 European countries, relating to 160 compounds in 345 formulations, including four applications pending with the European Medicines Agency (EMA).

Listed below are generic revenues highlights for the second quarter of 2016 in our main European markets:

**Germany:** Generic revenues in the second quarter of 2016 decreased 3%, or 4% in local currency terms, compared to the second quarter of 2015. The decrease in local currency terms was due to reduced prices and lower volumes. We maintained our position as one of Germany's leading suppliers of medicines and our position as the second largest generic pharmaceutical company.

**United Kingdom:** Generic revenues in the second quarter of 2016 decreased 9%, or 3% in local currency terms, compared to the second quarter of 2015. The decrease in local currency terms was mainly due to lower prices as a result of increased competition. We maintained our position as one of the largest generic pharmaceutical companies in the U.K.

**Italy:** Generic revenues in the second quarter of 2016 increased 7%, or 5% in local currency terms, compared to the second quarter of 2015. The increase in local currency terms was mainly due to new product launches and increased volumes, mainly related to market growth.

**Switzerland:** Generic revenues in the second quarter of 2016 increased 9%, or 12% in local currency terms, compared to the second quarter of 2015. The increase in local currency terms was mainly due to new product launches and higher volumes related to higher market share and market growth.

**France:** Generic revenues in the second quarter of 2016 increased 2%. In local currency terms, revenues were flat compared to the second quarter of 2015.

**Spain:** Generic revenues in the second quarter of 2016 increased 5%, or 3% in local currency terms, compared to the second quarter of 2015. The increase was mainly due to increased market share as a consequence of the implementation of new commercial policies to adapt to regulatory changes.

**Table of Contents**

***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 Venezuela, 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 generic markets such as Russia, certain Commonwealth of Independent States markets and Latin American markets.

In our ROW markets, generics revenues in the second quarter of 2016 amounted to \$742 million, an increase of 56% compared to the second quarter of 2015. In local currency terms, revenues increased 71%, mainly due to higher revenues principally in Japan, Venezuela and Canada.

Listed below are generic revenues highlights for the second quarter of 2016 in our main ROW markets:

**Venezuela:** Generic revenues in the second quarter of 2016 increased 69%, or 169% in local currency terms, compared to the second quarter of 2015, primarily due to inflation. Venezuela is a hyperinflationary economy with two official exchange rates: the DIPRO rate of 10 bolivars per U.S. dollar (which replaced the CENCOEX rate of 6.3 in March 2016) and the DICOM rate, which fluctuates and is currently approximately 640 bolivars per U.S. dollar. We used the CENCOEX rate until March 2016 and then replaced it with the DIPRO rate to report our Venezuelan financial position, results of operations and cash flows. In the event of an additional devaluation or if a less favorable exchange rate is used, our revenues in Venezuela would be substantially reduced. For further information, see below under [Impact of Currency Fluctuations on Results of Operations](#).

**Japan:** Generic revenues in the second quarter of 2016 increased 118%, or 95% in local currency terms compared to the second quarter of 2015. The increase in local currency terms was mainly due to our new business venture with Takeda, which commenced operations in April 2016. The Japanese generics market as a whole is expected to grow, bolstered by government incentives to increase generic penetration.

**Canada:** Generic revenues in the second quarter of 2016 increased 98%, or 108% in local currency terms, compared to the second quarter of 2015. The increase was mainly due to a legal settlement related to pricing of a product sold in previous years, volume increase and increased revenues from distribution arrangements. We maintained our position as one of the two leading generic pharmaceutical companies in Canada.

**Russia:** Generic revenues in the second quarter of 2016 decreased 16%, but increased 3% in local currency terms, compared to the second quarter of 2015. The increase in local currency terms was mainly attributable to inflation-related price increases. We maintained our position as one of the leading generic pharmaceutical companies in Russia.

***Generic Medicines Gross Profit***

In the second quarter of 2016, gross profit from our generic medicines segment amounted to \$1.1 billion, a decrease of \$126 million, or 11%, compared to the second quarter of 2015. In local currency terms, gross profit decreased 7%.

The lower gross profit was mainly a result of loss of exclusivity on certain products as well as increased competition on other products in the United States (as described above) and higher production expenses, partially offset by higher gross profit of our ROW markets, higher gross profit of our API business and higher gross profit of our European markets.

Gross profit margin for our generic medicines segment in the second quarter of 2016 decreased to 46.7%, from 48.6% in the second quarter of 2015.

The decrease in gross profit margin was mainly a result of higher production expenses (6.0 points) and lower profitability of our U.S. market (3.3 points), partially offset by higher profitability of our ROW markets (5.1 points), higher profitability of our API business (2.6 points) and higher profitability of our European markets (0.6 points).

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

R&D expenses relating to our generic medicines segment for the second quarter of 2016 amounted to \$125 million, compared to \$134 million in the second quarter of 2015. Expenses decreased 7%, or 6% in local currency terms. As a percentage of segment revenues, R&D expenses were 5.4% in the second quarter of 2016, flat compared to the second quarter of 2015.

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.

**Table of Contents****Generic Medicines S&M Expenses**

S&M expenses related to our generic medicines segment in the second quarter of 2016 amounted to \$333 million, a decrease of 1% compared to \$335 million in the second quarter of 2015. In local currency terms, S&M expenses increased 7%, mainly due to our ROW markets, particularly as a result of our acquisition of Rimsa in the first quarter of 2016 and the launch of our Takeda business venture.

As a result, as a percentage of segment revenues, S&M expenses increased to 14.5% in the second quarter of 2016 compared to 13.6% in the second quarter of 2015.

**Generic Medicines Profit**

The profit of our generic medicines segment is comprised of the gross profit for the segment less S&M expenses and R&D expenses related to this segment. Segment profit does not include G&A expenses, amortization and certain other items. See note 14 to our consolidated financial statements and **Operating Income** below for additional information.

Profit of our generic medicines segment amounted to \$614 million in the second quarter of 2016, compared to \$729 million in the second quarter of 2015. The decrease was mainly due to factors previously discussed, primarily lower gross profit.

Generic medicines profit as a percentage of generic medicines revenues was 26.8% in the second quarter of 2016, down from 29.6% in the second quarter of 2015. This decrease of 2.8 points was due to lower gross margin (1.9 points), as well as higher S&M expenses as a percentage of revenues (0.9 points).

**Specialty Medicines Segment**

Our specialty medicines business, which is focused on providing innovative solutions for patients and providers through medicines, devices and services in key regions and markets around the world, includes our core therapeutic areas of CNS (with a strong emphasis on MS, neurodegenerative disorders, movement disorders and pain care) and respiratory medicines (with a focus on asthma and chronic obstructive pulmonary disease). We also have specialty products in oncology, women's health and selected other areas.

The following table presents revenues, expenses and profit for our specialty medicines segment for the three months ended June 30, 2016 and 2015:

	<b>Three Months Ended June 30,</b>			
	<b>2016</b>		<b>2015</b>	
	<b>U.S.\$ in millions / % of Segment</b>			
	<b>Revenues</b>			
Revenues	\$ 2,271	100.0%	\$ 2,090	100.0%
Gross profit	1,978	87.1%	1,808	86.5%
R&D expenses	245	10.8%	220	10.5%
S&M expenses	478	21.0%	457	21.9%
Segment profit*	\$ 1,255	55.3%	\$ 1,131	54.1%

\* 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 14 to our consolidated financial statements and **Operating Income** below for additional information.

***Specialty Medicines Revenues***

Specialty medicines revenues in the second quarter of 2016 amounted to \$2.3 billion, an increase of 9% in both U.S. dollar and local currency terms compared to the second quarter of 2015. In the United States, our specialty medicines revenues were \$1.8 billion, an increase of 9% compared to the second quarter of 2015. Specialty medicines revenues in Europe were \$414 million, an increase of 10%, or 9% in local currency terms, compared to second quarter of 2015. ROW revenues were \$85 million, a decrease of 6%, or an increase of 5% in local currency terms, compared to the second quarter of 2015.



**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 June 30, 2016 and 2015:

	<b>Three Months Ended</b>		<b>Percentage Change</b>
	<b>June 30,</b>		
	<b>2016</b>	<b>2015</b>	<b>2016 - 2015</b>
	<b>U.S. \$ in millions</b>		
CNS	\$ 1,415	\$ 1,353	5%
Copaxone®	1,141	1,054	8%
Azilect®	108	105	3%
Nuvigil®	51	91	(44%)
Respiratory	313	253	24%
ProAir®	135	128	5%
QVAR®	116	83	40%
Oncology	334	293	14%
Treanda® and Bendeka	207	179	16%
Women s Health	117	110	6%
Other Specialty	92	81	14%
<b>Total Specialty Medicines</b>	<b>\$ 2,271</b>	<b>\$ 2,090</b>	<b>9%</b>

**Central Nervous System**

Our CNS specialty product line includes Copaxone®, Azilect®, Nuvigil®, Fentora®, Amrix® and several other medicines. In the second quarter of 2016, our CNS sales were \$1.4 billion, an increase of 5% compared to the second quarter of 2015, primarily due to higher revenues of Copaxone®, which were partially offset by lower sales of Nuvigil®.

**Copaxone®** (glatiramer acetate injection) continued to be the leading multiple sclerosis therapy in the United States and worldwide in the second quarter of 2016. Global sales of Copaxone® were \$1.1 billion, an increase of 8% compared to the second quarter of 2015.

Copaxone® revenues in the United States in the second quarter of 2016 were \$955 million, an increase of 10% compared to the second quarter of 2015. The increase was mainly due to a reduction of sales in the Medicaid channel, resulting in both lower rebates in the current quarter and a change in the estimate for rebates in prior quarters, which had an overall positive impact. Sales were also impacted by a price increase of 7.9% in January 2016 for both Copaxone® 20 mg/mL and 40 mg/mL. Over 82% of the total U.S. Copaxone® prescriptions are now filled with the 40 mg/mL version, driven by patient and physician choice of the 40 mg/mL version supported by payer access and patient support activities. Our U.S. market shares in terms of new and total prescriptions were 24.9% and 29.1%, respectively, according to June 2016 IMS data.

Revenues in the United States accounted for 84% of global Copaxone® revenues in the second quarter of 2016, similar to the second quarter of 2015.

Our Copaxone<sup>®</sup> revenues outside the United States amounted to \$186 million in the second quarter of 2016, an increase of 1%, or 3% in local currency terms, compared to the second quarter of 2015. The increase in local currency terms is mainly due to higher volumes in certain European and ROW markets.

Copaxone<sup>®</sup> accounted for approximately 23% of our revenues in the second quarter of 2016, and a significantly higher percentage contribution 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. Our patents on Copaxone<sup>®</sup> 20 mg/mL expired in May 2015 in most of the rest of the world.

Accordingly, a key part of our strategy has been the introduction of 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, which was launched in the United States in January 2014. This formulation allows for a less frequent dosing regimen administered subcutaneously for patients with relapsing forms of MS. In December 2014, we received EMA approval in a decentralized procedure for Copaxone<sup>®</sup> 40 mg/mL in Europe. To date, we have launched Copaxone<sup>®</sup> 40mg/mL in 23 European countries, with several other European launches planned for the remainder of 2016.

---

**Table of Contents**

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 inter parties review proceedings in the United States, and a fourth U.S. Orange Book patent expiring in 2030 that was issued in October 2015. This fourth patent is also being challenged in paragraph IV litigation and is the subject of a pending petition for post grant review at the patent office. A hearing in the inter parties review proceedings was held on May 12, 2016, and decisions for two of the patents are expected by August 25, 2016 and for the third patent by September 1, 2016. The decision on whether the patent office will institute a post grant review of the fourth patent is expected by August 24, 2016. The product is also protected by one European patent expiring in 2030, the validity of which was confirmed by the European Patent Office in December 2015, which rejected all invalidity claims.

The market for MS treatments continues to change as a result of new and emerging therapies as well as generic versions of Copaxone<sup>®</sup> 20 mg/mL. In particular, the increasing number of oral treatments, such as Tecfidera<sup>®</sup> by Biogen, Gilenya<sup>®</sup> by Novartis, and Aubagio<sup>®</sup> by Genzyme, continue to present significant and increasing competition. In June 2015, Sandoz launched its generic version of Copaxone<sup>®</sup> 20 mg/mL, Glatopa<sup>™</sup>, in the United States and in April 2016, Synthron received approval for its generic version of Copaxone<sup>®</sup> 20 mg/mL in Europe. Copaxone<sup>®</sup> also continues to face competition from existing injectable products, such as the four beta-interferons Avonex<sup>®</sup>, Betaseron<sup>®</sup>, Extavia<sup>®</sup> and Rebif<sup>®</sup>, as well as from the two monoclonal antibodies Tysabri<sup>®</sup> and Lemtrada<sup>®</sup>.

**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 exclusively market Azilect<sup>®</sup> in the United States, but expect generic competition commencing in early 2017. In Europe, we shared marketing rights with Lundbeck until the end of 2015, when the initial period of our agreement with Lundbeck ended and all marketing rights reverted to us. We continue to share marketing rights with Lundbeck in certain of our ROW markets. Data exclusivity protection for Azilect<sup>®</sup> in the EU expired in 2015.

Global in-market sales in the second quarter of 2016, which represent sales by Teva and Lundbeck to third parties, amounted to \$111 million, a decrease of 9% compared to the second quarter of 2015. The decrease was mainly due to generic competition in certain European markets. Our sales of Azilect<sup>®</sup> in the second quarter of 2016 amounted to \$108 million, an increase of 3% in both U.S. dollar and local currency terms compared to the second quarter of 2015, mainly due to higher sales in the U.S.

**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 second quarter of 2016 amounted to \$51 million, compared to \$91 million in the second quarter of 2015, due to generic competition.

Pursuant to an agreement with us, Mylan started to sell its generic version of Nuvigil<sup>®</sup> in the United States beginning in June 2016. We have entered into other agreements to permit the other generic filers to enter the market under license 180 days after Mylan's entry.

On May 31, 2016, we received a complete response letter from the FDA regarding the NDA for SD-809 (deutetrabenazine) tablets for the treatment of chorea associated Huntington disease. This is the first deuterated product to be reviewed by the FDA. The FDA asked us to examine blood levels of certain metabolites. These metabolites are not novel, and are the same seen in subjects who take tetrabenazine or deutetrabenazine. No new clinical trials have been requested. We continue to work closely with the FDA to bring SD-809 to the market. In addition to Huntington disease, our programs for the development of SD-809 for the treatment of patients with tardive dyskinesia and Tourette syndrome are ongoing.

On June 7, 2016, an FDA advisory committee recommended approval of **Vantrela ER** for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Vantrela ER is an extended-release formulation of hydrocodone bitartrate with Teva's proprietary abuse deterrence technology. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA for Vantrela ER.

On June 13, 2016, we voluntarily suspended sales, marketing and distribution of **Zecuity**<sup>®</sup>. We received post-marketing reports of application site reactions described as burns and scars in patients treated with Zecuity<sup>®</sup>, and are working with the FDA to better understand these adverse events. In addition to this voluntary suspension, we have initiated a pharmacy-level recall of the product. As a result, we have recorded an impairment of the full carrying value of Zecuity<sup>®</sup> and other related write-offs, primarily related to inventory, and have reversed contingent consideration accruals related to this product.

---

**Table of Contents****Respiratory**

Our respiratory portfolio includes ProAir<sup>®</sup>, QVAR<sup>®</sup>, DuoResp Spiromax<sup>®</sup>, Qnasl<sup>®</sup> and Cinqair<sup>®</sup>. Revenues from our specialty respiratory products in the second quarter of 2016 were \$313 million, an increase of 24% compared to the second quarter of 2015.

**ProAir<sup>®</sup>** includes ProAir<sup>®</sup> hydrofluoroalkane ( HFA ) and ProAir<sup>®</sup>RespiClick<sup>®</sup>, both sold only in the United States. ProAir<sup>®</sup> HFA is an inhalation aerosol with dose counter (albuterol sulfate), and 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> RespiClick<sup>®</sup> (albuterol sulfate) inhalation powder is 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. In April 2016, the FDA approved ProAir<sup>®</sup> RespiClick<sup>®</sup> for children 4 to 11 years of age.

Total ProAir<sup>®</sup> revenues in the second quarter of 2016 were \$135 million, an increase of 5% compared to the second quarter of 2015, due to positive net pricing effects, partially offset by lower volumes. ProAir<sup>®</sup> maintained its leadership in the short-acting beta-agonist market, with a market share of 47.9% in terms of total number of prescriptions during the second quarter of 2016, a decrease of 7.9 points compared to the second quarter of 2015.

**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> revenues in the second quarter of 2016 amounted to \$116 million, an increase of 40% compared to the second quarter of 2015, mainly due to net pricing effects. QVAR<sup>®</sup> maintained its second-place position in the inhaled corticosteroids category in the United States, with a market share of 37.9% in terms of total number of prescriptions during the second quarter of 2016, an increase of 1.2 point compared to the second quarter of 2015.

In April 2016, we launched **Cinqair<sup>®</sup>** (reslizumab) injection, an interleukin 5 antagonist monoclonal antibody indicated for add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype, in the United States. Cinqair<sup>®</sup> is administered by intravenous infusion at a weight-based dose of 3 mg/kg once every four weeks. In June 2016, the EMA issued a positive opinion recommending marketing authorization for this product under the name of Cinqaero<sup>®</sup>.

On June 28, 2016, the FDA accepted for review our NDAs for two products for adolescent and adult patients with asthma. The first, fluticasone propionate/salmeterol, is a fixed-dose combination inhaled corticosteroid (ICS) and long-acting beta agonist (LABA) delivered via our RespiClick<sup>®</sup> breath-actuated, multi-dose dry powder inhaler (MDPI). The second, fluticasone propionate, is an ICS monotherapy also delivered via the RespiClick<sup>®</sup> device. These NDAs have been accepted by the FDA for standard review, with regulatory action expected in the first quarter of 2017.

**Oncology**

Our oncology portfolio includes Treanda<sup>®</sup>/ Bendeka , Grani<sup>®</sup>and Trisenox<sup>®</sup> in the United States and Lonquex<sup>®</sup>, Myocet<sup>®</sup>, Eporatio<sup>®</sup>, Tevagrastim<sup>®</sup>/Ratiograstim<sup>®</sup> and Trisenox<sup>®</sup> outside the United States. Sales of our oncology products were \$334 million in the second quarter of 2016, compared to \$293 million in the second quarter of 2015. The increase resulted primarily from higher combined sales of Treanda<sup>®</sup>/ Bendeka .

**Treanda® / Bendeka** (bendamustine hydrochloride injection) are both 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. Bendeka, which was launched in the United States in January 2016, is a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride that we licensed from Eagle to complement our Treanda® franchise. At the end of March 2016, we suspended sales of the liquid formulation of Treanda®. On March 28, 2016, the FDA denied Eagle's request for seven years of orphan drug exclusivity in the United States for Bendeka. Bendeka is protected by six U.S. Orange Book patents extending from 2026 through 2033, with additional patent applications pending. In June 2016, the U.S. District Court for the District of Delaware ruled in our favor in a patent infringement lawsuit regarding Treanda® injection, affirming the validity of all four patents. As a result, we expect the court to enter an order enjoining the defendants from launching their respective generic versions of Treanda® until patent expiry in 2026.

Treanda® and Bendeka combined sales in the second quarter of 2016 amounted to \$207 million, compared to \$179 million in the second quarter of 2015 (Treanda® only), an increase of 16%, mainly due to higher volumes.

## **Table of Contents**

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

Our women s health portfolio includes ParaGard®, Plan B One-Step® OTC/Rx (levonorgestrel), Zoely®, Seasonique® and Ovaleap®, along with a number of other products that are marketed in various countries. Revenues from our global women s health products were \$117 million in the second quarter of 2016, an increase of 6% compared to the second quarter of 2015, mainly due to higher sales in the United States.

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

In the second quarter of 2016, gross profit from our specialty medicines segment were \$2.0 billion, an increase of \$170 million compared to the second quarter of 2015. The higher gross profit was mainly a result of higher revenues.

Gross profit margin for our specialty medicines segment in the second quarter of 2016 was 87.1%, compared to 86.5% in the second quarter of 2015.

### ***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 selected areas. R&D expenses relating to our specialty medicines segment in the second quarter of 2016 were \$245 million, an increase of 11% compared to \$220 million in the second quarter of 2015. In local currency terms, R&D expenses increased 12%, mainly due to development costs related to assets acquired through the Labrys and Auspex transactions. As a percentage of segment revenues, R&D spending was 10.8% in the second quarter of 2016, compared to 10.5% in the second quarter of 2015.

Specialty R&D expenditures include certain 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 and product registration costs and are reported net of contributions received from collaboration partners. 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; (d) life cycle management and post-approval studies for marketed products; and (e) incur indirect expenses that support our overall specialty R&D efforts but are not allocated by product or to specific R&D projects, such as the costs of internal administration, infrastructure and personnel. Furthermore, our R&D activities relating to innovation using existing molecules are managed and reported as part of our specialty R&D expenses.

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

S&M expenses related to our specialty medicines segment in the second quarter of 2016 were \$478 million, an increase of 5% both in U.S. dollar and local currency terms, compared to \$457 million in the second quarter of 2015 mainly due to increased royalties on sales.

As a percentage of segment revenues, S&M expenses decreased to 21.0% in the second quarter of 2016 from 21.9% in the second quarter of 2015.

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

The profit of our specialty medicines segment is comprised of the gross profit for the segment, less S&M expenses and R&D expenses related to this segment. Segment profit does not include G&A expenses, amortization and certain

other items. See note 14 to our consolidated financial statements and Operating Income below for additional information.

Profit of our specialty medicines segment amounted to \$1.3 billion in the second quarter of 2016, an increase of 11% compared to the second quarter of 2015. This is a result of the factors discussed above, mainly higher revenues.

Specialty medicines profit as a percentage of segment revenues was 55.3% in the second quarter of 2016, up 1.2 points from 54.1% in the second quarter of 2015. The increase was mainly attributable to lower S&M expenses as a percentage of specialty medicines revenues (0.9 points) and higher gross profit as a percentage of specialty medicines revenues (0.6 points), partially offset by higher R&D expenses as a percentage of specialty medicines (0.3 points).

Our MS franchise includes our Copaxone<sup>®</sup> products and laquinimod (a developmental compound for the treatment of MS). The profit of our MS franchise is comprised of Copaxone<sup>®</sup> revenues and 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 second quarter of 2016 amounted to \$928 million, compared to \$839 million in the second quarter of 2015, mainly due to higher revenues. Profit of our MS franchise as a percentage of Copaxone<sup>®</sup> revenues was 81.3% in the second quarter of 2016, compared to 79.6% in the second quarter of 2015.



## **Table of Contents**

### **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 from OTC products in the second quarter of 2016 amounted to \$262 million, an increase of 25% compared to \$210 million in the second quarter of 2015. In local currency terms, revenues increased 58%, mainly due to inflation in Venezuela.

PGT's in-market sales in the second quarter of 2016 amounted to \$379 million, an increase of \$54 million compared to the second quarter of 2015. The increase was mainly due to inflation in Venezuela. 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 second quarter of 2016 amounted to \$211 million, an increase of 6%, or 5% in local currency terms, compared to the second quarter of 2015.

### **Teva Consolidated Results**

#### **Revenues**

Revenues in the second quarter of 2016 amounted to \$5.0 billion, an increase of 1% compared to the second quarter of 2015, primarily due to higher revenues of our specialty medicines as well as of other activities, largely offset by lower revenues of our generic medicines, compared to the second quarter of 2015. See [Generic Medicines Revenues](#), [Specialty Medicines Revenues](#), and [Other Activities](#) above. Exchange rate movements during the second quarter of 2016 negatively impacted overall revenues by \$141 million, compared to the second quarter of 2015. In local currency terms, revenues increased 4%.

#### **Gross Profit**

In the second quarter of 2016, gross profit amounted to \$2.9 billion, a decrease of 1% compared to the second quarter of 2015.

The lower gross profit was mainly the result of the lower gross profit of our generic medicines segment as well as inventory step-up charges and higher costs related to regulatory actions taken in facilities, largely offset by higher gross profit of our specialty medicines segment as well as 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 57.1% in the second quarter of 2016, compared to 58.4% in the second quarter of 2015. The decrease in gross profit as a percentage of revenues primarily reflects the inventory step-up charges (1.7 points), lower profitability of our OTC activity (0.8 points), costs related to regulatory actions taken in

facilities (0.6 points), lower profitability of our generic medicines segment (0.5 points) and lower profitability of other activities (0.3 points), partially offset by higher profitability of our specialty medicines segment (1.4 points) and the lower amortization of purchased intangible assets (1.2 points).

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

Net R&D expenses for the second quarter of 2016 amounted to \$375 million, a decrease of 3% compared to the second quarter of 2015.

As a percentage of revenues, R&D spending was 7.4% in the second quarter of 2016, compared to 7.8% in the second quarter of 2015.

Our R&D expenses were primarily the result of the factors previously discussed under **Generic Medicines R&D Expenses** and **Specialty Medicines R&D Expenses** above.

## **Table of Contents**

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 second quarter of 2016 amounted to \$952 million, an increase of 11% compared to the second quarter of 2015. The increase was mainly due to higher S&M expenses related to our specialty medicines segment. See Specialty Medicines S&M Expenses above.

As a percentage of revenues, S&M expenses were 18.9% in the second quarter of 2016, compared to 17.3% in the second quarter of 2015.

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

G&A expenses in the second quarter of 2016 amounted to \$311 million, compared to \$325 million in the second quarter of 2015. As a percentage of revenues, G&A expenses were 6.2% in the second quarter of 2016, compared to 6.5% in the second quarter of 2015.

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

In the second quarter of 2016, we recorded expenses of \$712 million for impairments, restructuring and others, compared to \$285 million in the second quarter of 2015. The expenses in the second quarter of 2016 were mainly comprised of:

A \$258 million impairment of the full carrying value of our in-process R&D asset Revascor<sup>®</sup> (mesenchymal precursor cells), which was in-licensed from Mesoblast Ltd. On May 31, 2016, we exercised a contractual right to terminate our involvement with Mesoblast in the ongoing phase 3 trial of Revascor<sup>®</sup> (mesenchymal precursor cell) for chronic heart failure, forfeiting our rights relating to Revascor<sup>®</sup> in the cardiovascular field, resulting in this impairment;

A \$248 million impairment of the full carrying value of Zecuity<sup>®</sup> and other related write-offs, primarily related to inventory, amounting to \$53 million, partially offset by a reversal of \$122 million in related contingent consideration accruals, following our suspension and recall of this product; and

An increase of \$104 million in contingent consideration accruals related to Bendeka<sup>™</sup>, due to a change in the future sales outlook, following a court decision delaying generic competition in Treanda<sup>®</sup>.

Following an FDA inspection earlier this year, we voluntarily discontinued all manufacturing activities at our Godollo facility in order to assess and remediate quality concerns. In June, the FDA issued a U.S. import alert for all products from this facility, which can only be lifted after the FDA confirms regulatory compliance. We are in contact with the FDA to demonstrate the mitigation steps taken and agree on a date we can resume manufacturing. Consequently, production for and shipments to the U.S. market will likely not commence before year-end. If we do not reach an

agreement with the FDA, we may continue to incur related remediation expenses or experience impairments. In parallel, we are in the process of assessing when to commence production for and shipments to European and ROW markets, with the objective to resume shipments to these markets before year-end. Property, plant and equipment balances for this site as of June 30, 2016 amounted to approximately \$174 million.

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

In the second quarter of 2016, we recorded an expense of \$166 million for legal settlements and loss contingencies mainly due to a settlement in principle reached in connection with a patent litigation matter, compared to \$384 million in the second quarter of 2015. The expenses in 2015 consisted mainly of additional reserves relating to the settlement of the modafinil antitrust litigation, which were partially offset by insurance proceeds relating to the settlement of the pantoprazole patent litigation.

### **Operating Income**

Operating income was \$361 million in the second quarter of 2016, compared to \$662 million in the second quarter of 2015. As a percentage of revenues, operating income was 7.2% in the second quarter of 2016 compared to 13.3% in the second quarter of 2015.

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

**Table of Contents**

The decrease in operating income as a percentage of revenues was 6.1 points, mainly due to higher impairments, restructuring and others (8.4 points), lower profit of our generic segment (2.5 points) and higher other unallocated amounts (1.8 points), as well as lower profit from other activities (0.9 points), which were partially offset by lower legal settlements and loss contingencies (4.5 points), higher profit of our specialty medicines segment (2.1 points), lower amortization (0.5 points) and lower G&A expenses (0.4 points).

The following table presents a reconciliation of our segment profit to our consolidated operating income for the three months ended June 30, 2016 and 2015:

	<b>Three Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
	<b>U.S.\$ in millions</b>	
Generic medicines profit	\$ 614	\$ 729
Specialty medicines profit	1,255	1,131
<b>Total segment profit</b>	<b>1,869</b>	<b>1,860</b>
Profit of other activities	13	56
<b>Total profit</b>	<b>1,882</b>	<b>1,916</b>
Amounts not allocated to segments:		
Amortization	193	214
General and administrative expenses	311	325
Legal settlements and loss contingencies	166	384
Impairments, restructuring and others	712	285
Other unallocated amounts	139	46
<b>Consolidated operating income</b>	<b>361</b>	<b>662</b>
<b>Financial expenses - net</b>	<b>105</b>	<b>41</b>
<b>Consolidated income before income taxes</b>	<b>\$ 256</b>	<b>\$ 621</b>

**Financial Expenses-Net**

In the second quarter of 2016, financial expenses amounted to \$105 million, compared to \$41 million in the second quarter of 2015. The increase was mainly due to a \$99 million impairment of our investment in Mesoblast, partially offset by financial income derived from activities related to exchange rate fluctuations in the British pound.

**Tax Rate**

In the second quarter of 2016, income taxes amounted to \$29 million, or 11%, on pre-tax income of \$256 million. In the second quarter of 2015, income taxes amounted to \$88 million, or 14%, on pre-tax income of \$621 million.

Our tax rate for the second quarter of 2016 was lower than the tax rate in the comparable quarter of 2015, mainly due to nonrecurring tax benefits in jurisdictions with higher tax rates.

The statutory Israeli corporate tax rate is 25% in 2016.

Our tax rate differs from the Israeli statutory tax rate mainly due to the mix of profits generated in various jurisdictions where we benefit from tax rates lower than the Israeli rate and tax benefits in Israel and other countries, as well as infrequent or nonrecurring items.

### **Net Income**

Net income attributable to Teva in the second quarter of 2016 was \$254 million, compared to \$539 million in the second quarter of 2015. This decrease was due to the factors previously discussed, primarily our lower operating income and higher financial expenses, partially offset by lower income tax.

Net income attributable to ordinary shareholders in the second quarter of 2016 amounted to \$188 million. The difference from net income attributable to Teva is due to the \$66 million dividend paid to holders of our mandatory convertible preferred shares in the second quarter of 2016.

## **Table of Contents**

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

On December 8, 2015, we issued 54 million ADSs at \$62.50 per ADS and 3,375,000 of our 7.00% mandatory convertible preferred shares at \$1,000 per share. In addition, on January 6, 2016, we issued an additional 5.4 million ADSs and 337,500 mandatory convertible preferred shares pursuant to the exercise of the underwriters' over-allotment option. The net proceeds from the offerings were approximately \$7.24 billion, after estimated underwriting discounts, commissions and offering expenses.

The average weighted diluted shares outstanding used for the fully diluted share calculation for the second quarter of 2016 and 2015 were 920 million and 859 million shares, respectively.

Diluted earnings per share for the three months ended June 30, 2016 and 2015 take into account the potential dilution that could occur upon the exercise of options and non-vested RSUs granted under employee stock compensation plans, and one series of convertible senior debentures, using the treasury stock method.

Additionally, for the three months ended June 30, 2016, no account was taken of the potential dilution of the mandatory convertible preferred shares amounting to 59 million weighted average shares, since they had an anti-dilutive effect on earnings per share.

The increase in number of shares outstanding compared to the second quarter of 2015 was mainly due to the December 2015 and January 2016 ADS issuances mentioned above and the issuance of shares for employee options exercised and vested RSUs. On August 2, 2016, we issued approximately 100.3 million shares to Allergan as part of the consideration in the Actavis Generics acquisition.

Diluted earnings per share amounted to \$0.20 in the second quarter of 2016, compared to \$0.63 in the second quarter of 2015.

### **Share Count for Market Capitalization**

As of June 30, 2016 and 2015, the fully diluted share count for purposes of calculating Teva's market capitalization was approximately 995 million and 880 million, respectively. Commencing with the fourth quarter of 2015, we calculate these share amounts, using the outstanding number of shares (i.e., excluding treasury shares) plus shares that would be outstanding upon the exercise of options and vesting of RSUs and PSUs, as well as the conversion of our convertible senior debentures and mandatory convertible preferred shares, in each case, at period end.

The share count at June 30, 2015 was adjusted to be comparable to the fully diluted share count at June 30, 2016, as described above, for purposes of calculating Teva's market capitalization.

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

In the second quarter of 2016, approximately 47% of our revenues came from sales outside of the United States. Because our results are reported in U.S. dollars, we are subject to significant foreign currency risks and accordingly, changes in the rate of exchange between the U.S. dollar and the local currencies in the markets in which we operate (primarily the Venezuelan bolivar, euro, Israeli shekel, Russian ruble, Canadian dollar, British pound and Japanese yen) impact our results. In the second quarter of 2016, compared to the second quarter of 2015, the following currencies decreased in value against the U.S. dollar: the Russian ruble by 20%, the Canadian dollar by 5%, the British pound by 6%, the Argentinean peso by 37% and the Mexican peso by 15%, while the following currencies increased: the euro by 2%, the Japanese yen by 12% and the Israeli shekel by 2% (all compared on a quarterly average

basis).

As a result, exchange rate movements during the second quarter of 2016 in comparison with the second quarter of 2015 negatively impacted overall revenues by \$141 million and negatively impacted our operating income by \$55 million, both of which are net of profits from certain hedging transactions.

**Venezuela.** Our Venezuelan operations use the U.S. dollar as the functional currency due to the hyperinflationary state of the Venezuelan economy. Our revenues in Venezuela from generic medicines in the second quarter of 2016 were \$98 million, compared to \$57 million in the second quarter of 2015. Our revenues in Venezuela from OTC medicines in the second quarter of 2016 were \$108 million, compared to \$64 million in the second quarter of 2015. As our OTC business in Venezuela is part of the PGT joint venture, profits from the sales of OTC medicines in the country are shared 49%-51% between Teva and P&G.

The government of Venezuela currently has two official exchange rates: the DIPRO rate of 10 bolivars per U.S. dollar (which replaced the CENCOEX rate of 6.3 in March 2016) and the DICOM rate, which fluctuates and is currently approximately 640 bolivars per U.S. dollar. We used the CENCOEX rate until March 2016 and then replaced it with the DIPRO rate to report our Venezuelan financial position, results of



**Table of Contents**

operations and cash flows, since we believe that the nature of our business operations in Venezuela, which include the importation, manufacture and distribution of pharmaceutical products, qualifies for the most preferential rates permitted by law.

In the first quarter of 2016, we impaired our monetary balance sheet items using the new DIPRO rate and recorded the net negative difference of \$246 million in financial expenses net. In the event of an additional devaluation or a less favorable exchange rate is used, we are exposed to a potential impairment of our net monetary assets in Venezuela, which, as of June 30, 2016, amounted to approximately \$355 million using the DIPRO rate. We are also exposed to a potential negative impact on our revenues and our profits in Venezuela.

We cannot predict whether there will be a further devaluation of the Venezuelan currency or whether our use of the DIPRO rate will continue to be supported by the facts and circumstances.

**Comparison of Six Months Ended June 30, 2016 to Six Months Ended June 30, 2015****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 six months ended June 30, 2016 and 2015. Additional factors affecting the six 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 six months ended June 30, 2015:

	Percentage of Net Revenues Six Months Ended June 30,		Percentage Change 2016 from 2015
	2016 %	2015 %	2015 %
Net revenues	100.0	100.0	(1)
Gross profit	57.6	57.7	(1)
Research and development expenses	7.8	7.2	6
Selling and marketing expenses	18.2	17.9	1
General and administrative expenses	6.2	6.4	(3)
Impairments, restructuring and others	8.5	5.9	42
Legal settlements and loss contingencies	1.4	6.2	(77)
Operating income	15.5	14.1	8
Financial expenses net	4.1	2.3	73
Income before income taxes	11.4	11.8	(5)
Income taxes	2.6	1.9	34
Share in losses of associated companies net	(0.1)	*	n/a
Net loss attributable to non-controlling interests	(0.1)	*	n/a
Net income attributable to Teva	9.0	9.9	(10)

\* Represents an amount less than 0.05%.



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

The following table presents revenues and profit of our generic medicines segment for the six months ended June 30, 2016 and 2015:

	<b>Generics</b>			
	<b>Six months ended June 30,</b>		<b>2015</b>	
	<b>2016</b>		<b>2015</b>	
	<b>U.S.\$ in millions / % of Segment</b>			
	<b>Revenues</b>			
Revenues	\$ 4,464	100.0%	\$ 5,087	100.0%
Gross profit	2,071	46.4%	2,482	48.8%
R&D expenses	261	5.8%	245	4.8%
S&M expenses	612	13.8%	709	14.0%
Segment profit*	\$ 1,198	26.8%	\$ 1,528	30.0%

\* 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 14 to our consolidated financial statements and Operating Income below for additional information.

**Generic Medicine Revenues**

Our generic medicines segment includes sales of generic medicines as well as API sales to third parties. In the first six months of 2016, revenues from our generic medicines segment amounted to \$4.5 billion, a decrease of \$623 million, or 12%, compared to the first six months of 2015. In local currency terms, revenues decreased 10%.

API sales to third parties in the first six months of 2016 amounted to \$404 million, compared to \$340 million in the first six months of 2015. In local currency terms, sales increased 18%.

The following table presents generic segment revenues by geographic area for the six months ended June 30, 2016 and 2015:

	<b>Six Months Ended June 30, Percentage Change</b>		
	<b>2016</b>	<b>2015</b>	<b>2016 - 2015</b>
	<b>U.S. \$ in millions</b>		
United States	\$ 1,868	\$ 2,765	(32%)
Europe*	1,331	1,345	(1%)
Rest of the World	1,265	977	29%
Total Generic Medicines	\$ 4,464	\$ 5,087	(12%)

\* 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 six months of 2016 amounted to \$1.9 billion, a decrease of 32% compared to \$2.8 billion in the first six months of 2015. The decrease resulted mainly from the loss of exclusivity on aripiprazole (the generic equivalent of Abilify®) and esomeprazole (the generic equivalent of Nexium®) as well as a decline in sales of budesonide (the generic equivalent of Pulmicort®).

Among the most significant generic products we sold in the United States in the first six months of 2016 were generic versions of Pulmicort® (budesonide inhalation), Adderall XR® (mixed amphetamine salts ER), Abilify® (aripiprazole), Xeloda® (capecitabine), Accutane® (isotretinoin), Lovenox® (enoxaparin), Aggrenox® (aspirin/extended-release dipyridamole) and Adderall IR® (amphetamine salts IR).

**Table of Contents**

***Europe Generic Medicines Revenues***

Revenues from generic medicines in Europe in the first six months of 2016 amounted to \$1.3 billion, a decrease of 1% compared to the first six months of 2015. In local currency terms, revenues were flat compared to the first six months of 2015.

***ROW Generic Medicines Revenues***

Revenues from generic medicines in our ROW markets in the first six months of 2016 amounted to \$1.3 billion, an increase of 29% compared to \$1.0 billion in the first six months of 2015. In local currency terms, revenues increased 41%.

***Generic Medicines Gross Profit***

In the first six months of 2016, gross profit from our generic medicines segment amounted to \$2.1 billion, a decrease of \$411 million, or 17%, compared to \$2.5 billion in the first six months of 2015.

Gross profit margin for our generic medicines segment in the first six months of 2016 decreased to 46.4%, compared to 48.8% in the first six months of 2015.

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

Research and development expenses relating to our generic medicines segment for the first six months of 2016 amounted to \$261 million, an increase of 7% compared to the first six months of 2015, mainly due to increased development of complex generic products such as sterile and respiratory medicines. As a percentage of segment revenues, R&D expenses were 5.8% in the first six months of 2016, compared to 4.8% the first six months of 2015.

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

Selling and marketing expenses related to our generic medicines segment in the first six months of 2016 amounted to \$612 million, a decrease of 14% compared to \$709 million in the first six months of 2015.

As a percentage of segment revenues, selling and marketing expenses decreased to 13.8% in the first six months of 2016 from 14.0% in the first six months of 2015.

***Generic Medicines Profit***

Profit of our generic medicines segment amounted to \$1.2 billion in the first six months of 2016, compared to \$1.5 billion in the first six months of 2015.

**Specialty Medicines Segment**

The following table presents revenues and profit of our specialty medicines segment for the six months ended June 30, 2016 and 2015:

**Specialty**



**Table of Contents**

million, an increase of 3% from the first six months of 2015. In local currency terms, specialty medicines revenues in Europe increased 4%. Specialty medicines revenues in ROW amounted to \$166 million, an increase of 2%, or 15% in local currency terms, compared to the first six months of 2015.

**Specialty Medicines Revenues Breakdown**

The following table presents revenues by therapeutic area and key products for our specialty medicines segment for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30,		Percentage
	2016	2015	Change
	U.S. \$ in millions		2016 - 2015
CNS	\$ 2,738	\$ 2,573	6%
Copaxone®	2,147	1,978	9%
Azilect®	221	212	4%
Nuvigil®	154	176	(13%)
Respiratory	679	518	31%
ProAir®	308	252	22%
QVAR®	250	181	38%
Oncology	602	557	8%
Treanda® and Bendeka	362	336	8%
Women's Health	227	239	(5%)
Other Specialty	177	159	11%
<b>Total Specialty Medicines</b>	<b>\$ 4,423</b>	<b>\$ 4,046</b>	<b>9%</b>

**Central Nervous System**

In the first six months of 2016, our CNS sales amounted to \$2.7 billion, an increase of 6% compared to the first six months of 2015.

**Copaxone®.** In the first six months of 2016, sales of Copaxone® amounted to \$2.1 billion, an increase of 9% compared to the first six months of 2015.

Copaxone® revenues in the United States, which include our revenues from both Copaxone® 20 mg/mL and Copaxone® 40 mg/mL products, amounted to \$1.8 billion, an increase of 11% compared to the first six months of 2015.

Our Copaxone® revenues outside the United States amounted to \$371 million during the first six months of 2016, a decrease of 1% compared to the first six months of 2015, or an increase of 2% in local currency terms.

**Azilect®.** Our sales of Azilect® amounted to \$221 million, an increase of 4% compared to the first six months of 2015.

Global in-market sales of Azilect® amounted to \$228 million in the first six months of 2016 compared to \$256 million in the first six months of 2015, a decrease of 11%.

**Nuvigil®.** Our sales of Nuvigil® in the first six months of 2016 amounted to \$154 million, compared to \$176 million in the first six months of 2015.

***Respiratory Products***

In the first six months of 2016, revenues from our specialty respiratory products increased 31% to \$679 million, compared to the first six months of 2015.

**ProAir®** revenues in the first six months of 2016 amounted to \$308 million, an increase of 22% compared to the first six months of 2015.

**QVAR®** global sales in the first six months of 2016 amounted to \$250 million, an increase of 38% compared to the first six months of 2015.



## **Table of Contents**

### ***Oncology Products***

Sales of our oncology products amounted to \$602 million in the first six months of 2016, compared to \$557 million in the first six months of 2015.

Combined Sales of Treanda® and Bendeka amounted to \$362 million in the first six months of 2016, compared to \$336 million in the first six months of 2015 (Treanda® only).

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

Revenues from our global women's health products amounted to \$227 million in the first six months of 2016, a decrease of 5% compared to the first six months of 2015.

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

In the first six months of 2016, gross profit from our specialty medicines segment amounted to \$3.8 billion, an increase of 10% compared to the first six months of 2015.

Gross profit margin for our specialty medicines segment in the first six months of 2016 was 87.0%, compared to 86.2% in the first six months of 2015.

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

Research and development expenses relating to our specialty medicines segment in the first six months of 2016 amounted to \$474 million, an increase of 9% compared to the first six months of 2015. As a percentage of segment revenues, R&D spending was 10.7% in the first six months of 2016, compared to 10.8% in the first six months of 2015.

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

Selling and marketing expenses related to our specialty medicines segment in the first six months of 2016 amounted to \$935 million a decrease of 1% compared to the first six months of 2015.

As a percentage of segment revenues, selling and marketing expenses were 21.1% in the first six months of 2016, compared to 23.3% in the first six months of 2015.

### ***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 14 to our consolidated financial statements and Operating Income below for additional information.

Profit of our specialty medicines segment amounted to \$2.4 billion in the first six months of 2016, an increase of 16% compared to the first six months of 2015.

Specialty medicines profit as a percentage of segment revenues was 55.2% in the first six months of 2016, compared to 52.1% in the first six months of 2015, an increase of 3.1 points.

Our multiple sclerosis franchise includes our Copaxone® products and laquinimod (a developmental compound for the treatment of MS). The profit of our multiple sclerosis franchise consists of Copaxone® 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 six months of 2016 was \$1.7 billion, an increase of 16% compared to the first six months of 2015. Profit of our multiple sclerosis franchise as a percentage of Copaxone® revenues was 80.7% in the first six months of 2016 compared to 75.6% in the first six months of 2015.

### **Other Activities**

#### *OTC*

Our revenues from OTC products in the first six months of 2016 amounted to \$550 million, an increase of 30% compared to \$423 million in the first six months of 2015. In local currency terms, revenues increased 52%.

PGT's in-market sales in the first six months of 2016 amounted to \$790 million, \$91 million higher than the first six months of 2015.

## **Table of Contents**

### ***Others***

In the first six months of 2016, we recorded revenues of \$411 million from our other activities, an increase of 5% compared to sales of \$392 million in the first six months of 2015.

### **Teva Consolidated Results**

#### **Revenues**

Revenues in the first six months of 2016 amounted to \$9.8 billion, a decrease of 1% compared to the first six months of 2015. Exchange rate movements during the first six months of 2016 in comparison with the first six months of 2015 negatively impacted revenues by \$247 million. In local currency terms, revenues increased 1%. See [Generic Medicines Revenues](#) , [Specialty Medicines Revenues](#) and [Other Activities](#) above.

#### **Gross Profit**

In the first six months of 2016, gross profit amounted to \$5.7 billion, a decrease of 1% compared to the first six months of 2015.

The lower gross profit was mainly a result of the lower gross profit of our generic medicines segment as well as inventory step-up charges and higher costs related to regulatory actions taken in facilities, partially offset by higher gross profit of our specialty medicines segment, lower amortization of purchased intangible assets and higher gross profit of our OTC activity. 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 six months of 2016, compared to 57.7% in the first six months of 2015.

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

Net research and development expenses for the first six months of 2016 amounted to \$764 million, an increase of 6% compared to the first six months of 2015. See [Generic Medicines R&D Expenses](#) and [Specialty Medicines R&D Expenses](#) above.

As a percentage of revenues, R&D spending was 7.8% in the first six months of 2016, compared to 7.2% in the first six months of 2015.

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

Selling and marketing expenses in the first six months of 2016 amounted to \$1.8 billion, an increase of 1% compared to the first six months of 2015. See [Generic Medicines S&M Expenses](#) and [Specialty Medicines S&M Expenses](#) above.

As a percentage of revenues, S&M expenses were 18.2% in the first six months of 2016 compared to 17.9% in the first six months of 2015.

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

G&A expenses in the first six months of 2016 amounted to \$615 million, compared to \$632 million in the first six months of 2015. As a percentage of revenues, G&A expenses decreased to 6.2% in the first six months of 2016, from 6.4% in the first six months of 2015.

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

In the first six months of 2016, we recorded \$831 million in impairments, restructuring and others, compared to \$584 million in the first six months of 2015. These expenses were mainly comprised of:

A \$258 million impairment of the full carrying value of our in-process R&D asset Revascor<sup>®</sup> (mesenchymal precursor cells);

A \$248 million impairment of the full carrying value of Zecuity<sup>®</sup> and other write-offs amounting to \$53 million, partially offset by a reversal of \$122 million in related contingent consideration, following our suspension and recall of this product; and

An increase of \$104 million in contingent consideration related to Bendeka<sup>™</sup>, due to a change in the future sales outlook, following a court decision delaying generic competition in Treanda<sup>®</sup>.

**Table of Contents****Legal Settlements and Loss Contingencies**

Legal settlements and loss contingencies for the first six months of 2016 amounted to an expense of \$141 million mainly due to a settlement in principle in connection with a patent litigation matter, compared to \$611 million in the first six months of 2015, which mainly consisted of additional reserves relating to the settlement of the modafinil antitrust litigation, partially offset by insurance proceeds relating to the settlement of the pantoprazole patent litigation.

**Operating Income**

Operating income amounted to \$1.5 billion in the first six months of 2016, compared to \$1.4 billion in the first six months of 2015. As a percentage of revenues, operating income was 15.5% in the first six months of 2016, compared to 14.1% in the first six months of 2015.

The following table presents a reconciliation of our segment profit to our consolidated operating income for the six months ended June 30, 2016 and 2015:

	<b>Six months ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
	<b>U.S.\$ in millions</b>	
Generic medicines profit	\$ 1,198	\$ 1,528
Specialty medicines profit	2,440	2,108
<b>Total segment profit</b>	<b>3,638</b>	<b>3,636</b>
Profit of other activities	64	106
<b>Total profit</b>	<b>3,702</b>	<b>3,742</b>
Amounts not allocated to segments:		
Amortization	382	434
General and administrative expenses	615	632
Legal settlements and loss contingencies	141	611
Impairments, restructuring and others	831	584
Other unallocated amounts	207	70
<b>Consolidated operating income</b>	<b>1,526</b>	<b>1,411</b>
<b>Financial expenses - net</b>	<b>403</b>	<b>233</b>
<b>Consolidated income before income taxes</b>	<b>\$ 1,123</b>	<b>\$ 1,178</b>

**Financial Expenses-Net**

In the first six months of 2016, financial expenses amounted to \$403 million, compared to \$233 million in the first six months of 2015. The increase was mainly due to a \$246 million impairment of our monetary assets in Venezuela and a

\$99 million impairment of our investment in Mesoblast, partially offset by higher financial income and lower expenses.

Venezuela has experienced hyperinflation in recent years and has two official exchange rates, which deviate significantly among themselves as well as from unofficial market rates. In addition, remittance of cash outside of Venezuela is limited. We currently prepare our financial statements using an official preferential industry exchange rate, which was devaluated in March 2016 from 6.3 to 10 bolivars per U.S. dollar. In the event of an additional devaluation or if a less favorable exchange rate is used, we are exposed to a potential impairment of our net monetary assets in Venezuela, which, as of June 30, 2016, amounted to approximately \$355 million using the current official preferential exchange rate.

### **Tax Rate**

In the first six months of 2016, income taxes amounted to \$257 million, or 23%, on pre-tax income of \$1.1 billion. In the first six months of 2015, income taxes amounted to \$192 million, or 16%, on pre-tax income of \$1.2 billion.

Our tax rate for the first six months of 2016 was higher than the tax rate in the comparable period of 2015, mainly due to mix of products generated in various jurisdictions and infrequent or nonrecurring items.

## **Table of Contents**

### **Net Income**

Net income attributable to Teva in the first six months of 2016 amounted to \$0.9 billion, compared to \$1.0 billion in the first six months of 2015.

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

On December 8, 2015, we issued 54 million ADSs at \$62.50 per ADS and 3,375,000 of our 7.00% mandatory convertible preferred shares at \$1,000 per share. In addition, on January 6, 2016, we issued an additional 5.4 million ADSs and 337,500 mandatory convertible preferred shares pursuant to the exercise of the underwriters' over-allotment option. The net proceeds from the offerings were approximately \$7.24 billion, after estimated underwriting discounts, commissions and offering expenses.

The average weighted diluted shares outstanding used for the fully diluted share calculation for the first six months of 2016 and 2015 were 922 million and 859 million shares, respectively.

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. We did not repurchase any shares during the second quarter of 2015 or during the first and second quarters of 2016.

Diluted earnings per share for the six months ended June 30, 2016 and 2015 take into account the potential dilution that could occur upon the exercise of options and non-vested RSUs granted under employee stock compensation plans, and one series of convertible senior debentures, using the treasury stock method.

Additionally, for the six months ended June 30, 2016, no account was taken of the potential dilution of the mandatory convertible preferred shares amounting to 59 million weighted average shares, since they had an anti-dilutive effect on earnings per share.

The increase in number of shares outstanding compared to the first six months ended June 30, 2015 was mainly due to the December 2015 and January 2016 ADS issuances mentioned above and the issuance of shares for employee options exercised and vested RSUs, partially offset by the impact of the shares repurchased pursuant to our share repurchase program during the first quarter of 2015. On August 2, 2016, we issued approximately 100.3 million shares to Allergan as part of the consideration in the Actavis Generics acquisition.

Diluted earnings per share amounted to \$0.82 in the first six months of 2016, compared to \$1.15 in the first six months of 2015.

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

In the first six months of 2016, approximately 46% of our revenues came from sales outside of the United States. 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 six months of 2016, the following currencies decreased in value against the U.S. dollar: the Russian ruble by 18%, the Canadian dollar by 7%, the British pound by 6%, the Argentinean peso by 38% and the Mexican peso by 16%, the euro was unchanged, the Israeli shekel increased by 1%, and the Japanese yen increased by 8% (all compared on a six-monthly average basis).

As a result, exchange rate movements during the first six months of 2016 in comparison with the first six months of 2015 negatively impacted overall revenues by \$247 million and reduced our operating income by \$85 million.

### **Liquidity and Capital Resources**

Total balance sheet assets amounted to \$57.9 billion as of June 30, 2016, compared to \$55.1 billion as of March 31, 2016. The increase was mainly due to an increase of \$2.2 billion of goodwill and other intangible assets related to the Takeda business venture and an increase of \$1 billion in cash and cash equivalents, partially offset by impairments of \$0.5 billion related to Revascor<sup>®</sup> and Zecuity<sup>®</sup>.

Inventory balances as of June 30, 2016 amounted to \$3.9 billion, compared to \$4.0 billion as of March 31, 2016.

Accounts receivable as of June 30, 2016, net of sales reserves and allowances ( SR&A ), amounted to negative \$0.8 billion, compared to negative \$1.3 billion as of March 31, 2016.

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 \$3.9 billion as of June 30, 2016, compared to \$3.5 billion as of March 31, 2016.



## **Table of Contents**

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 negative \$169 million as of June 30, 2016, compared to negative \$294 million as of March 31, 2016. The increase was mainly due to a decrease in SR&A, as well as an increase in account receivables and other current assets, partially offset by an increase in accounts payable and accruals and a decrease in inventories.

Investment in property, plant and equipment in the second quarter of 2016 was approximately \$175 million, compared to \$169 million in the second quarter of 2015. Depreciation amounted to \$111 million in the second quarter of 2016, compared to \$108 million in the second quarter of 2015.

Cash and cash equivalents and short-term and long-term investments as of June 30, 2016 amounted to \$8.2 billion, compared to \$7.2 billion as of March 31, 2016. The increase was mainly due to proceeds received in connection with short-term borrowings as well as cash generated during the quarter, partially offset by payment made to the tax authorities in connection with the Rimsa acquisition and a decline in the fair market value of our Mylan shares.

As of June 30, 2016, we held net monetary assets of approximately \$355 million in Venezuela, which were negatively affected by the devaluation following the replacement of the 6.3 bolivar preferential CENCOEX exchange rate with the 10 bolivar DIPRO exchange rate. This amount is at significant risk of further decrease in the event of an additional devaluation or a change in the official exchange rate used. Our ability to repatriate this amount is also significantly limited.

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, which was not utilized as of June 30, 2016, as well as internally generated funds, which we believe are sufficient to meet our on-going operating needs. As mentioned below, following the closing of the Actavis Generics acquisition, our \$3 billion syndicated revolving line of credit was increased to \$4.5 billion. Upon closing, we utilized \$3 billion of this credit facility, which we expect to repay shortly.

## **2016 Debt Movements**

In June 2016, we entered into a £510 million short term loan.

As of June 30, 2016, our debt was \$10.9 billion, an increase of \$0.7 billion compared to \$10.2 billion as of March 31, 2016. The increase was mainly due to short-term borrowing mentioned above.

## **Aggregate Debt**

Our debt as of June 30, 2016 was effectively denominated in the following currencies: U.S. dollar 41%, euro 36%, Japanese yen 13%, British pound 6% and Swiss franc 4%.

The portion of total debt classified as short-term as of June 30, 2016 was 26%, compared to 16% as of March 31, 2016. The increase was mainly due to short-term borrowing denominated in British pound as well as classification of a loan denominated in Japanese yen due in April 2017 as short-term.

Our financial leverage was 25% as of June 30, 2016, flat compared to March 31, 2016.

Our average debt maturity was approximately 5.6 years as of June 30, 2016.

Commencing the third quarter of 2015, we entered into forward starting interest rate swap and treasury lock agreements designated as cash flow hedges of the U.S. dollar debt issuance in July 2016, with respect to \$5.25 billion notional amount in multiple transactions. These agreements hedge the variability in anticipated future interest payments due to possible changes in the benchmark interest rate between the date the agreements were entered into and the expected date of the U.S. dollar debt issuance of July 2016 (in connection with the closing of the Actavis Generics acquisition). As of June 30, 2016, we incurred a loss of \$336 million related to a decline in interest rates, due to the maturity of transactions during the first half of 2016, which will be settled by October 7, 2016. Following our U.S. dollar debt issuance in July 2016, these agreements were terminated incurring an additional loss of \$157 million, for a total of \$493 million, including the \$336 million loss mentioned above. This loss is recorded in other comprehensive income and will be amortized under financial expenses-net over the life of the debt.

## **Table of Contents**

In anticipation of the closing of the Actavis Generics acquisition, in July 2016, we completed debt issuances for an aggregate principal amount of \$20.4 billion, or \$20.3 billion net proceeds, consisting of senior notes with aggregate principal amount of \$15 billion, 4 billion and CHF 1 billion and maturities of two to 30 years. The effective average interest rate of the newly issued notes is 2.32% per annum.

Upon closing of the Actavis Generics acquisition, we borrowed \$5 billion under our term loan facility to finance the acquisition, and terminated our \$22 billion bridge loan credit agreement.

In November 2015, we entered into a \$3 billion five-year syndicated revolving line of credit, which increased to \$4.5 billion upon closing of the Actavis Generics acquisition. As of June 30, 2016, the credit facility was unutilized. Upon closing of the Actavis Generics acquisition, we borrowed \$3 billion under this credit facility, which we expect to repay shortly.

## **Shareholders Equity**

Total shareholders equity was \$32.0 billion as of June 30, 2016, compared to \$30.6 billion as of March 31, 2016. The increase was mainly due to the \$1.8 billion impact of our business venture with Takeda and \$0.2 billion of net income, partially offset by \$0.4 billion in dividend payments, \$0.3 billion unrealized loss from derivative financial instruments and unrealized loss from available-for-sale securities.

Exchange rate fluctuations affected our balance sheet, as approximately 25% of our net assets in the second quarter of 2016 (including both non-monetary and monetary assets) were in currencies other than the U.S. dollar. When compared to March 31, 2016, changes in currency rates had a negative impact of \$0.2 billion on our equity as of June 30, 2016, mainly due to the change in value against the U.S. dollar of: the Mexican peso by 7%, the Polish zloty by 5%, the euro by 2%, the British pound by 7%, the Hungarian forint by 3% and the Russian ruble by (7%). All comparisons are on a quarter-end to quarter-end basis.

## **Cash Flow**

Cash flow generated from operating activities during the second quarter of 2016 amounted to \$1.0 billion, compared to \$1.5 billion in the second quarter of 2015. The decrease was mainly due to an increase in accounts receivable, net of SR&A, partially offset by an increase in accounts payable.

Cash flow generated from operating activities in the second quarter of 2016, net of cash used for capital investments, amounted to \$0.8 billion, compared to \$1.3 billion in the second quarter of 2015. The decrease resulted mainly from lower cash flow generated from operating activities.

## **Dividends**

We announced a dividend for the second quarter of 2016 of \$0.34 per ordinary share. The dividend payment is expected to take place on September 8, 2016 to holders of record as of August 22, 2016.

We further announced a quarterly dividend of \$17.50 per mandatory convertible preferred share. The dividend payment is expected to take place on September 15, 2016 to holders of record as of September 1, 2016.

## **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 R&D activities.

On August 2, 2016, we consummated our acquisition of Actavis Generics. At closing, we paid consideration of approximately \$33.4 billion in cash and approximately 100.3 million Teva shares issued to Allergan.

See [Aggregate Debt](#) above regarding our funding of the Actavis Generics acquisition.

Commencing the third quarter of 2015, we entered into forward starting interest rate swaps and treasury lock agreements, to hedge part of the risk associated with possible changes in interest rates until our July 2016 U.S. dollar debt issuances. See [Aggregate Debt](#) above.

## **Table of Contents**

We are committed to pay royalties to owners of know-how, partners in alliances and certain other arrangements and to parties that financed R&D, 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.

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 Company utilizes certain non-GAAP financial measures to evaluate performance, in conjunction with other performance metrics. The following are examples of how we utilize the non-GAAP measures:

our management and board of directors use the non-GAAP measures to evaluate our operational performance, to compare against work plans and budgets, and ultimately to evaluate the performance of management;

our annual budgets are prepared on a non-GAAP basis; and

senior management's annual compensation is derived, in part, using these non-GAAP measures. While qualitative factors and judgment also affect annual bonuses, the principal quantitative element in the determination of such bonuses is performance targets tied to the work plan, and thus is based on the non-GAAP presentation set forth below.

Non-GAAP financial measures have no standardized meaning and accordingly have limitations in their usefulness to investors. 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 U.S. 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 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.**

In arriving at our non-GAAP presentation, we exclude 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. In addition, we also exclude equity compensation expenses to facilitate a better understanding of our financial results, since we believe that this exclusion is important for understanding the trends in our financial results and that these expenses do not affect our business operations. While not all inclusive, examples of these items include:

amortization of purchased intangible assets;

legal settlements and/or loss contingencies, due to the difficulty in predicting their timing and size;

impairments of long-lived assets, including intangibles, property, plant and equipment and goodwill;

restructuring expenses, including severance, retention costs, contract cancellation costs and certain accelerated depreciation expenses primarily related to the rationalization of our plants, or to certain other strategic activities such as the realignment of R&D focus or other similar activities;

acquisition or divestment related items, including, contingent consideration, integration costs, banker and other professional fees, inventory step-up and in-process R&D acquired in development deals;

expenses related to our equity compensation;

**Table of Contents**

significant one-time related financing costs or impairments of monetary assets due to changes in foreign currency exchange rates;

material tax and other awards or settlements, both amounts paid and received;

other exceptional items that we believe are sufficiently large that their exclusion is important to understanding trends in our financial results, such as impacts due to changes in accounting, significant costs for remediation of plants such as inventory write-offs or other consulting costs or other unusual events; and

tax effects of the foregoing items.

The following tables 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 June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
	<b>U.S. \$ in millions</b>		<b>U.S. \$ in millions</b>	
Impairment of long-lived assets	\$ 572	\$ 81	\$ 585	\$ 146
Amortization of purchased intangible assets	193	214	382	434
Legal settlements and loss contingencies	166	384	141	611
Inventory step-up	85		91	
Acquisition and related expenses	62	174	163	419
Other write-offs associated with the impairment of Zecuity®	53		53	
Costs related to regulatory actions taken in facilities	39	10	77	19
Equity compensation	28	31	52	58
Restructuring expenses	20	48	39	51
Other non-GAAP items	4	6	3	(6)
Financial expense	99		345	143
Minority interest	(43)		(43)	
Corresponding tax benefit	(304)	(257)	(378)	(465)

**Table of Contents**

**Three Months Ended June 30, 2016    Three Months Ended June 30, 2015**  
**U.S. dollars and shares in millions (except per share amounts)**

**Dividends**

on

**Non-GAAP Preferred Non- % of Net                      Non-GAAP Non- % of Net**  
**GAAP Adjustments Shares GAAP Revenues    GAAP Adjustments GAAP Revenues**

Gross profit (1)	2,877	273	3,150	63%	2,902	218	3,120	63%	
Operating income (1)(2)	361	1,222	1,583	31%	662	948	1,610	32%	
Net income attributable to ordinary shareholders (1)(2)(3)(4)	188	974	66	1,228	24%	539	691	1,230	25%
Earnings per share attributable to ordinary shareholders - diluted (5)	0.20	1.05	1.25		0.63	0.80	1.43		
(1) Amortization of purchased intangible assets		146				206			
Equity compensation		3				2			
Other COGS related adjustments		124				10			
Gross profit adjustments		273				218			
(2) Legal settlements and loss contingencies		166				384			
Acquisition and related expenses		62				174			
Equity compensation		25				29			
Restructuring expenses		20				48			
Impairment of long-lived assets		572				81			
Amortization of purchased intangible assets		47				8			
Other operating related adjustments		57				6			
Operating income adjustments		949				730			
Operating income adjustments		1,222				948			
(3) Financial expense		99							
Tax effect		(304)				(257)			
Minority interest		(43)							
Net income adjustments		974				691			



- (4) Dividends on the mandatory convertible preferred shares of \$66 million for the three months ended June 30, 2016 are added back to non-GAAP net income attributable to ordinary shareholders, since such preferred shares had a dilutive effect on non-GAAP earnings per share, as described in the following footnote.
- (5) The non-GAAP weighted average number of shares was 979 and 859 million for the three months ended June 30, 2016 and 2015, respectively. The non-GAAP weighted average number of shares for the three months ended June 30, 2016 takes into account the potential dilution of the mandatory convertible preferred shares (amounting to 59 million weighted average shares), which had a dilutive effect on non-GAAP earnings per share. Non-GAAP earnings per share can be reconciled with GAAP earnings per share by dividing each of the amounts included in footnotes 1-4 above by the applicable weighted average share number.

**Table of Contents**

	Six Months Ended June 30, 2016				Six Months Ended June 30, 2015				
	U.S. dollars and shares in millions (except per share amounts)								
	Dividends								
	on								
	Non-GAAP Preferred Non- % of Net				Non-GAAP Non- % of Net				
	GAAP	Adjustments	Shares	GAAP	Revenues	GAAP	Adjustments	GAAP	Revenues
Gross profit (1)	5,668	498		6,166	63%	5,738	444	6,182	62%
Operating income (1)(2)	1,526	1,583		3,109	32%	1,411	1,732	3,143	32%
Net income attributable to ordinary shareholders (1)(2)(3)(4)	758	1,510	132	2,400	24%	985	1,410	2,395	24%
Earnings per share attributable to ordinary shareholders - diluted (5)	0.82	1.63		2.45		1.15	1.64	2.79	
(1) Amortization of purchased intangible assets		324					418		
Costs related to regulatory actions taken in facilities		77					19		
Equity compensation		6					5		
Other COGS related adjustments		91					2		
Gross profit adjustments		498					444		
(2) Contingent consideration		51					262		
Legal settlements and loss contingencies		141					611		
Acquisition and related expenses		109					157		
Equity compensation		46					53		
Restructuring expenses		39					51		
Impairment of long-lived assets		585					146		
Amortization of purchased intangible assets		58					16		
Other operating related expenses (income)		56					(8)		

	1,085	1,288
Operating income adjustments	1,583	1,732
(3) Financial expense	345	143
Tax effect	(378)	(465)
Impairment of equity investment net	3	
Minority interest	(43)	
Net income adjustments	1,510	1,410

- (4) Dividends on the mandatory convertible preferred shares of \$132 million for the six months ended June 30, 2016 are added to non-GAAP net income attributable to ordinary shareholders, since such preferred shares had a dilutive effect on non-GAAP earnings per share, as described in the following footnote.
- (5) The non-GAAP weighted average number of shares was 981 and 859 million for the six months ended June 30, 2016 and 2015, respectively. The non-GAAP weighted average number of shares for the six months ended June 30, 2016 takes into account the potential dilution of the mandatory convertible preferred shares (amounting to 59 million weighted average shares), which had a dilutive effect on non-GAAP earnings per share. Non-GAAP earnings per share can be reconciled with GAAP earnings per share by dividing each of the amounts included in footnotes 1-4 above by the applicable weighted average share number.

## **Table of Contents**

### **Non-GAAP Tax Rate**

Non-GAAP income taxes for the second quarter of 2016 amounted to \$333 million, or 21%, on pre-tax non-GAAP income of \$1.6 billion. Non-GAAP income taxes in the comparable quarter of 2015 were \$345 million, or 22%, on pre-tax non-GAAP income of \$1.6 billion.

Non-GAAP income taxes for the first six months of 2016 amounted to \$635 million, or 21%, on pre-tax non-GAAP income of \$3.1 billion. Non-GAAP income taxes in the comparable period of 2015 was \$657 million, or 22% on pre-tax income of \$3.1 billion.

We expect our annual non-GAAP tax rate for 2016 to be similar to the annual non-GAAP tax rate of 21% for 2015.

### **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, 2015. 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, 2015 for a summary of our significant accounting policies.

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

See the notes to the consolidated financial statements included in this report.

### **RISK FACTORS**

There are no material changes to the risk factors previously disclosed in our Annual Report on Form 20-F for the year ended December 31, 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, 2015.

### **LEGAL PROCEEDINGS**

We are subject to various litigation and other legal proceedings. For a discussion of these matters, see Contingencies included in note 13 to the 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: August 4, 2016

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

61