TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 10-Q
May 02, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2019

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 001-16174

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Exact name of registrant as specified in its charter)

Israel **(State or other jurisdiction of incorporation or organization)**	**Not Applicable** **(IRS Employer Identification Number)**
5 Basel Street, Petach Tikva, ISRAEL **(Address of principal executive offices)**	**4951033** **(Zip code)**

+972 (3) 914-8171

(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
American Depositary Shares, each representing one Ordinary Share	**TEVA**	**New York Stock Exchange**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company

Emerging growth company
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of March 31, 2019, the registrant had 1,091,598,003 ordinary shares outstanding.

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INTRODUCTION AND USE OF CERTAIN TERMS

Unless otherwise indicated, all references to the Company, we, our and Teva refer to Teva Pharmaceutical Industrie Limited and its subsidiaries, and references to revenues refer to net revenues. References to U.S. dollars, 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, is based on information provided by IQVIA (formerly IMS Health Inc.), a provider of market research to the pharmaceutical industry (IQVIA), unless otherwise stated. References to Actavis Generics are to the generic pharmaceuticals business we purchased from Allergan plc (Allergan) on August 2, 2016. References to R&D are to Research and Development, references to IPR&D are to in-process R&D, references to S&M are to Selling and Marketing and references to G&A are to General and Administrative. Some amounts in this report may not add up due to rounding. All percentages have been calculated using unrounded amounts.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical information, this Quarterly Report on Form 10-Q, and the reports and documents incorporated by reference in this Quarterly Report on Form 10-Q, may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management s current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. You can identify these forward-looking statements by the use of words such as should, expect, anticipate, estimate, target, may, project, guidance, intend, plan, believe and other words meaning and expression in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include risks relating to:

- our ability to successfully compete in the marketplace, including: that we are substantially dependent on our generic products; competition for our specialty products, especially COPAXONE®, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives; the uncertainty of commercial success of AJOVY® or AUSTEDO®; competition from companies with greater resources and capabilities; efforts of pharmaceutical companies to limit the use of generics, including through legislation and regulations; consolidation of our customer base and commercial alliances among our customers; the increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products; price erosion relating to our products, both from competing products and increased regulation; delays in launches of new products and our ability to achieve expected results from investments in our product pipeline; our ability to take advantage of high-value opportunities; the difficulty and expense of obtaining licenses to proprietary technologies; and the effectiveness of our patents and other measures to protect our intellectual property rights;

- our substantial indebtedness, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, may result in a further downgrade of our credit ratings; and our inability to raise debt or borrow funds in amounts or on terms that are favorable to us;

our business and operations in general, including: failure to effectively execute our restructuring plan announced in December 2017; uncertainties related to, and failure to achieve, the potential benefits and success of our senior management team and organizational structure; harm to our pipeline of future products due to the ongoing review of our R&D programs; our ability to develop and commercialize additional pharmaceutical products; potential additional adverse consequences following our resolution with the U.S. government of our FCPA investigation; compliance with sanctions and other trade control laws; manufacturing or quality control problems, which may damage our reputation for quality production and require costly remediation; interruptions in our supply chain; disruptions of our or third party information technology systems or breaches of our data security; the failure to recruit or retain key personnel; variations in intellectual property laws that may adversely affect our ability to manufacture our products; challenges associated with conducting business globally, including adverse effects of political or economic instability, major hostilities or terrorism; significant sales to a limited number of customers in our U.S. market; our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; and our prospects and opportunities for growth if we sell assets;

compliance, regulatory and litigation matters, including: costs and delays resulting from the extensive governmental regulation to which we are subject; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; increased legal and regulatory action in connection with public concern over the abuse of opioid medications in the U.S.; governmental investigations into S&M practices; potential liability for patent infringement; product liability claims; increased government scrutiny of our patent settlement agreements; failure to comply with complex Medicare and Medicaid reporting and payment obligations; and environmental risks;

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other financial and economic risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; potential impairments of our intangible assets; potential significant increases in tax liabilities; and 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;

and other factors discussed in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2018, including in the sections captioned Risk Factors. 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 herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,973	$ 1,782
Trade receivables	5,108	5,822
Inventories	4,782	4,731
Prepaid expenses	969	899
Other current assets	438	468
Assets held for sale	162	92
Total current assets	13,431	13,794
Deferred income taxes	351	368
Other non-current assets	756	731
Property, plant and equipment, net	6,785	6,868
Operating lease right-of-use assets	517	
Identifiable intangible assets, net	13,191	14,005
Goodwill	24,822	24,917
Total assets	$ 59,854	$ 60,683
LIABILITIES AND EQUITY		
Current liabilities:		
Short-term debt	$ 2,790	$ 2,216
Sales reserves and allowances	6,200	6,711
Trade payables	1,763	1,853
Employee-related obligations	633	870
Accrued expenses	1,869	1,868
Other current liabilities	773	804
Total current liabilities	14,028	14,322
Long-term liabilities:		
Deferred income taxes	2,079	2,140

Other taxes and long-term liabilities	1,669	1,727
Senior notes and loans	25,834	26,700
Operating Lease Liabilities	424	
Total long-term liabilities	30,005	30,567
Commitments and contingencies, see note 16		
Total liabilities	44,033	44,889
Equity:		
Teva shareholders equity:		
Ordinary shares of NIS 0.10 par value per share; March 31, 2019 and December 31, 2018: authorized 2,495 million shares; issued 1,198 million shares and 1,196 million shares, respectively	56	56
Additional paid-in capital	27,234	27,210
Accumulated deficit	(6,063)	(5,958)
Accumulated other comprehensive loss	(2,359)	(2,459)
Treasury shares as of March 31, 2019 and December 31, 2018 107 million ordinary shares and 106 million ordinary shares, respectively	(4,137)	(4,142)
	14,732	14,707
Non-controlling interests	1,089	1,087
Total equity	15,821	15,794
Total liabilities and equity	$ 59,854	$ 60,683

Amounts may not add up due to rounding.

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

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TEVA PHARMACEUTICAL INDUSTRIES LIMITED

CONSOLIDATED STATEMENTS OF INCOME (LOSS)

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

(Unaudited)

	Three months ended March 31,	
	2019	**2018**
Net revenues	$ 4,295	$ 5,065
Cost of sales	2,440	2,750
Gross profit	1,856	2,315
Research and development expenses	261	317
Selling and marketing expenses	648	738
General and administrative expenses	292	329
Intangible assets impairment	469	206
Goodwill impairment		180
Other assets impairments, restructuring and other items	1	501
Legal settlements and loss contingencies	57	(1,278)
Other income	(6)	(203)
Operating income	134	1,525
Financial expenses, net	218	271
Income (loss) before income taxes	(84)	1,254
Income taxes	9	46
Share in losses of associated companies, net	4	74
Net income (loss)	(97)	1,134
Net income attributable to non-controlling interests	8	14
Net income (loss) attributable to Teva	(105)	1,120
Dividends on preferred shares		65
Net income (loss) attributable to ordinary shareholders	$ (105)	$ 1,055
Earnings (loss) per share attributable to ordinary shareholders:		
Basic	$ (0.10)	$ 1.04
Diluted	$ (0.10)	$ 1.03

Weighted average number of shares (in millions):		
Basic	1,090	1,017
Diluted	1,090	1,020

Amounts may not add up due to rounding.

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

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TEVA PHARMACEUTICAL INDUSTRIES LIMITED

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(U.S. dollars in millions)

(Unaudited)

	Three months ended March 31,	
	2019	**2018**
Net income (loss)	$ (97)	$ 1,134
Other comprehensive income (loss), net of tax:		
Currency translation adjustment	47	239
Unrealized gain (loss) from derivative financial instruments	47	(44)
Unrealized gain from available-for-sale securities		1
Total other comprehensive income	94	196
Total comprehensive income (loss)	(3)	1,330
Comprehensive income attributable to non-controlling interests	2	97
Comprehensive income (loss) attributable to Teva	$ (5)	$ 1,233

Amounts may not add up due to rounding.

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

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Teva shareholders equity									
	Ordinary shares									
	Number of shares (in millions)	Stated value	MCPS*	Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other compre-hensive (loss)	Treasury shares	Total Teva share-holders equity	Non-controlling interests	Total equity
					(U.S. dollars in millions)					
Balance at December 31, 2017	1,124	54	3,631	23,479	(3,803)	(1,853)	(4,149)	17,359	1,386	18,745
Cumulative effect of new accounting standard					(5)	5				
Comprehensive income (loss)					1,120	113		1,233	97	1,330
Stock-based compensation expense				29				29		29
Dividends to preferred shareholders			65	(65)				0		0
Transactions with non-controlling interests									(2)	(2)
Balance at March 31, 2018	1,124	$ 54	$ 3,696	$ 23,443	$ (2,688)	$ (1,735)	$ (4,149)	$ 18,621	$ 1,481	$ 20,102

* Mandatory convertible preferred shares.

	Teva shareholders equity									
	Ordinary shares									
	Number of shares (in millions)	Stated value	MCPS*	Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other compre-hensive (loss)	Treasury shares	Total Teva share-holders equity	Non-controlling interests	Total equity
					(U.S. dollars in millions)					
	1,196	56	0	27,210	(5,958)	(2,459)	(4,142)	14,707	1,087	15,794

Balance at December 31, 2018									
Comprehensive income (loss)				(105)	100		(5)	2	(3)
Issuance of Shares	2	**							
Issuance of Treasury Shares			(3)			5	2		2
Stock-based compensation expense			34				34		34
Other			(6)				(6)		(6)
Balance at March 31, 2019	1,198	$ 56	$ 27,234	$ (6,063)	$ (2,359)	$ (4,137)	$ 14,732	$ 1,089	$ 15,821

* Mandatory convertible preferred shares.
** Represents an amount less than $0.5 million.

Amounts may not add up due to rounding.

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

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TEVA PHARMACEUTICAL INDUSTRIES LIMITED

CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars in millions)

(Unaudited)

	Three months ended March 31,	
	2019	**2018**
Operating activities:		
Net income (loss)	$ (97)	$ 1,134
Adjustments to reconcile net income (loss) to net cash provided by operations:		
Net change in operating assets and liabilities	(805)	(592)
Impairment of long-lived assets	489	432
Depreciation and amortization	443	507
Other items	83	(16)
Stock-based compensation	34	30
Deferred income taxes net and uncertain tax positions	(33)	(221)
Net gain from sale of long-lived assets and investments	(2)	(106)
Goodwill impairment		180
Impairment of equity investment		94
Research and development in process		54
Net cash provided by operating activities	112	1,496
Investing activities:		
Beneficial interest collected in exchange for securitized trade receivables	362	444
Purchases of property, plant and equipment	(125)	(163)
Other investing activities	23	(10)
Proceeds from sales of business, investments and long-lived assets	13	824
Purchases of investments and other assets	(1)	(56)
Net cash provided by investing activities	272	1,039
Financing activities:		
Repayment of senior notes and loans and other long-term liabilities	(126)	(6,243)
Tax withholding payments made on shares and dividends	(52)	(22)
Other financing activities	(10)	(5)
Net change in short-term debt	(1)	(261)
Proceeds from senior notes and loans, net of issuance costs		4,440
Net cash used in financing activities	(189)	(2,091)

Translation adjustment on cash and cash equivalents	(4)	11
Net change in cash and cash equivalents	191	455
Balance of cash and cash equivalents at beginning of period	1,782	963
Balance of cash and cash equivalents at end of period	$ 1,973	$ 1,418
Non-cash financing and investing activities:		
Beneficial interest obtained in exchange for securitized trade receivables	$ 396	$ 551

Amounts may not add up due to rounding

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

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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 recurring adjustments necessary to fairly state the financial position and results of operations of Teva. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company s Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission (SEC). Amounts as of December 31, 2018 were derived from the audited balance sheet at that date, but not all disclosures required by generally accepted accounting principles in the United States (U.S. GAAP) are included. Certain comparative figures have been reclassified to conform to current presentation. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of results that could be expected for the entire fiscal year. Certain amounts in the consolidated financial statements and associated notes may not add up due to rounding. All percentages have been calculated using unrounded amounts.

Note 2 Significant accounting policies:

Recently adopted accounting pronouncements

In June 2018, the FASB issued ASU 2018-07 Improvement to Nonemployee Share-Based Payments Accounting. This guidance simplifies the accounting for non-employee share-based payment transactions. The amendments specify that ASC 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor s own operations by issuing share-based payment awards. Teva adopted the provisions of this update as of January 1, 2019 with no material impact on its consolidated financial statements.

In August 2017, the FASB issued ASU 2017-12 Derivatives and Hedging Targeted Improvements to Accounting for Hedging Activities. This guidance expands and refines hedge accounting for both non-financial and financial risk components and aligns the recognition and presentation of the effects of the hedging instrument and the hedged item in the financial statements. Teva adopted the provisions of this update as of January 1, 2019 with no material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02 Leases . The guidance establishes a right-of-use model (ROU) that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The guidance became effective on January 1, 2019. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application.

Teva adopted the new accounting standard ASC 842 Leases and all the related amendments on January 1, 2019 and used the effective date as Teva s date of initial application. Consequently, financial information was not updated and the disclosures required under the new standard are not provided for dates and periods before January 1, 2019.

The new standard provides a number of optional practical expedients in transition. Teva did not elect the package of practical expedients , which permits the Company not to reassess its prior conclusions regarding lease identification, lease classification and initial direct costs under the new standard. However, the Company did elect the practical expedient pertaining to the use-of hindsight.

The new standard also provides practical expedients for an entity s ongoing accounting. Teva elected the short-term lease recognition exemption for all leases with a term shorter than 12 months. This means, for those leases, Teva does not recognize ROU assets or lease liabilities, including not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Teva also elected the practical expedient to not separate lease and non-lease components for all of Teva s leases, other than leases of real estate.

Additionally, following the adoption of the new Lease Standard and in subsequent measurements, Teva applies the portfolio approach to account for the operating lease ROU assets and liabilities for certain car leases and incremental borrowing rates.

The adoption of this standard has a material effect on Teva s financial statements. The most significant impact is reflected in: (i) the recognition of approximately $553 million ROU assets and $561 million lease liabilities on Teva s balance sheet for its operating leases of real estate, vehicles and equipment (the difference between the additional lease assets and lease liabilities did not impact the retained earnings), and (ii) the requirement to provide significant new disclosures regarding Teva s leasing activities and to enable users of financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. However, the adoption of this standard does not have a material impact on Teva s consolidated statements of income and consolidated statements of cash flows. Also, Company s accounting for finance leases remained substantially unchanged. See note 20 for further discussion.

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Notes to Consolidated Financial Statements

(Unaudited)

Recently issued accounting pronouncements, not yet adopted

In November 2018, the FASB issued ASU 2018-18 Collaborative Arrangements (Topic 808) Clarifying the interaction between Topic 808 and Topic 606. The amendments provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606. It also specifically (i) addresses when the participant should be considered a customer in the context of a unit of account, (ii) adds unit-of-account guidance in ASC 808 to align with guidance in ASC 606, and (iii) precludes presenting revenue from a collaborative arrangement together with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer. The guidance will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted and should be applied retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15 Intangibles Goodwill and other Internal-use software (Subtopic 350-40): Customer s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract. This guidance aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance will be effective for fiscal years beginning after December 15, 2019, although early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13 Fair Value Measurement (Topic 820) Disclosure Framework Changes to the Disclosure Requirements for Fair Value Measurement. This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. Certain disclosures required by this guidance must be applied on a retrospective basis and others on a prospective basis. The guidance will be effective for fiscal years beginning after December 15, 2019, although early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13 Financial Instruments Credit Losses Measurement of Credit Losses on Financial Instruments. This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance will be effective for the fiscal year beginning on January 1, 2020, including interim periods within that year. Teva is currently evaluating the potential effect of the guidance on its consolidated financial statements.

NOTE 3 Certain transactions:

Business acquisitions:

Actavis Generics and Anda acquisitions

On August 2, 2016, Teva completed the acquisition of Allergan plc s (Allergan) worldwide generic pharmaceuticals business (Actavis Generics). At closing, Teva transferred to Allergan consideration of approximately $33.4 billion in cash and approximately 100.3 million Teva shares.

On October 3, 2016, Teva completed the acquisition of Anda Inc. (Anda), a medicines distribution business in the United States, from Allergan, for cash consideration of $500 million. This transaction was related to the Actavis Generics acquisition and, as such, the purchase price accounting and related disclosures were treated on a combined basis.

The final cash consideration for the Actavis Generics acquisition was subject to certain net working capital adjustments. On January 31, 2018, Teva and Allergan entered into a settlement agreement and mutual releases for which Allergan made a one-time payment of $703 million to Teva to settle the working capital adjustments under the Master Purchase Agreement, dated July 26, 2015. As the measurement period has ended, this amount was recorded as a gain under legal settlements and loss contingencies in the first quarter of 2018.

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TEVA PHARMACEUTICAL INDUSTRIES LIMITED

Notes to Consolidated Financial Statements

(Unaudited)

Rimsa

On March 3, 2016, Teva completed the acquisition of Representaciones e Investigaciones Médicas, S.A. de C.V. (Rimsa), a pharmaceutical manufacturing and distribution company in Mexico, for $2.3 billion, in a cash free, debt free set of transactions. Teva financed the transaction using cash on hand.

Following the closing of the acquisition, Teva identified issues concerning Rimsa s pre-acquisition quality, manufacturing and other practices, at which point Teva began an assessment of the extent and cost of remediation required to return its products to the market. In September 2016, two lawsuits were filed: a pre-emptive suit by the Rimsa sellers against Teva and Teva s lawsuit alleging fraud and breach of contract against the Rimsa sellers. The Rimsa sellers subsequently dismissed their lawsuit and the dismissal was approved by court order on December 20, 2016.

On February 15, 2018, Teva and the Rimsa sellers entered into a settlement agreement and mutual releases with respect to Teva s breach of contract claim, pursuant to which the Rimsa sellers made a one-time payment to Teva. Teva s breach of contract claim was subsequently dismissed by the court. As the measurement period has ended, this payment was recorded as a gain under legal settlements and loss contingencies in the first quarter of 2018.

Assets and Liabilities Held For Sale:

The table below summarizes the major classes of assets and liabilities included as held for sale as of March 31, 2019 and December 31, 2018:

	March 31, 2019	December 31, 2018
	(U.S. $ in millions)	
Inventories	$ 25	$
Property, plant and equipment, net	114	92
Identifiable intangible assets, net	13	
Goodwill	79	51
Adjustments of assets held for sale to fair value	(69)	(51)
Total assets of the disposal group classified as held for sale in the consolidated balance sheets	$ 162	$ 92

Other significant agreements:

The Company has entered into alliances and other arrangements with third parties to acquire rights to products it does not have, to access markets it does not operate in and to otherwise share development costs or business risks. The Company s most significant agreements of this nature are summarized below.

Eli Lilly and Alder BioPharmaceuticals

In December 2018, Teva entered into an agreement with Eli Lilly, resolving the European Patent Office opposition they had filed against Teva s AJOVY patents. The settlement agreement with Lilly also resolved Lilly s action to revoke the patent protecting AJOVY in the U.K.

On January 8, 2018, Teva signed a global license agreement with Alder BioPharmaceuticals (Alder). The agreement validates Teva s IP and resolves Alder s opposition to Teva s European patent with respect to anti-calcitonin gene-related peptide (CGRP) antibodies, including the withdrawal of Alder s appeal before the European Patent Office. Under the terms of the agreement, Alder will receive a non-exclusive license to Teva s anti-CGRP antibodies patent portfolio to develop, manufacture and commercialize eptinezumab in the U.S. and worldwide, excluding Japan and Korea. Teva received a $25 million upfront payment that was recognized as revenue during the first quarter of 2018. The agreement stipulates additional milestone payments to Teva of up to $175 million, as well as future royalties.

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TEVA PHARMACEUTICAL INDUSTRIES LIMITED

Notes to Consolidated Financial Statements

(Unaudited)

PGT Healthcare Partnership

In July 2018, Teva terminated its joint venture with the Procter & Gamble Company (P&G), PGT Healthcare partnership (PGT), which the two companies established in 2011 to market over-the-counter (OTC) medicines. Teva will continue to maintain its OTC business on an independent basis.

As part of the separation, Teva transferred to P&G the shares it held in New Chapter Inc. and ownership rights in an OTC plant located in India. Teva provides certain services to P&G after the separation for a transition period.

During the first quarter of 2018, Teva classified the plant in India as an asset held for sale and recorded an impairment of $64 million under other assets impairments, restructuring and other items. In addition, Teva recorded a write-down of $94 million of its investment in New Chapter Inc. under share in losses of associated companies.

During September 2018, Teva and P&G completed the final net asset distribution as part of the dissolution and Teva recorded a gain of $50 million to reflect the cash payment received from P&G under the dissolution agreement.

AUSTEDO

On September, 19, 2017, Teva entered into a partnership agreement with Nuvelution Pharma, Inc. (Nuvelution) for development of AUSTEDO for the treatment of Tourette syndrome in pediatric patients in the United States. Nuvelution will fund and manage clinical development, driving all operational aspects of the phase 3 program, and Teva will lead the regulatory process and be responsible for commercialization. Upon and subject to FDA approval of AUSTEDO for the treatment of Tourette syndrome, Teva will pay Nuvelution a pre-agreed amount as compensation for their contribution to the partnership.

Otsuka

On May 12, 2017, Teva entered into a license and collaboration agreement with Otsuka Pharmaceutical Co. Ltd. (Otsuka), providing Otsuka with an exclusive license to conduct phase 2 and 3 clinical trials for AJOVY in Japan and, if approved, to commercialize the product in Japan. Otsuka paid Teva an upfront payment of $50 million in consideration for the transaction. Teva may receive additional milestone payments upon filing with Japanese regulatory authorities, receipt of regulatory approval and achievement of certain revenue targets. Otsuka will also pay Teva royalties on AJOVY sales in Japan.

Attenukine™

In December 2016, Teva entered into a license agreement for research, development, manufacture and commercializing of Attenukine technology with a subsidiary of Takeda Pharmaceutical Company Ltd. (Takeda). Teva received a $30 million upfront payment. The agreement stipulates additional milestone payments to Teva of up to $280 million, as well as future royalties.

Celltrion

In October 2016, Teva and Celltrion, Inc. (Celltrion) entered into a collaborative agreement to commercialize Truxima® and Herzuma®, two biosimilar products in development for the U.S. and Canadian markets. Teva paid Celltrion $160 million, of which up to $60 million is refundable or creditable under certain circumstances. Teva and Celltrion will share the profit from the commercialization of these products.

Regeneron

In September 2016, Teva and Regeneron Pharmaceuticals, Inc. (Regeneron) entered into a collaborative agreement to develop and commercialize Regeneron s pain medication product, fasinumab. Teva and Regeneron share equally in the global commercial rights to this product, as well as ongoing associated R&D costs of approximately $1 billion. Teva made an upfront payment of $250 million to Regeneron in the third quarter of 2016 as part of the agreement. Milestone payments of $25 million, $35 million and $60 million were paid in the second quarter of 2017, the first quarter of 2018 and the fourth quarter of 2018, respectively.

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NOTE 4 Inventories:

Inventories, net of reserves, consisted of the following:

	March 31, 2019	December 31, 2018
	(U.S. $ in millions)	
Finished products	$ 2,641	$ 2,665
Raw and packaging materials	1,357	1,328
Products in process	613	590
Materials in transit and payments on account	171	148
	$ 4,782	$ 4,731

NOTE 5 Property, plant and equipment:

Property, plant and equipment, net, consisted of the following:

	March 31, 2019	December 31, 2018
	(U.S. $ in millions)	
Machinery and equipment	$ 5,699	$ 5,691
Buildings	3,124	3,143
Computer equipment and other assets	2,113	2,097
Payments on account	520	514
Land	370	351
	11,826	11,796
Less accumulated depreciation	(5,041)	(4,928)
	$ 6,785	$ 6,868

NOTE 6 Identifiable intangible assets:

Identifiable intangible assets consisted of the following:

	Gross carrying amount net of impairment		Accumulated amortization		Net carrying amount	
	March 31, 2019	December 31, 2018	March 31, 2019	December 31, 2018	March 31, 2019	December 31, 2018
	(U.S. $ in millions)					
Product rights	$ 20,201	$ 20,361	$ 9,706	$ 9,565	$ 10,494	$ 10,796
Trade names	603	606	100	91	503	515
In process research and development	2,193	2,694			2,193	2,694
Total	$ 22,997	$ 23,661	$ 9,806	$ 9,656	$ 13,191	$ 14,005

Product rights and trade names

Product rights and trade names are assets presented at amortized cost. Product rights and trade names represent a portfolio of pharmaceutical products from various categories with a weighted average life of approximately 12 years. Amortization of intangible assets amounted to $283 million and $310 million in the three months ended March 31, 2019 and 2018, respectively.

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IPR&D

Teva s IPR&D are assets that have not yet been approved in major markets. Teva s IPR&D is comprised mainly of the following acquisitions and related assets: various generic products (Actavis Generics) $1,935 million; various generic products (Rimsa) $47 million and AUSTEDO $211 million. IPR&D carries intrinsic risks that the asset might not succeed in advanced phases and may be impaired in future periods.

In the first three months of 2019, Teva reclassified $236 million of products from IPR&D to product rights following regulatory approval, mainly $174 million in connection with Methyl ER.

Intangible assets impairment

Impairments of long-lived intangible assets in the first three months of 2019 and 2018 were $469 million and $206 million, respectively. Impairments in the first quarter of 2019 consisted of:

a) IPR&D assets of $265 million, mainly due to: (i) $125 million related to lenalidomide (generic equivalent of Revlimid®) due to modified competition assumptions as a result of settlements between the innovator and other generic filers and (ii) $140 million of other generic products acquired from Actavis Generics due to development progress and changes in other key valuation indications (e.g., market size, competition assumptions, legal landscape, launch date or discount rate); and

b) Identifiable product rights of $204 million, mainly due to updated market assumptions regarding price and volume of products acquired from Actavis Generics and primarily marketed in the United States.

NOTE 7 Goodwill:

The changes in the carrying amount of goodwill for the period ended March 31, 2019 were as follows:

	North America	International Europe	International Markets	Other	Total
	(U.S. $ in millions)				
Balance as of January 1, 2019	$ 11,098	$ 8,653	$ 2,479	$ 2,687	$ 24,917
Changes during the period:					
Goodwill reclassified as assets to held for sale	(23)	(5)			(28)
Translation differences	8	(117)	41	1	(67)

Balance as of March 31, 2019	$ 11,083	$ 8,531	$ 2,520	$ 2,688	$ 24,822

Teva operates its business through three segments: North America, Europe and International Markets. Teva began reporting its financial results under this structure in the first quarter of 2018. In addition to these three segments, Teva has other sources of revenues, primarily the sale of APIs to third parties, certain contract manufacturing services and an out-licensing platform offering a portfolio of products to other pharmaceutical companies through its affiliate Medis. See note 17.

Teva determines the fair value of its reporting units using the income approach. The income approach is a forward-looking approach for estimating fair value. Within the income approach, the method used is the discounted cash flow method. Teva starts with a forecast of all the expected net cash flows associated with the reporting unit, which includes the application of a terminal value, and then applies a discount rate to arrive at a net present value amount. Cash flow projections are based on Teva s estimates of revenue growth rates and operating margins, taking into consideration industry and market conditions. The discount rate used is based on the WACC, adjusted for the relevant risk associated with country-specific and business-specific characteristics. If any of these expectations were to vary materially from Teva s assumptions, Teva could face impairment of goodwill allocated to these reporting units in the future.

During the first quarter of 2019, management assessed developments during the quarter to determine if it was more likely than not that the fair value of any of its reporting units was below its carrying amount. This includes the International Markets, Medis and Europe reporting units, which had headroom of 6% or less as of December 31, 2018. As part of this assessment, the Company also considered the sensitivity of its conclusions as they relate to changes in the estimates and assumptions used in the latest forecast available for each period.

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In addition, Teva analyzed the aggregate fair value of its reporting units, calculated as part of the annual goodwill impairment test performed in the fourth quarter of 2018, compared to its market capitalization. Despite the decrease in share price during the first quarter of 2019 compared to the average share price used to assess the reasonableness of the results of the cash flow projections used for the goodwill impairment analysis in the fourth quarter of 2018, management believes that its fair value assessment is reasonably supported by Teva s market capitalization. Management will continue to monitor business conditions and will also consider future developments in Teva s market capitalization when assessing whether additional goodwill impairment is required in future periods.

Based on this assessment, management has concluded that it is not more likely than not that the fair value of any of the reporting units is below its carrying value as of March 31, 2019 and, therefore, no quantitative assessments were performed.

NOTE 8 Earnings (Loss) per share:

Basic earnings and loss per share are computed by dividing net results 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 the diluted loss per share for the three months ended March 31, 2019, no account was taken of the potential dilution by the assumed exercise of employee stock options and non-vested RSUs granted under employee stock compensation plans, and convertible senior debentures, since they had an anti-dilutive effect on loss per share. Diluted earnings per share for the three months ended March 31, 2018 took into account the potential dilution that could occur upon the exercise of options and non-vested RSUs granted under employee stock compensation plans, using the treasury stock method.

Additionally, in the three months ended March 31, 2018, no account was taken of the potential dilution by the mandatory convertible preferred shares, amounting to 64 million shares (including shares that were issued due to unpaid dividends until that date), since they had an anti-dilutive effect on loss per share.

On December 17, 2018, the mandatory convertible preferred shares automatically converted into ADSs and all of the accumulated and unpaid dividends on the mandatory convertible preferred shares were paid in ADSs. As a result of this conversion, Teva issued 70.6 million ADSs in December 2018.

NOTE 9 Revenue from contracts with customers:

Disaggregation of revenue

The following table disaggregates Teva s revenues by major revenue streams. For additional information on disaggregation of revenues see note 17.

	Three months ended March 31, 2019				
	North America	Europe	International Markets	Other activities	Total
	(U.S.$ in millions)				
Sale of goods	1,637	1,259	468	187	3,551
Licensing arrangements	31	5	§	1	37
Distribution	379	§	151		530
Other		§	48	128	177
	$ 2,047	$ 1,264	$ 668	$ 317	$ 4,295

§ Represents an amount less than $1 million.

	Three months ended March 31, 2018				
	North America	Europe	International Markets	Other activities	Total
	(U.S.$ in millions)				
Sale of goods	2,168	1,429	519	177	4,293
Licensing arrangements	32	10	20	2	64
Distribution	331	3	153		487
Other			58	163	221
	$ 2,531	$ 1,442	$ 750	$ 342	$ 5,065

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Variable consideration

Variable consideration mainly includes sales reserves and allowances (SR&A), comprised of rebates (including Medicaid and other governmental program discounts), chargebacks, returns and other promotional (including shelf stock adjustments) items. Provisions for prompt payment discounts are netted against trade receivables.

The Company recognizes these provisions at the time of sale and adjusts them if the actual amounts differ from the estimated provisions.

SR&A to U.S. customers comprised approximately 83% of the Company s total SR&A as of March 31, 2019, with the remaining balance primarily in Canada and Germany. The changes in SR&A for third-party sales for the three months ended March 31, 2019 were as follows:

		Sales Reserves and Allowances						
	Reserves included in Accounts Receivable, net	Rebates	Medicaid and other governmental allowances	Chargebacks	Returns	Other	Total reserves included in Sales Reserves and Allowances	Total
				(U.S.$ in millions)				
Balance at December 31, 2018	$ 175	$ 3,006	$ 1,361	$ 1,530	$ 638	$ 176	$ 6,711	$ 6,886
Provisions related to sales made in current year period	112	1,350	324	2,320	72	114	4,180	4,292
Provisions related to sales made in prior periods			1	(5)	3	(1)	(2)	(2)
Credits and payments	(125)	(1,613)	(438)	(2,413)	(117)	(101)	(4,682)	(4,807)
Translation differences		(6)	(1)				(7)	(7)
Balance at March 31, 2019	$ 162	2,737	$ 1,247	$ 1,432	$ 596	$ 188	$ 6,200	$ 6,362

NOTE 10 Accumulated other comprehensive loss:

The components of, and changes within, accumulated other comprehensive losses attributable to Teva are presented in the table below:

	Net Unrealized Gains/(Losses)			Benefit Plans	
	Foreign currency translation adjustments	Available-for-sale securities	Derivative financial instruments	Actuarial gains/(losses) and prior service (costs)/credits	Total
	(U.S.$ in millions)				
Balance as of December 31, 2017*	$ (1,316)	$ 1	$ (442)	$ (91)	$ (1,848)
Other comprehensive income (loss) before reclassifications	156	1	(51)		106
Amounts reclassified to the statements of income			7		7
Net other comprehensive income (loss) before tax	156	1	(44)		113
Net other comprehensive income (loss) after tax* *	156	1	(44)		113
Balance as of March 31, 2018	$ (1,160)	$ 2	$ (486)	$ (91)	$ (1,735)

* Following the adoption of ASU 2016-01, the Company recorded a $5 million opening balance reclassification from accumulated other comprehensive income to retained earnings.

** Amounts do not include a $83 million gain from foreign currency translation adjustments attributable to non-controlling interests.

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	Net Unrealized Gains/(Losses)			Benefit Plans Actuarial gains/(losses) and prior service (costs)/credits	
	Foreign currency translation adjustments	Available-for-sale securities	Derivative financial instruments		Total
	(U.S.$ in millions)				
Balance as of December 31, 2018	$ (2,055)	$ 1	$ (327)	$ (78)	$ (2,459)
Other comprehensive income (loss) before reclassifications	53		40		93
Amounts reclassified to the statements of income			7		7
Net other comprehensive income (loss) before tax	53		47		100
Net other comprehensive income (loss) after tax*	53		47		100
Balance as of March 31, 2019	$ (2,002)	$ 1	$ (280)	$ (78)	$ (2,359)

* Amounts do not include a $6 million loss from foreign currency translation adjustments attributable to non-controlling interests.

NOTE 11 Debt obligations:

a. Short-term debt:

	Weighted average interest rate as of March 31, 2019	Maturity	March 31, 2019	December 31, 2018
			(U.S. $ in millions)	
Bank and financial institutions	6.94%		$ 2	$ 2
Convertible debentures	0.25%	2026	514	514
Current maturities of long-term liabilities			2,274	1,700
Total short term debt			$ 2,790	$ 2,216

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Long-term debt:

	Weighted average interest rate as of March 31, 2019 %	Maturity	March 31, 2019	December 31, 2018
			(U.S. $ in millions)	
Senior notes EUR 1,660 million	0.38%	2020	$ 1,860	$ 1,897
Senior notes EUR 1,500 million	1.13%	2024	1,674	1,707
Senior notes EUR 1,300 million	1.25%	2023	1,452	1,480
Senior notes EUR 900 million	4.50%	2025	1,010	1,029
Senior notes EUR 750 million	1.63%	2028	834	850
Senior notes EUR 700 million	3.25%	2022	785	801
Senior notes EUR 700 million	1.88%	2027	783	798
Senior notes USD 3,500 million	3.15%	2026	3,493	3,493
Senior notes USD 3,000 million	2.20%	2021	2,998	2,997
Senior notes USD 3,000 million	2.80%	2023	2,994	2,993
Senior notes USD 1,574 million (1)	1.70%	2019	1,574	1,700
Senior notes USD 2,000 million	4.10%	2046	1,985	1,985
Senior notes USD 1,250 million	6.00%	2024	1,250	1,250
Senior notes USD 1,250 million	6.75%	2028	1,250	1,250
Senior notes USD 844 million	2.95%	2022	859	860
Senior notes USD 789 million	6.15%	2036	782	782
Senior notes USD 700 million	2.25%	2020	700	700
Senior notes USD 613 million	3.65%	2021	620	621
Senior notes USD 588 million	3.65%	2021	587	587
Senior notes CHF 350 million	0.50%	2022	352	356
Senior notes CHF 350 million	1.00%	2025	352	356
Fair value hedge accounting adjustments			(6)	(9)
Total senior notes			28,188	28,483
Other long term debt	4.58%	2026	13	12
Less current maturities			(2,274)	(1,700)
Derivative instruments			6	9
Less debt issuance costs			(99)	(104)
Total senior notes and loans			$ 25,834	$ 26,700

(1) During the first quarter of 2019, Teva repurchased and canceled approximately $126 million principal amount of its $1,700 million 1.7% senior notes due in July 2019.

Long term debt was issued by several indirect wholly-owned subsidiaries of the Company and is fully and unconditionally guaranteed by the Company as to payment of all principal, interest, discount and additional amounts (as defined), if any.

Long term debt as of March 31, 2019 is effectively denominated (taking into consideration cross currency swap agreements) in the following currencies: U.S. dollar 66%, euro 31% and Swiss franc 3%.

Teva s principal sources of short-term liquidity are its existing cash investments, liquid securities and available credit facilities, primarily its $2.3 billion revolving credit facility (RCF).

In April 2019, the Company entered into a $2.3 billion unsecured syndicated revolving credit facility, which replaced the previous $3 billion revolving credit facility. The RCF contains certain covenants, including certain limitations on incurring liens and indebtedness and maintenance of certain financial ratios, including a maximum leverage ratio, which becomes more restrictive over time. As of March 31, 2019, the Company did not have any outstanding debt under its then-applicable RCF, which was its only debt subject to a maximum leverage ratio, and met all financial covenants thereunder.

Teva expects that it will continue to have sufficient cash resources to support its debt service payments and all other financial obligations for at least twelve months from the date of this report.

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NOTE 12 Fair value measurement:

Teva s financial instruments consist mainly of cash and cash equivalents, investment in securities, current and non-current receivables, short-term debt, current and non-current payables, contingent consideration, senior notes and loans, convertible senior debentures and derivatives.

The fair value of the financial instruments included in working capital and non-current receivables and payables approximates their carrying value. The fair value of loans and bank facilities 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.

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.

There were no transfers between Level 1, Level 2 and Level 3 during the first three months of 2019.

Financial items carried at fair value as of March 31, 2019 and December 31, 2018 are classified in the tables below in one of the three categories described above:

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	March 31, 2019			
	Level 1	Level 2	Level 3	Total
	(U.S. $ in millions)			
Cash and cash equivalents:				
Money markets	$ 319	$	$	$ 319
Cash, deposits and other	1,654			1,654
Investment in securities:				
Equity securities	52			52
Other, mainly debt securities	2		13	15
Derivatives:				
Asset derivatives options and forward contracts		32		32
Asset derivatives cross currency swaps		76		76
Liabilities derivatives options and forward contracts		(11)		(11)
Liabilities derivatives interest rate and cross-currency swaps		(28)		(28)
Contingent consideration*			(405)	(405)
Total	$ 2,027	$ 69	$ (392)	$ 1,704

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
	(U.S. $ in millions)			
Cash and cash equivalents:				
Money markets	$ 203	$	$	$ 203
Cash, deposits and other	1,579			1,579
Investment in securities:				
Equity securities	51			51
Other, mainly debt securities	2		10	12
Derivatives:				
Asset derivatives options and forward contracts		18		18
Asset derivatives cross-currency swaps		58		58
Liability derivatives options and forward contracts		(26)		(26)
Liabilities derivatives interest rate and cross-currency swaps		(50)		(50)
Contingent consideration*			(507)	(507)
Total	$ 1,835	$	$ (497)	$ 1,338

* Contingent consideration represents liabilities recorded at fair value in connection with acquisitions.

Teva determined the fair value of the liability for the contingent consideration based on a probability-weighted discounted cash flow analysis. This fair value measurement is based on significant unobservable inputs in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value of the contingent consideration is based on several factors, such as: the cash flows projected from the success of unapproved product candidates; the probability of success of product candidates, including risks associated with uncertainty regarding achievement and payment of milestone events; the time and resources needed to complete the development and approval of product candidates; the life of the potential commercialized products and associated risks of obtaining regulatory approvals in the U.S. and Europe, and the risk adjusted discount rate for fair value measurement.

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

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

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

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	Three months ended March 31, 2019 (U.S. $ in millions)
Fair value at the beginning of the period	$ (497)
Revaluation of debt securities	3
Adjustments to provisions for contingent consideration:	
Actavis Generics transaction see note 14	106
Labrys transaction	
Eagle transaction	(35)
Settlement of contingent consideration:	
Eagle transaction	31
Fair value at the end of the period	$ (392)

Financial instruments not measured at fair value

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

	Estimated fair value*	
	March 31, 2019	December 31, 2018
	(U.S. $ in millions)	
Senior notes included under senior notes and loans	$ 23,622	$ 23,560
Senior notes and convertible senior debentures included under short-term debt	2,732	2,140
Total	$ 26,354	$ 25,700

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

NOTE 13 Derivative instruments and hedging activities:

a. Foreign exchange risk management:

In the first quarter of 2019, approximately 49% of Teva s revenues were denominated in currencies other than the U.S. dollar. As a result, Teva is subject to significant foreign currency risks.

The Company enters into forward exchange contracts, purchases and writes options in order to hedge the currency exposure on balance sheet items. In addition, the Company takes measures to reduce exposure by using natural hedging. The Company also acts to offset risks in opposite directions among the companies in the Group. The currency hedged items are usually denominated in the following main currencies: the new Israeli shekel (NIS), the euro (EUR), the Swiss franc (CHF), the Japanese yen (JPY), the British pound (GBP), the Canadian dollar (CAD), the Polish zloty (PLN), the Indian rupee (INR) and other European and Latin American currencies.

Depending on market conditions, foreign currency risk is also managed through the use of foreign currency debt.

The Company hedges against possible fluctuations in foreign subsidiaries net assets (net investment hedge) and entered into cross currency swaps and forward contracts in order to hedge such an exposure.

Most of the counterparties to the derivatives are major banks and the Company is monitoring the associated inherent credit risks. The Company does not enter into derivative transactions for trading purposes.

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b. Interest risk management:

The Company raises capital through various debt instruments, including straight notes that bear a fixed or variable interest rate, bank loans, securitizations and convertible debentures. In some cases, the Company has swapped from a fixed to a floating interest rate (fair value hedge) and from a fixed to a fixed interest rate with an exchange from a currency other than the functional currency (cash flow hedge), thereby reducing overall interest expenses or hedging risks associated with interest rate fluctuations.

c. Derivative instruments notional amounts

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

	March 31, 2019	December 31, 2018
	(U.S. $ in millions)	
Cross-currency swap cash flow hedge	$ 588	$ 588
Cross-currency swap net investment hedge	1,000	1,000
Interest rate swap fair value hedge	500	500
	2,088	2,088

d. Derivative instrument outstanding:

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

	Fair value			
	Designated as hedging instruments		Not designated as hedging instruments	
	March 31, 2019	December 31, 2018	March 31, 2019	December 31, 2018
Reported under	(U.S. $ in millions)			
Asset derivatives:				
Other current assets:				

Option and forward contracts	$	$	$ 32	$ 18
Other non-current assets:				
Cross-currency swaps cash flow hedge	76	58		
Liability derivatives:				
Other current liabilities:				
Option and forward contracts			(11)	(26)
Cross-currency swaps net investment hedge	(22)			
Other taxes and long-term liabilities:				
Cross-currency swaps net investment hedge		(41)		
Senior notes and loans:				
Interest rate swaps fair value hedge	(6)	(9)		

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The table below provides information regarding the location and amount of pretax (gains) losses from derivatives designated in fair value or cash flow hedging relationships:

	Reported under Financial expenses, net		Other Comprehensive income	
	Period ended,			
	March 31, 2019	March 31, 2018**	March 31, 2019	March 31, 2018**
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	$ 218	$ 271	$ 100	$ 113
Cross-currency swaps cash flow hedge (1)	(1)	*	(20)	17
Cross-currency swaps net investment hedge (2)	(7)	(7)	(20)	$ 30
Interest rate swaps fair value hedge (3)	$ 1	$ *	$	$

* Represents an amount less than $0.5 million.

** Comparative figures are based on prior hedge accounting standard.

The table below provides information regarding the location and amount of pretax (gains) losses from derivatives not designated as hedging instruments:

	Reported under Financial expenses, net		Net Revenues	
	Period ended,			
	March 31, 2019	March 31, 2018	March 31, 2019	March 31, 2018
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	218	271	4,295	5,065
Option and forward contracts (4)	$ (42)	$ 19	$	$

(1) With respect to cross-currency swap agreements, Teva recognized gains which mainly reflect the differences between the fixed interest rate and the floating interest rate.

(2) In each of the first and second quarters of 2017, Teva entered into a cross currency swap agreement with a notional amount of $500 million maturing in 2020. These cross currency swaps were designated as a net investment hedge of Teva s foreign subsidiaries euro denominated net assets, in order to reduce the risk of adverse exchange rate fluctuations. With respect to these cross currency swap agreements, Teva recognized gains which mainly reflect the differences between the float-for-float interest rates paid and received. No amounts were reclassified from AOCI into income related to the sale of a subsidiary.

(3) In the fourth quarter of 2016, Teva entered into an interest rate swap agreement designated as fair value hedge relating to its 2.8% senior notes due 2023 with respect to $500 million notional amount of outstanding debt. With respect to this interest rate swap agreement, Teva recognized a loss which mainly reflects the differences between the fixed interest rate and the floating interest rate.

(4) Teva uses foreign exchange contracts (mainly option and forward contracts) to hedge balance sheet items from currency exposure. These foreign exchange contracts are not designated as hedging instruments for accounting purposes. In connection with these foreign exchange contracts, Teva recognizes gains or losses that offset the revaluation of the balance sheet items also recorded under financial expenses net.

e. Matured forward starting interest rate swaps and treasury lock agreements:

Commencing in 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 actual date of the U.S. dollar debt issuance in July 2016 (in connection with the closing of the Actavis Generics acquisition). See note 11.

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Certain of the forward starting interest rate swaps and treasury lock agreements matured during the first half of 2016. In July 2016, in connection with the debt issuances, Teva terminated the remaining forward starting interest rate swaps and treasury lock agreements. The termination of these transactions resulted in a loss position of $493 million, of which $242 million were settled on October 7, 2016 and the remaining amount was settled in January 2017. The change in fair value of these instruments recorded in other comprehensive income (loss) will be amortized under financial expenses-net over the life of the debt. Such losses mainly reflect the changes in the benchmark interest rate between the date the agreements were entered into and the actual date of the U.S. debt issuance in July 2016.

With respect to the forward starting interest rate swaps and treasury lock agreements, losses of $7 million were recognized under financial expenses, net for the three months ended March 31, 2019 and 2018.

In the third quarter of 2016, Teva terminated interest rate swap agreements designated as fair value hedge relating to its 2.95% senior notes due 2022 with respect to $844 million notional amount and its 3.65% senior notes due 2021 with respect to $450 million notional amount. Settlement of these transactions resulted in a gain position of $41 million. The fair value hedge accounting adjustments of these instruments, which are recorded under senior notes and loans, are amortized under financial expenses-net over the life of the debt as additional interest expense.

With respect to the interest rate swap agreements, gains of $2 million were recognized under financial expenses, net for the three months ended March 31, 2019 and 2018.

NOTE 14 Other assets impairments, restructuring and other items:

	Three months ended March 31,	
	2019	2018
	(U.S. $ in millions)	
Impairments of long-lived tangible assets (1)	$ 20	$ 226
Contingent consideration	(71)	8
Restructuring	32	247
Other	20	20
Total	$ 1	$ 501

(1) Including impairments related to exit and disposal activities

Impairments

Impairments of property, plant and equipment for the first three months of 2019 were $20 million, consisting mainly of impairment of lease-related assets in North America.

As a result of Teva s plant rationalization acceleration in connection with the two year restructuring plan announced in December, 2017, to the extent the Company changes its plans on any given asset and/or the assumptions underlying such plans, there may be additional impairments in the future.

Contingent consideration

In the three months ended March 31, 2019, Teva recorded $71 million of contingent consideration income, compared to $8 million expense in the three months ended March 31, 2018. The income in the first quarter of 2019 mainly related to the decrease in the expected royalty payments in connection with lenalidomide (generic equivalent of Revlimid®) which was part of the Actavis acquisition.

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Restructuring

In the three months ended March 31, 2019, Teva recorded $32 million of restructuring expenses, compared to $247 million in the three months ended March 31, 2018.

Since the announcement of its restructuring plan, Teva reduced its global headcount by approximately 10,400 full-time-equivalent employees.

The following tables provide the components of costs associated with Teva s restructuring plan, including other costs associated with Teva s restructuring plan and recorded under different items:

	Three months ended March 31,	
	2019	2018
	(U.S. $ in millions)	
Restructuring		
Employee termination	$ 20	$ 228
Other	12	19
Total	$ 32	$ 247

The following table provides the components of and changes in the Company s restructuring accruals:

	Employee termination costs	Other	Total
	(U.S. $ in millions)		
Balance as of January 1, 2019	$ (204)	$ (29)	$ (233)
Provision	(20)	(12)	(32)
Utilization and other*	32	34	66
Balance as of March 31, 2019	$ (192)	$ (7)	$ (199)

* Includes adjustments for foreign currency translation.

Significant regulatory events

In July 2018, the FDA completed an inspection of Teva s manufacturing plant in Davie, Florida in the United States, and issued a Form FDA-483 to the site. In October 2018, the FDA notified Teva that the inspection of the site is classified as official action indicated (OAI). On February 5, 2019, Teva received a warning letter from the FDA that contains four enumerated concerns related to production, quality control, and investigations at this site. Teva is working diligently to remediate the FDA s concerns in a manner consistent with current good manufacturing practice (CGMP) requirements, and to address those concerns as quickly and as thoroughly as possible. If Teva is unable to remediate the warning letter findings to the FDA s satisfaction, it may face additional consequences, including delays in FDA approval for future products from the site, financial implications due to loss of revenues, impairments, inventory write offs, customer penalties, idle capacity charges, costs of additional remediation and possible FDA enforcement action. Teva expects to generate approximately $240 million in revenues from this site for the remainder of 2019, assuming remediation or enforcement does not cause any unscheduled slowdown or stoppage at the facility.

In July 2018, Teva announced the voluntary recall of valsartan and certain combination valsartan medicines in various countries due to the detection of trace amounts of a previously unknown impurity called NDMA found in valsartan API supplied to Teva by Zhejiang Huahai Pharmaceutical. Since July 2018, Teva has been actively engaged with regulatory agencies around the world in reviewing its valsartan and other sartan products for NDMA and other related impurities and, where necessary, has initiated additional voluntary recalls. The impact of this recall on Teva s 2018 financial statements was $51 million, primarily related to inventory reserves. Teva expects to continue to experience loss of revenues and profits in connection with this matter. In addition, multiple lawsuits have been filed in connection with this matter, for which litigation costs are currently being incurred. Teva may also incur additional customer penalties, impairments and litigation costs going forward.

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NOTE 15 Legal Settlements and Loss Contingencies:

Legal settlements and loss contingencies for the first three months of 2019 amounted to an expense of $57 million, compared to an income of $1,278 million in the first three months of 2018. The income in the first quarter of 2018 consisted primarily of the working capital adjustment with Allergan, the Rimsa settlement and a reversal of the reserve related to the carvedilol judgment.

As of March 31, 2019 and December 31, 2018, Teva s provision for legal settlements and loss contingencies recorded under accrued expenses was $618 million and $562 million, respectively.

NOTE 16 Commitments and 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 generally believes that it has meritorious defenses to the 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 the cases described below, 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. Teva continuously reviews the matters described below and may, from time to time, remove previously disclosed matters that the Company has determined no longer meet the materiality threshold for disclosure.

If one or more of such proceedings described below 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.

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. Among other things, 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. Except as otherwise noted, all third party sales figures given below are based on IQVIA (formerly IMS Health Inc.) data.

For income tax contingencies, see note 15 to Teva s Annual Report on Form 10-K for the year ended December 31, 2018.

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. 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, which could be material to its results of operations and cash flows in a given period.

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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 generally be calculated based on the sales of Teva s product. The amount of lost profits would generally be based on the lost sales of the patentee s product. 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. The laws concerning generic pharmaceuticals and patents differ from country to country. Damages for patent infringement in Europe may include lost profits or a reasonable royalty, but enhanced damages for willful infringement are generally not available.

In July 2014, GlaxoSmithKline (GSK) sued Teva in Delaware federal court for infringement of a patent expiring in June 2015 directed to using carvedilol in a specified manner to decrease the risk of mortality in patients with congestive heart failure. Teva and eight other generic producers began selling their carvedilol tablets (the generic version of GSK s Coreg®) in September 2007. A jury trial was held and the jury returned a verdict in GSK s favor finding Teva liable for induced infringement, including willful infringement, and assessing damages of $235.5 million, not including pre- or post-judgment interest. Following post-trial motions filed by the parties, on March 28, 2018, the district court issued an opinion overturning the jury verdict and instead found no induced infringement by Teva, thereby finding that Teva did not owe any damages; the district court also denied Teva s motion seeking to overturn the jury verdict with respect to invalidity. On May 25, 2018, both parties filed an appeal. If the appeal of the district court s decision is decided against Teva, the case would be remanded to the district court for it to consider Teva s other legal and equitable defenses that have not yet been considered by the district court. The provision that was included in the financial statements for this matter was reversed as the exposure is no longer considered probable.

In 2014, Teva Canada succeeded in its challenge of the bortezomib (the generic equivalent of Velcade®) product and mannitol ester patents under the Patented Medicines (Notice Of Compliance) Regulations (PM(NOC)). At the time of Teva s launch in 2015, annual sales of Velcade were approximately 94 million Canadian dollars. Additionally, Teva commenced an action under Section 8 of PM(NOC) to recover damages for being kept off of the market during the PM(NOC) proceedings. Janssen and Millennium filed a counterclaim for infringement of the same two patents as well as a patent covering a process to prepare bortezomib. The product patent expired in October 2015; the other patents expire in January 2022 and March 2025. In 2017, Teva entered into an agreement with Janssen and Millennium which limits the damages payable by either party depending on the outcome of the infringement/impeachment action. As a result, the most Janssen and Millennium could recover is 200 million Canadian dollars plus post-judgment interest. In June 2018, the court ruled that Janssen and Millennium pay Teva 5 million Canadian dollars in Section 8 damages. Janssen and Millennium filed an appeal that is currently pending. If the decision is overturned on appeal, Teva could owe the capped damages set forth above. In addition to the potential damages that could be awarded, Teva could be ordered to cease sales of its bortezomib product.

On July 8, 2011, Helsinn sued Teva over its filing of an ANDA to market a generic version of palonosetron IV solution (the generic equivalent of Aloxi®) and in November 2015, the District Court of New Jersey ruled against Teva. Teva appealed this decision and in May 2017, the Federal Circuit Court of Appeals reversed the district court s ruling and found the asserted patents invalid. In January 2018, full appellate review of that decision was denied. Helsinn filed an appeal with the US Supreme Court, which was granted. On January 22, 2019, the Supreme Court affirmed the appellate court s decision finding the asserted patent invalid. Helsinn has no further opportunity to appeal this patent decision. Separately, in October 2014, Helsinn filed an additional claim on later-acquired patents. On January 30, 2018, the District Court of New Jersey denied Helsinn s request for a preliminary injunction based on these later acquired patents. Teva launched its generic palonosetron IV solution after obtaining final regulatory approval on March 23, 2018. If Teva ultimately loses the case on the later-acquired patents discussed above, Teva may be ordered to cease sales of its generic product and/or pay damages to Helsinn. Aloxi® annual U.S. sales as of November 2017 were $459 million.

In July 2015, Janssen sued Actavis and Teva (along with 10 other filers) over their filing of an ANDA to market their abiraterone acetate tablets, 250mg (generic versions of Zytiga®). In August 2017, Janssen sued Teva over its ANDA filing to market a 500mg generic version of Zytiga. In both cases, Janssen asserted a method of treatment patent. In January 2018, following a petition for *inter partes* review, the Patent Trials and Appeals Board (PTAB) found the patent to be invalid. In October 2018, the New Jersey District Court also found the patent to be invalid. Both the District Court and PTAB decisions are currently on appeal. Teva launched its generic 250mg product in November 2018. If Teva ultimately loses this case, Teva may be ordered by the court to cease sales of its generic product and/or pay damages to Janssen. Annual U.S. sales of Zytiga at the time of generic entry were about $1.3 billion.

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Product Liability Litigation

Teva s business inherently exposes it to potential product liability claims. 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 its product liability 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 insurance it desires, or any insurance on reasonable terms, in all of its markets.

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.

Teva and its subsidiaries have increasingly been named as defendants in cases that allege antitrust violations arising from such settlement agreements. The plaintiffs in these cases, which are usually direct and indirect purchasers of pharmaceutical products, and often assert claims on behalf of classes of all direct and indirect purchasers, typically allege that (1) Teva received something of value from the innovator in exchange for an agreement to delay generic entry, and (2) significant savings could have been realized if there had been no settlement agreement and generic competition had commenced earlier. These class action 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, which are automatically tripled under the relevant statutes, plus attorneys fees and costs. The alleged damages generally depend on the size of the branded market and the length of the alleged delay, and can be substantial potentially measured in multiples of the annual brand sales particularly where the alleged delays are lengthy or branded drugs with annual sales in the billions of dollars are involved.

Teva believes that its settlement agreements are lawful and serve to increase competition, and has defended them vigorously. In Teva s experience to date, these cases have typically settled for a fraction of the high end of the damages sought, although there can be no assurance that such outcomes will continue.

In June 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 has resulted in increased scrutiny of Teva s patent

settlements, additional action by the FTC and state and local authorities, 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 U.S. 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 filed by a purported class of direct purchasers. Similar complaints were also filed by a purported class of indirect purchasers, certain 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. Teva has either settled or reached agreements in principle to settle with all of the plaintiffs in the Philadelphia Modafinil Action. Additionally, Cephalon and Teva have reached a settlement with 48 state attorneys general, which was approved by the court on November 7, 2016. Certain other claimants, including the State of California, have given notices of potential claims related to these settlement agreements. Teva has produced documents and information in response to discovery requests issued by the California Attorney General s office as part of its ongoing investigation of generic competition to PROVIGIL.

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In May 2015, Cephalon entered into a consent decree with the FTC (the Modafinil Consent Decree) 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 settlement fund does not cover any judgments or settlements outside the United States. Under the Modafinal 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. In February 2019, in connection with the settlement of other unrelated FTC antitrust lawsuits, as described below, Teva and the FTC agreed to amend certain provisions of the Modafinil Consent Decree and to restart its ten-year term.

Additionally, following an investigation initiated by the European Commission in April 2011 regarding a modafinil patent settlement in Europe, the European Commission issued a Statement of Objections in July 2017 against both Cephalon and Teva alleging that the 2005 settlement agreement between the parties had the object and effect of hindering the entry of generic modafinil. No final decision regarding infringement has yet been taken by the European Commission. The sales of modafinil in the European Economic Area during the last full year of the alleged infringement amounted to EUR 46.5 million.

In January 2009, the FTC and the State of California filed a complaint for injunctive relief in California federal court alleging that a September 2006 patent lawsuit settlement between Watson Pharmaceuticals, Inc. (Watson), now a Teva subsidiary, and Solvay Pharmaceuticals, Inc. (Solvay) relating to AndroGel® 1% (testosterone gel) violated the antitrust laws. Additional lawsuits alleging similar claims were later filed by private plaintiffs (including plaintiffs purporting to represent classes of similarly situated claimants as well as retailer plaintiffs filing separately) and the various actions were consolidated in a multidistrict litigation in Georgia federal court. On July 16, 2018, the direct purchaser plaintiffs motion for class certification was denied. As a result, the three direct purchasers that had sought class certification can proceed as individual plaintiffs, but any other member of the proposed direct purchaser class will need to file a separate, individual lawsuit if it wishes to participate in the litigation. On February 22, 2019, the FTC stipulated to the dismissal of its claims against Watson, in exchange for Teva s agreement to amend the Modafinil Consent Decree, as described above. Teva settled with most of the retailer plaintiffs in April 2019. Trial on the remaining private plaintiffs claims has been scheduled to begin in February 2020. Annual sales of AndroGel® 1% were approximately $350 million at the time of the settlement and approximately $140 million at the time Actavis launched its generic version of AndroGel® 1% in November 2015. A provision for this case was included in the financial statements.

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 in the United States District Court for the District of New Jersey. The plaintiffs claim that the settlement agreement between Wyeth and Teva unlawfully delayed generic entry. In October 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 appealed and, in August 2017, the Third Circuit reversed the district court s decision and remanded for further proceedings. Annual sales of Effexor XR®

were approximately $2.6 billion at the time of settlement and at the time Teva launched its generic version of Effexor XR® in July 2010.

In February 2012, two purported classes of direct-purchaser plaintiffs sued GSK and Teva in New Jersey federal court for alleged violations of the antitrust laws in connection with their settlement of patent litigation involving lamotrigine (generic Lamictal®) entered into in February 2005. The plaintiffs claim that the settlement agreement unlawfully delayed generic entry and seek unspecified damages. In December 2012, the court dismissed the case, but in June 2015, the Third Circuit reversed and remanded for further proceedings. In December 2018, the court granted the direct-purchaser plaintiffs motion for class certification. On March 18, 2019, the Third Circuit granted the defendants petition for immediate appellate review and the district court has stayed the litigation pending the outcome of the Third Circuit appeal. Annual sales of Lamictal® were approximately $950 million at the time of the settlement and approximately $2.3 billion at the time Teva launched its generic version of Lamictal® in July 2008.

In April 2013, purported classes of direct purchasers of, and end payers 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 U.S. District Court for the Eastern District of Pennsylvania. Throughout 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 and, in December 2018, both the direct-purchaser class plaintiffs and indirect-purchaser class plaintiffs filed motions for class certification, which remain pending. In October 2016, the District Attorney for Orange County, California, filed a similar complaint, which has since been amended, in California state court, alleging violations of state law. Defendants moved to strike the District Attorney s claims for restitution and civil penalties to the extent not limited to alleged activity occurring in Orange County. The Superior Court denied that motion. The Court of Appeal subsequently reversed the decision and review of the Appellate Court decision is now pending before the California Supreme Court. Annual sales of Niaspan® were approximately $416 million at the time of the settlement and approximately $1.1 billion at the time Teva launched its generic version of Niaspan® in September 2013.

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In November 2013, a putative class action was filed in Pennsylvania federal court against Actavis, Inc. and certain of its affiliates, alleging that Watson s 2012 patent lawsuit settlement with Endo Pharmaceuticals Inc. relating to Lidoderm® (lidocaine transdermal patches) violated the antitrust laws. Additional lawsuits containing similar allegations followed on behalf of other classes of putative direct purchaser and end-payer plaintiffs, as well as retailers acting in their individual capacities, and those cases were consolidated as a multidistrict litigation in federal court in California. On February 21, 2017, the court granted both the indirect purchaser plaintiffs and the direct purchaser plaintiffs motions for class certification. Teva settled the multidistrict litigation with the various plaintiff groups in the first quarter of 2018 and a provision was included in the financial statements. The FTC also filed suit to challenge the Lidoderm® settlement, initially bringing antitrust claims against Watson, Endo and Allergan in Pennsylvania federal court in March 2016. The FTC later voluntarily dismissed those claims and refiled them (along with a stipulated order for permanent injunction to settle its claims against Endo) in the same California federal court in which the private multidistrict litigation referenced above was pending. On February 3, 2017, the State of California filed its own complaint against Allergan and Watson, and that complaint was also assigned to the California federal court presiding over the multidistrict litigation. On February 22, 2019, the FTC dismissed its claims against Actavis and Allergan, in exchange for Teva s agreement to amend the Modafinil Consent Decree, as described above. The State of California s claims remain pending, but have been stayed as the parties engage in settlement negotiations. Annual sales of Lidoderm® at the time of the settlement were approximately $1.2 billion and approximately $1.4 billion at the time Actavis launched its generic version in September 2013.

Since November 2013, numerous lawsuits have been filed in various federal courts by purported classes of end payers for, and direct purchasers of, Aggrenox® (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 U.S. District Court for the District of Connecticut. On April 11, 2017, the Orange County District Attorney filed a complaint for violations of California s Unfair Competition Law based on the Aggrenox® patent litigation settlement. Teva has settled with the putative classes of direct purchasers and end payers, as well as with the opt-out direct purchaser plaintiffs, and with two of the opt-out end payer plaintiffs. A provision with respect to the settlements was included in the financial statements. The district court overruled certain objections to the end payer settlement, including objections made by the Orange County District Attorney, and approved the settlement. The District Attorney subsequently appealed the court s approval to the Second Circuit. Opt-outs from the end payer class have also appealed certain aspects of the court s approval order to the Second Circuit. Those appeals remain pending. Annual sales of Aggrenox® were approximately $340 million at the time of the settlement and approximately $455 million at the time Teva launched its authorized generic version of Aggrenox® in July 2015.

Since January 2014, numerous lawsuits have been filed in the U.S. District Court for the Southern District of New York by purported classes of end payers for, and direct purchasers of, Actos® and Actoplus Met (pioglitazone and pioglitazone plus metformin) against Takeda, the innovator, and several generic manufacturers, including Teva, Actavis and Watson. The lawsuits allege, among other things, that the settlement agreements between Takeda and the generic manufacturers violated the antitrust laws. The court dismissed the end payer lawsuits against all defendants in September 2015. On February 8, 2017, the Court of Appeals for the Second Circuit affirmed the dismissal in part and

vacated and remanded the dismissal in part with respect to the claims against Takeda. The direct purchasers case had been stayed pending resolution of the appeal in the end payer matter and the direct purchasers amended their complaint for a second time following the Second Circuit s decision. Defendants moved to dismiss the direct purchasers complaint, and that motion remains pending. At the time of the settlement, annual sales of Actos® and Actoplus Met were approximately $3.7 billion and approximately $500 million, respectively. At the time Teva launched its authorized generic version of Actos® and Actoplus Met in August 2012, annual sales of Actos® and Actoplus Met were approximately $2.8 billion and approximately $430 million, respectively.

In September 2014, the FTC sued AbbVie Inc. and certain of its affiliates (AbbVie) as well as Teva in the U.S. 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® patent litigation and a supply agreement under which AbbVie agreed to supply Teva with an authorized generic version of TriCor®. 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. In May 2015, the court dismissed the FTC s claim concerning the settlement and supply agreements, and thus dismissed Teva from the case entirely. The FTC proceeded with a separate claim against AbbVie alone and in June 2018, following a bench trial, the court held that AbbVie had violated the antitrust laws by filing sham patent infringement lawsuits against both Teva and Perrigo in the underlying AndroGel patent litigation. The court ordered AbbVie to pay $448 million in disgorgement but declined to award injunctive relief. The FTC filed a notice of appeal as to, among other things, the district court s May 2015 dismissal of the FTC s claim against Teva, but in February 2019, the FTC stipulated to dismiss Teva from its appeal, in exchange for Teva s agreement to amend the Modafinil Consent Decree, as described above.

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In May 2015, a purported class of end payers for Namenda IR® (memantine hydrochloride) filed a lawsuit against Forest Laboratories, LLC (Forest), the innovator, and several generic manufacturers, including Teva. The lawsuit alleges, among other things, that settlement agreements between Forest and the generic manufacturers to resolve patent litigation over Namenda IR® violated the antitrust laws. The court has denied defendants motions to dismiss and in September 2018 referred the parties to mediation. Annual sales of Namenda IR® at the time of the settlement were approximately $1.1 billion and approximately $550 million at the time other manufacturers first launched generic versions of Namenda IR® in July 2015.

On December 16, 2016, the U.K. Competition and Markets Authority (CMA) issued a statement of objections (a provisional finding of infringement of the Competition Act) in respect of certain allegations against Allergan, Actavis UK and certain Auden Mckenzie entities alleging competition law breaches in connection with the supply of 10mg and 20mg hydrocortisone tablets in the U.K. On December 18, 2017, the CMA issued a Statement of Draft Penalty Calculation. No final decision regarding infringement of competition law has yet been issued. On March 3, 2017, the CMA issued a second statement of objections in respect of certain additional allegations (relating to the same products and covering part of the same time period as in the first statement of objections) against Actavis UK, Allergan and certain Auden Mckenzie entities. On February 28, 2019, the CMA issued a third statement of objections with allegations of additional infringements relating to the supply of 10mg and 20mg hydrocortisone tablets in the U.K against certain Auden Mckenzie entities and others. On January 9, 2017, Teva completed the sale of Actavis UK to Accord Healthcare Limited, pursuant to which Teva will indemnify Accord Healthcare for potential fines imposed by the CMA and/or damages awarded by a court against Actavis UK in relation to the December 18, 2017 and March 3, 2017 statements of objections, and resulting from conduct prior to the closing date of the sale. In addition, Teva agreed to indemnify Allergan against losses arising from this matter, pursuant to the agreement the parties entered into on January 31, 2018. See note 3. In the event of any such fines or damages, Teva expects to assert claims, including claims for breach of warranty, against the sellers of Auden Mckenzie. The terms of the purchase agreement may preclude a full recovery by Teva. A liability for this matter has been recorded in purchase accounting related to the acquisition of Actavis Generics.

Since November 2016, several putative indirect purchaser and direct purchaser class actions were filed in federal courts in Wisconsin, Massachusetts and Florida against Shire U.S., Inc. and Shire LLC (collectively, Shire), Actavis and Teva, alleging that Shire s 2013 patent litigation settlement with Actavis related to the ADHD drug Intuniv® (guanfacine) violated various state consumer protection and antitrust laws. All cases are now in Massachusetts federal court. Annual sales of Intuniv® were approximately $335 million at the time of the settlement and approximately $327 million at the time Actavis launched its generic version of Intuniv® in 2014.

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 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.

A number of state attorneys general have filed various actions against Teva and/or certain of its subsidiaries relating to reimbursements or drug price reporting under Medicaid or other programs. Such price reporting is alleged to have caused states and others to pay inflated reimbursements for covered drugs. Teva and its subsidiaries have reached settlements in most of these cases. On October 4, 2018, Teva settled longstanding litigation filed by the State of Illinois against subsidiaries of Teva and Watson for a total settlement amount of $135 million, the majority of which was paid in December of 2018. Teva accepted the settlement while denying any liability with respect to the claims made by the state. Pending the final settlement payment, the Illinois litigation is stayed. In August 2013, judgment was entered in a separate case brought by the State of Mississippi against Watson, pursuant to which Watson was ordered to pay compensatory damages amounting to $12.4 million. In March 2014, the Mississippi court amended the judgment to also include punitive damages in the amount of $17.9 million. The judgment was affirmed in all respects by the Mississippi Supreme Court in January 2018 and has since been satisfied in full. Certain Actavis subsidiaries were dismissed by the trial court in an action brought by the State of Utah. That dismissal was affirmed by the Utah Court of Appeals on February 28, 2019. The State s time to seek further appellate review has expired and the matter is now concluded. A provision for these cases was included in the financial statements.

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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 January 2014, Teva received a civil investigative demand from the U.S. 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®, focusing on educational and speaker programs. The demand states that the government is investigating possible civil violations of the federal False Claims Act. In March 2015, the docket in this matter and a False Claims Act civil *qui tam* complaint concerning this matter were unsealed by the court after the government declined to intervene. In February 2016, the court denied Teva s motions to dismiss the False Claims Act claims and instructed the relators to amend their complaint with additional information. In March 2016, the relators filed an amended complaint. Teva s motion for summary judgment on all claims was denied on February 27, 2019.

In January 2014, a *qui tam* complaint was filed in Rhode Island federal court alleging that Teva and several other defendants, including manufacturers of MS drugs and pharmacy benefit managers, violated the False Claims Act. The *qui tam* action was unsealed on April 4, 2018 after the government declined to intervene. The relator alleges that Teva and the other defendants induced fraudulent overpayments for illegitimate Bona Fide Service Fees in excess of fair market value to inflate prices for the Medicare Part D program. Teva moved to dismiss the complaint. The DOJ also moved to dismiss the complaint, arguing that it lacked merit and was not in the government s interest to continue. Both motions are pending.

In May 2017, a *qui tam* action was filed against a number of Teva subsidiaries. The *qui tam* action was unsealed on June 13, 2018 after the government declined to intervene. The relator in the case alleges that Teva violated the False Claims Act by devising and engaging in promotional schemes that violate the Anti-Kickback Statute (AKS), resulting in false certifications of compliance with the AKS. Specifically, the relator alleges that Teva paid in-kind remuneration to physicians through reimbursement support and nursing services in order to increase the number of COPAXONE prescriptions. An amended complaint was filed on October 15, 2018. Teva and the DOJ moved to dismiss the case. These motions are pending.

Since May 2014, approximately 1,500 complaints have been filed with respect to opioid sales and distribution against various Teva affiliates, along with several other pharmaceutical companies, by a number of cities, counties, states, other governmental agencies and private plaintiffs in both state and federal courts. Most of the federal cases have been consolidated into a multidistrict litigation in the Northern District of Ohio (MDL Opioid Proceeding) and many of the cases filed in state court have been removed to federal court and consolidated into the MDL Opioid Proceeding. Complaints asserting claims under similar provisions of different state law, generally contend that the defendants allegedly engaged in improper marketing and distribution of opioids, including ACTIQ® and FENTORA®. The complaints also assert claims related to Teva s generic opioid products. In addition, several dozen complaints filed by cities, counties and the State of Delaware have named Anda, Inc. (and other distributors and manufacturers) alleging that Anda failed to develop and implement systems sufficient to identify suspicious orders of opioid products and prevent the abuse and diversion of such products to individuals who used them for other than legitimate medical purposes. Plaintiffs seek a variety of remedies, including restitution, civil penalties, disgorgement of profits, treble

damages, attorneys fees and injunctive relief. Certain plaintiffs assert that the measure of damages is the entirety of the costs associated with addressing the abuse of opioids and opioid addiction. None of the complaints specify the exact amount of damages at issue; however, an adverse resolution of any of these lawsuits or investigations may involve large monetary penalties and could have a material and adverse effect on Teva s reputation, business, results of operations and cash flows. Teva and its affiliates that are defendants in the various lawsuits deny all allegations asserted in these complaints and have filed or will file motions to dismiss where possible. On October 5, 2018, the magistrate judge in the MDL Opioid Proceeding issued a Report & Recommendation rejecting the first motion to dismiss, except for the common law public nuisance claim, which was dismissed. On December 19, 2018, the District Court judge overruled defendants objections to the Report & Recommendation. Motions to dismiss in additional similar cases remain pending. On April 1, 2019, the magistrate judge in the MDL Opioid Proceeding issued two Report & Recommendations in which he recommended that the court grant in part and deny in part pending motions to dismiss of the manufacturer, distributor, pharmacy, and generic manufacturing defendants. Specifically, the magistrate judge recommended that The Muscogee (Creek) Nation s Lanham Act claim be dismissed as to all defendants, and that its claims against the generic manufacturers are partially preempted; he recommended that the motions to dismiss be denied as to the remaining claims. The magistrate judge also recommended that the Blackfeet Tribe of the Blackfeet Indian Reservation s federal common law public nuisance and Montana Unfair Trade Practices and Consumer Protection Act claims be dismissed, and that its claims against the generic manufacturers are partially preempted; he recommended that the motions to dismiss be denied as to the remaining claims. Fact discovery in the MDL Opioid Proceeding for the first track of cases is closed, and expert discovery is proceeding with a trial scheduled for October 2019. Other cases remain pending in various state courts, including Oklahoma, where a trial is scheduled to begin in May 2019, and where the plaintiffs are seeking joint and several damages among all defendants. In some jurisdictions, such as Illinois, New York, Pennsylvania, South Carolina and Texas, certain state court cases have been transferred to a single court within their respective state court systems for coordinated pretrial proceedings. On April 27, 2018, Teva received subpoena requests from the DOJ seeking documents relating to the manufacture, marketing and sale of opioids. Teva is complying with this subpoena. In addition, a number of state attorneys general, including a coordinated multistate effort, have initiated investigations into sales and marketing practices of Teva and its affiliates with respect to opioids. Other states are conducting their own investigations outside of the multistate group. Teva is cooperating with these ongoing investigations and cannot predict the outcome at this time.

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On June 21, 2016, Teva USA received a subpoena from the DOJ Antitrust Division seeking documents and other information relating to the marketing and pricing of certain Teva USA generic products and communications with competitors about such products. Actavis received a similar subpoena in June 2015. Teva and Actavis are cooperating with the DOJ subpoena requests. 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. In 2015, Actavis received a similar subpoena from the Connecticut Attorney General.

On December 15, 2016, a civil action was brought by the attorneys general of twenty states against Teva USA and several other companies asserting claims under federal antitrust law alleging price fixing of generic products in the United States. An amended complaint was filed on March 1, 2017 adding twenty additional states to the named plaintiffs and adding supplemental state law claims. The states seek a finding that the defendants actions violated federal antitrust law and state antitrust and consumer protection laws, as well as injunctive relief, disgorgement, damages on behalf of various state and governmental entities and consumers, civil penalties and costs. On August 3, 2017, the action was transferred to the generic drug multidistrict litigation in the Eastern District of Pennsylvania (Pennsylvania MDL). On July 17, 2017, a new complaint was filed in the District Court of Connecticut on behalf of four additional states with the same factual allegations and claims that are at issue in the Pennsylvania MDL case. The complaint was subsequently transferred to the Pennsylvania MDL. On October 31, 2017, the attorneys general filed a motion for leave to file an amended complaint which named Actavis and Teva as defendants, and added new allegations and claims to those appearing in the prior complaints. On June 5, 2018, the District Court for the Eastern District of Pennsylvania granted the attorneys general s motion to amend and on June 18, 2018, the attorneys general of 47 states plus Puerto Rico and the District of Columbia filed a consolidated amended complaint.

Beginning on March 2, 2016, numerous complaints have been filed in the United States on behalf of putative classes of direct and indirect purchasers of several generic drug products, as well as several individual direct purchaser opt-out plaintiffs. These complaints, which allege that the defendants engaged in conspiracies to fix prices and/or allocate market share of generic products have been brought against various manufacturer defendants, including Teva and Actavis. The plaintiffs generally seek injunctive relief and damages under federal antitrust law, and damages under various state laws. On April 6, 2017, these cases were transferred to the Pennsylvania MDL. Additional cases were transferred to that court and the plaintiffs filed consolidated amended complaints on August 15, 2017. On October 16, 2018, the court denied certain of the defendants motions to dismiss as to certain federal claims, and on February 15, 2019, the court granted in part and denied in part defendants motions to dismiss as to certain state law claims. Teva and Actavis deny having engaged in any conduct that would give rise to liability with respect to the above-mentioned complaints.

In May 2018, Teva received a civil investigative demand from the DOJ Civil Division, pursuant to the federal False Claims Act, seeking documents and information produced since January 1, 2009 relevant to the Civil Division s investigation concerning allegations that generic pharmaceutical manufacturers, including Teva, engaged in market allocation and price-fixing agreements, paid illegal remuneration, and caused false claims to be submitted in violation of the False Claims Act. Teva is cooperating with this subpoena.

On March 21, 2017, Teva received a subpoena from the U.S. Attorney s office in Boston, Massachusetts requesting documents related to Teva s donations to patient assistance programs. Teva is cooperating in responding to the subpoena.

In December 2016, Teva resolved certain claims under the U.S. Foreign Corrupt Practices Act (FCPA) with the SEC and the DOJ, as more fully described in Teva s 2017 Annual Report. The settlement included a fine, disgorgement and prejudgment interest; a three-year deferred prosecution agreement (DPA) for Teva and the retention of an independent compliance monitor for a period of three years. If, during the term of the DPA (approximately three years unless extended), the DOJ determines that Teva has committed a felony under federal law, provided deliberately false or misleading information or otherwise breached the DPA, Teva could be subject to prosecution and additional fines or penalties, including the deferred charges. Following the above resolution with the SEC and DOJ, Teva has had requests for documents and information from various Russian government entities. In addition, on January 14, 2018, Teva entered into an arrangement for the Contingent Cessation of Proceedings pursuant to the Israeli Securities Law with the Government of Israel that ended the investigation of the Israeli government into the conduct that was subject to the FCPA investigation, and provided a payment of approximately $22 million.

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Shareholder Litigation

On November 6, 2016 and December 27, 2016, two putative securities class actions were filed in the U.S. District Court for the Central District of California against Teva and certain of its current and former officers and directors. After those two lawsuits were consolidated and transferred to the U.S. District Court for the District of Connecticut, the court appointed the Ontario Teachers Pension Plan Board as lead plaintiff (the Ontario Teachers Securities Litigation). The lead plaintiff then filed a consolidated amended complaint. On April 3, 2018, the court dismissed the case without prejudice. Lead plaintiff filed a second amended complaint on June 22, 2018, purportedly on behalf of purchasers of Teva s securities between February 6, 2014 and August 3, 2017. The second complaint asserts that Teva and certain of its current and former officers and directors violated federal securities laws in connection with Teva s alleged failure to disclose pricing strategies for various drugs in its generic drug portfolio and by making allegedly false or misleading statements in certain offering materials issued during the class period. The second complaint seeks unspecified damages, legal fees, interest, and costs. Teva and the current and former officer and director defendants filed motions to dismiss the second complaint on September 14, 2018. Those motions are pending before the court.

On July 17, 2017, a lawsuit was filed in the U.S. District Court for the Southern District of Ohio derivatively on behalf of the Teva Employee Stock Purchase Plan, and alternatively as a putative class action lawsuit on behalf of individuals who purchased Teva stock through that plan. That lawsuit seeks unspecified damages, legal fees, interest and costs. The complaint alleges that Teva failed to maintain adequate financial controls based on the facts underpinning Teva s FCPA DPA and also based on allegations substantially similar to those in the Ontario Teachers Securities Litigation. On November 29, 2017, the court granted Teva s motion to transfer the litigation to the U.S. District Court for the District of Connecticut where the Ontario Teachers Securities Litigation is pending. On February 12, 2018, the district court stayed the case pending resolution of the motions to dismiss filed in the Ontario Teachers Securities Litigation described above.

On August 3, 2017, a lawsuit was filed in the U.S. District Court for the District of Connecticut by OZ ELS Master Fund, Ltd. and related entities. The complaint asserts that Teva and certain of its current and former officers violated the federal securities laws in connection with Teva s alleged failure to disclose Teva s participation in an alleged anticompetitive scheme to fix prices and allocate markets for generic drugs in the United States. On August 30, 2017, the court entered an order deferring all deadlines pending the resolution of the motions to dismiss filed in the Ontario Teachers Securities Litigation described above.

On August 21 and 30, 2017, Elliot Grodko and Barry Baker filed putative securities class actions in the U.S. District Court for the Eastern District of Pennsylvania purportedly on behalf of purchasers of Teva s securities between November 15, 2016 and August 2, 2017 seeking unspecified damages, legal fees, interest, and costs. The complaints allege that Teva and certain of its current and former officers violated the federal securities laws and Israeli securities laws by making false and misleading statements in connection with Teva s acquisition and integration of Actavis Generics. On November 1, 2017, the court consolidated the Baker and Grodko cases. On April 10, 2018, the court granted Teva s motion to transfer the consolidated action to the District of Connecticut where the Ontario Teachers Securities Litigation is currently pending.

Between August 2018 and February 2019, ten complaints were filed against Teva and current and former officer and director defendants seeking unspecified compensatory and rescissory damages, legal fees, costs and expenses. The allegations in these complaints are substantially similar to the allegations in the Ontario Teachers Securities Litigation, but have been brought on behalf of plaintiffs that have opted out of the putative class in the Ontario Teachers Securities Litigation. The plaintiffs in these opt-out cases filed their complaints in the Court of Common Pleas of Montgomery County, Pennsylvania, the U.S. District Court for the Eastern District of Pennsylvania and the U.S. District Court for the District of Connecticut. Teva and the current and former officer and director defendants filed or will file motions or stipulations to transfer the cases filed in Pennsylvania to the U.S. District Court for the District of Connecticut, where the Ontario Teachers Securities Litigation is pending. The cases filed in, or transferred to, Connecticut have been or will request to be stayed pending resolution of the motions to dismiss filed in the Ontario Teachers Securities Litigation described above.

Motions to approve derivative actions against certain past and present directors and officers have been filed in Israel alleging negligence and recklessness with respect to the acquisition of the Rimsa business and the acquisition of Actavis Generics. Motions for document disclosure prior to initiating derivative actions were filed with respect to dividend distribution, executive compensation, several patent settlement agreements, opioids and the U.S. price-fixing investigations. Motions to approve securities class actions against Teva and certain of its current and former directors and officers were filed in Israel based on allegations of improper disclosure of the above-mentioned pricing investigation, as well as lack of disclosure of negative developments in the generic sector, including price erosion with respect to Teva s products. Other motions were filed in Israel to approve a derivative action, discovery and a class action related to claims regarding Teva s above-mentioned FCPA resolution with the SEC and DOJ.

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Environmental Matters

Teva or its subsidiaries are party to a number of environmental proceedings, or have received claims, including under the federal Superfund law or other federal, provincial or state and local laws, imposing liability for alleged noncompliance, 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 that impacted a site, to investigate and clean the site or to pay or reimburse others for such activities, including for oversight by governmental authorities and any related damages to natural resources. Teva or its subsidiaries have received claims, or been made a party to these proceedings, along with others, 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.

Although liability among the responsible parties, under certain circumstances, may be joint and several, these proceedings are frequently resolved so that the allocation of clean-up 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; for some sites the costs of the investigation, clean-up 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 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 clean-up costs from insurers, indemnitors, former site owners or operators or other potentially responsible parties. In addition, enforcement proceedings relating to alleged violations of federal, state, commonwealth or local requirements at some of Teva s facilities 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 costs and natural resource damages, and may require that corrective actions and enhanced compliance measures be implemented.

Other Matters

On February 1, 2018, former shareholders of Ception Therapeutics, Inc., a company that was acquired by and merged into Cephalon in 2010, prior to Cephalon s acquisition by Teva, filed breach of contract and other related claims against the Company, Teva USA and Cephalon in the Delaware Court of Chancery. Among other things, the plaintiffs allege that Cephalon breached the terms of the 2010 Ception-Cephalon merger agreement by failing to exercise commercially reasonable efforts to develop and commercialize CINQAIR® (reslizumab) for the treatment of eosinophilic esophagitis (EE). The plaintiffs claim damages of at least $200 million, an amount they allege is equivalent to the milestones payable to the former shareholders of Ception in the event Cephalon were to obtain regulatory approval for EE in the United States ($150 million) and Europe ($50 million). Defendants moved to dismiss the complaint and on December 28, 2018, the court granted the motion in part and dismissed all of plaintiffs claims, except for their claim against Cephalon for breach of contract.

NOTE 17 Segments:

Teva operates its business and reports its financial results in three segments:

(a) North America segment, which includes the United States and Canada.

(b) Europe segment, which includes the European Union and certain other European countries.

(c) International Markets segment, which includes all countries other than those in the North America and Europe segments.

The Company began reporting its financial results under this structure in the first quarter of 2018. This change was reflected through retroactive revision of prior period segment information.

In addition to these three segments, Teva has other sources of revenues, primarily the sale of APIs to third parties, certain contract manufacturing services and an out-licensing platform offering a portfolio of products to other pharmaceutical companies through its affiliate Medis.

Teva s Chief Executive Officer (CEO), 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 three identified reportable segments, namely North America, Europe and International Markets, to make decisions about resources to be allocated to the segments and assess their performance.

Segment profit is comprised of gross profit for the segment less R&D expenses, S&M expenses, G&A expenses and other income related to the segment. Segment profit does not include amortization and certain other items.

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Teva manages its assets on a 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 CEO may review its strategy and organizational structure. Any changes in strategy may lead to a reevaluation of the Company s segments and goodwill allocation to reporting units, as well as fair value attributable to its reporting units. See note 7.

a. Segment information:

	Three months ended March 31, 2019		
	North America	Europe	International Markets
	(U.S. $ in millions)		
Revenues	$ 2,047	$ 1,264	$ 668
Gross profit	1,039	730	269
R&D expenses	165	66	22
S&M expenses	268	215	115
G&A expenses	112	48	36
Other income	(4)	(1)	(0.2)
Segment profit	$ 498	$ 403	$ 97

	Three months ended March 31, 2018		
	North America	Europe	International Markets
	(U.S. $ in millions)		
Revenues	$ 2,531	$ 1,442	$ 750
Gross profit	1,403	792	313
R&D expenses	188	73	24
S&M expenses	276	250	134
G&A expenses	126	91	41
Other (income) loss	(102)	1	(8)
Segment profit	$ 915	$ 377	$ 122

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	Three months ended March 31,	
	2019	2018
	(U.S.$ in millions)	
North America profit	$ 498	$ 915
Europe profit	403	377
International Markets profit	97	122
Total segment profit	998	1,414
Profit of other activities	21	21
	1,019	1,435
Amounts not allocated to segments:		
Amortization	283	310
Other assets impairments, restructuring and other items	1	501
Goodwill impairment		180
Intangible asset impairments	469	206
Gain on divestitures, net of divestitures related costs	§	(93)
Other R&D expenses	§	22
Costs related to regulatory actions taken in facilities	4	1
Legal settlements and loss contingencies	57	(1,278)
Other unallocated amounts	70	61
Consolidated operating income	134	1,525
Financial expenses, net	218	271
Consolidated (loss) income before income taxes	$ (84)	$ 1,254

§ Represents an amount less than $0.5 million.

b. Segment revenues by major products and activities:

The following tables present revenues by major products and activities for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,	
	2019	2018
	(U.S.$ in millions)	
North America		
Generic products	$ 966	$ 1,088
COPAXONE	208	476
BENDEKA / TREANDA	122	181
ProAir	59	130
QVAR	64	107
AJOVY	20	
AUSTEDO	74	30
Anda	379	331
Other	155	188
Total	$ 2,047	$ 2,531

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	Three months ended March 31,	
	2019	2018
	(U.S.$ in millions)	
Europe		
Generic products	$ 919	$ 997
COPAXONE	114	153
Respiratory products	91	113
Other	140	179
Total	$ 1,264	$ 1,442

	Three months ended March 31,	
	2019	2018
	(U.S.$ in millions)	
International markets		
Generic products	$ 441	$ 488
COPAXONE	13	16
Distribution	151	153
Other	62	93
Total	$ 668	$ 750

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 has patent exclusivity on these products, and subject to regulatory approval, generic pharmaceutical manufacturers are able to produce and market similar (or purportedly similar) products and sell them for a lower price. The launch 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 expiration or loss of such intellectual property rights could therefore significantly adversely affect Teva s results of operations and financial condition.

NOTE 18 Other income:

Three months ended March 31,	
2019	2018
(U.S. $ in millions)	
$ (1)	93

Gain on divestitures, net of divestitures related costs (1)		
Section 8 and similar payments (2)		99
Gain on sale of assets	1	8
Other, net	6	3
Total other income	$ 6	$ 203

(1) Mainly related to the divestment of the women s health business and the dissolution of PGT in 2018.
(2) Section 8 of the Patented Medicines (Notice of Compliance) Regulation relates to recoveries of lost revenue related to patent infringement proceedings in Canada.

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NOTE 19 Income taxes:

In the first quarter of 2019, Teva recognized a tax expense of $9 million, or 11%, on pre-tax loss of $84 million. In the first quarter of 2018, Teva recognized a tax expense of $46 million, or 4%, on pre-tax income of $1,254 million. Teva s tax rate for the first quarter of 2019 was mainly affected by impairments, amortization and interest disallowance as a result of the U.S. Tax Cuts and Jobs Act.

The statutory Israeli corporate tax rate is 23% in 2019. Teva s tax rate differs from the Israeli statutory tax rate, mainly due to generation of profits in various jurisdictions in which tax rates are different than the Israeli tax rate, tax benefits in Israel and other countries.

NOTE 20 Leases:

Leases prior to the adoption of the new Lease Standard

Teva leases real estate, cars and equipment for use in its operations, which are classified as operating leases. In addition to rent, the leases may require Teva to pay directly for fees, insurance, maintenance and other operating expenses. Rental expense for the three months ended March 31, 2018 and the 12 months ended December 31, 2018 was $46 million and $175 million, respectively. The Company also has capital leases for properties.

Leases following the adoption of the new Lease Standard

Teva adopted the new accounting standard ASC 842 Leases and all the related amendments on January 1, 2019 and used the effective date as Teva s date of initial application.

Teva determines if an arrangement is a lease at inception. Lease classification is governed by five criteria in ASC 842-10-25-2. If any of these five criteria is met, Teva classifies the lease as a finance lease. Otherwise, Teva classifies the lease as an operating lease. When determining lease classification, Teva s approach in assessing two of the mentioned criteria is: (i) generally 75% or more of the remaining economic life of the underlying asset is a major part of the remaining economic life of that underlying asset; and (ii) generally 90% or more of the fair value of the underlying asset comprises substantially all of the fair value of the underlying asset.

Operating leases are included in operating lease right-of-use (ROU) assets, other current liabilities, and operating lease liabilities in the consolidated balance sheets. Finance leases are included in property, plant and equipment, other current liabilities, and other long-term liabilities in the consolidated balance sheets. Finance leases of land include long-term leasehold rights in various locations, with useful lives between 30 and 99 years.

ROU assets represent Teva s right to use an underlying asset for the lease term and lease liabilities represent Teva s obligation to make lease payments arising from the lease. Operating and finance lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. Teva uses its

incremental borrowing rate based on the information available at the commencement date to determine the present value of the lease payments.

For finance leases, Teva recognizes interest on the lease liability separately from amortization of the ROU assets in the statement of comprehensive income. For operating leases, lease expenses are recognized on a straight-line basis over the lease term.

The new standard also provides practical expedients for an entity s ongoing accounting. Teva elected the short-term lease recognition exemption for all leases with a term shorter than 12 months. This means that for those leases, Teva does not recognize ROU assets or lease liabilities, including not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition, but recognizes lease expenses over the lease term on a straight line basis. Teva also elected the practical expedient to not separate lease and non-lease components for all of Teva s leases, other than leases of real estate.

Lease terms will include options to extend or terminate the lease when it is reasonably certain that Teva will exercise or not exercise the option to renew or terminate the lease.

Teva s lease agreements have remaining lease terms ranging from 1 year to 80 years. Some of these agreements include options to extend the leases for up to 15 years and some include options to terminate the leases immediately. Certain leases also include options to purchase the leased property.

The depreciable life of leasehold improvements is limited by the expected lease term, unless there is a transfer of title or a purchase option for the leased asset reasonably certain of exercise.

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TEVA PHARMACEUTICAL INDUSTRIES LIMITED

Notes to Consolidated Financial Statements

(Unaudited)

Some of our vehicle lease agreements include rental payments based on the actual usage of the vehicles and other lease agreements include rental payments adjusted periodically for inflation. Teva s lease agreements do not contain any material residual value guarantees.

Teva does not believe the new Lease Standard will have a notable impact on its liquidity. The new standard will have no impact on Teva s debt-covenant compliance under its RCF.

Teva rents out or subleases certain real estate to third parties, which has an immaterial impact on Teva s consolidated financial statements.

The components of lease cost in the first quarter of 2019 were as follows:

	Three months ended March 31, 2019 (U.S. $ in millions)
Operating lease cost:	$
Fixed payments and variable payments that depend on an index or rate	42
Variable lease payments not included in the lease liability	2
Short-term lease cost	2
Total operating lease cost	$ 46

Supplemental cash flow information related to operating leases was as follows:

	Three months ended March 31, 2019 (U.S. $ in millions)
Cash paid for amounts included in the measurement of lease liabilities:	$
Operating cash flows from operating leases	39
Right-of-use assets obtained in exchange for lease obligations (non-cash):	$

Operating leases	15

Supplemental balance sheet information related to operating leases was as follows:

	March 31, 2019 (U.S. $ in millions)
Operating leases:	$
Operating lease ROU assets	517
Other current liabilities	114
Operating lease liabilities	424
Total operating lease liabilities	$ 538

	March 31, 2019
Weighted average remaining lease term	
Operating leases	7.6 years
Weighted average discount rate	
Operating leases	6.1%

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TEVA PHARMACEUTICAL INDUSTRIES LIMITED

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(Unaudited)

Maturities of operating lease liabilities were as follows:

	March 31, 2019 (U.S. $ in millions)
2019 (excluding the three months ended March 31, 2019)	$ 108
2020	115
2021	91
2022	71
2023	50
After 2024	253
Total operating lease payments	$ 688
Less: imputed interest	150
Present value of lease liabilities	$ 538

	December 31, 2018 (U.S. $ in millions)
2019	$ 193
2020	154
2021	118
2022	91
2023	66
After 2024	283
Total lease payments	$ 905

As of March 31, 2019, Teva has additional operating leases for office space, which have yet to commence, with undiscounted future payments of $106 million. These operating leases will commence between fiscal year 2019 and fiscal year 2020 with lease terms of 9 to 12 years.

As of March 31, 2019 Teva s total finance lease assets and finance lease liabilities are $76 million and $26 million, respectively. The difference between those amounts is mainly due to prepaid payments.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Business Overview

We are a global pharmaceutical company, committed to helping patients around the world to access affordable medicines and benefit from innovations to improve their health. Our mission is to be a global leader in generics, specialty medicines and biopharmaceuticals, improving the lives of patients.

We operate worldwide, with headquarters in Israel and a significant presence in the United States, Europe and many other markets around the world. Our key strengths include our world-leading generic medicines expertise and portfolio, focused specialty medicines portfolio and global infrastructure and scale.

Teva was incorporated in Israel on February 13, 1944 and is the successor to a number of Israeli corporations, the oldest of which was established in 1901.

Our Business Segments

We operate our business through three segments: North America, Europe and International Markets. Each business segment manages our entire product portfolio in its region, including generics, specialty medicines and OTC products. This structure enables strong alignment and integration between operations, commercial regions, R&D and our global marketing and portfolio function, optimizing our product lifecycle across therapeutic areas.

In addition to these three segments, we have other activities, primarily the sale of APIs to third parties and certain contract manufacturing services.

In December 2017, we announced a comprehensive restructuring plan intended to significantly reduce our cost base, unify and simplify our organization and improve business performance, profitability, cash flow generation and productivity. This plan is intended to reduce our total cost base by $3 billion by the end of 2019.

Highlights

Significant highlights in the first quarter of 2019 included:

Revenues in the first quarter of 2019 were $4,295 million, a decrease of 15%, or 12% in local currency terms, compared to the first quarter of 2018, mainly due to generic competition to COPAXONE, as well as declines in revenues from our respiratory products and U.S. generics business.

Our North America segment generated revenues of $2,047 million and profit of $498 million in the first quarter of 2019. Revenues decreased by 19% compared to the first quarter of 2018, mainly due to a decline in revenues from COPAXONE, our U.S. generics business, as well as certain other specialty products. Profit decreased by 46%, mainly due to lower revenues from COPAXONE, a decline in sales of certain other specialty products and generic products, as well as lower other income.

Our Europe segment generated revenues of $1,264 million and profit of $403 million in the first quarter of 2019. Revenues decreased by 12%, or 5% in local currency terms, compared to the first quarter of 2018, mainly due to a decline in COPAXONE revenues due to the entry of competing glatiramer acetate products, the termination of the PGT joint venture and the sale of our women s health business, partially offset by new generic product launches. Profit increased by 7%, mainly due to lower cost of goods sold related to the termination of the PGT joint venture, cost reductions and efficiency measures as part of the restructuring plan.

Our International Markets segment generated revenues of $668 million and profit of $97 million in the first quarter of 2019. Revenues decreased by 11%, or 3% in local currency terms, and profit decreased by 20% compared to the first quarter of 2018. The decrease in revenues and profit was mainly due to lower sales in Japan resulting from regulatory pricing reductions and generic competition to off-patent products, partially offset by higher sales in Russia and cost reductions and efficiency measures as part of the restructuring plan.

Identifiable intangible asset impairments were $469 million in the first quarter of 2019, compared to $206 million in the first quarter of 2018. The impairment expenses in the first quarter of 2019 were related to IPR&D assets of $265 million and identifiable product rights of $204 million.

Operating income was $134 million in the first quarter of 2019, compared to $1,525 million in the first quarter of 2018. The decrease in operating income was mainly due to income from legal settlements and loss contingencies in the first quarter of 2018.

Exchange rate movements between the first quarter of 2019 and the first quarter of 2018 negatively impacted revenues by $177 million and operating income by $49 million.

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As of March 31, 2019, our debt was $28,624 million, compared to $28,916 million as of December 31, 2018. The decrease was mainly due to favorable exchange rates, as well as the repurchase and cancellation of $126 million of our $1,700 million 1.7% senior notes due July 2019.

Cash flow generated from operating activities was $112 million in the first quarter of 2019, compared to $1,496 million in the first quarter of 2018. The higher cash flow in the first quarter of 2018 was mainly due to the proceeds from the working capital adjustment with Allergan and the legal settlement with Rimsa. In addition, the lower cash flow in the first quarter of 2019 was mainly due to lower revenues from COPAXONE, as well as a decline in sales of certain other specialty products and generic products and performance incentive payments to employees for 2018.

Results of Operations

Comparison of Three Months Ended March 31, 2019 to Three Months Ended March 31, 2018

The following table sets forth, for the periods indicated, certain financial data derived from our financial statements:

	Percentage of Net Revenues Three Months Ended March 31,		Percentage Change
	2019	2018	2019 - 2018
	%	%	%
Net revenues	100	100	(15)
Gross profit	43	46	(20)
Research and development expenses	6	6	(18)
Selling and marketing expenses	15	15	(12)
General and administrative expenses	7	6	(11)
Intangible assets impairment	11	4	127
Goodwill impairment		4	(100)
Other assets impairments, restructuring and other items	§	10	(100)
Legal settlements and loss contingencies	1	(25)	
Other income	§	(4)	
Operating income	3	30	(91)
Financial expenses, net	5	5	(19)
Income (loss) before income taxes	(2)	25	
Income taxes	§	1	(80)
Share in losses of associated companies, net	§	1	(95)
Net income attributable to non-controlling interests	§	§	(44)
Net income (loss) attributable to Teva	(2)	22	
Dividends on preferred shares		1	(100)
Net income (loss) attributable to ordinary shareholders	(2)	21	

§ Represents an amount less than 0.5%.

Segment Information

North America Segment

The following table presents revenues, expenses and profit for our North America segment for the three months ended March 31, 2019 and 2018:

	2019		2018	
	(U.S.$ in millions / % of Segment Revenues) Three months ended March 31,			
Revenues	2,047	100%	2,531	100.0%
Gross profit	1,039	50.8%	1,403	55.5%
R&D expenses	165	8.1%	188	7.4%
S&M expenses	268	13.1%	276	10.9%
G&A expenses	112	5.5%	126	5.0%
Other income	(4)	§	(102)	(4.0%)
Segment profit*	498	24.3%	915	36.2%

* Segment profit does not include amortization and certain other items.
§ Represents an amount less than 0.5%.

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North America Revenues

Our North America segment includes the United States and Canada. Revenues from our North America segment in the first quarter of 2019 were $2,047 million, a decrease of $484 million, or 19%, compared to the first quarter of 2018, mainly due to a decline in revenues of COPAXONE, our U.S. generics business, BENDEKA® / TREANDA® and QVAR®, partially offset by higher revenues from our Anda business, AUSTEDO and AJOVY.

Revenues by Major Products and Activities

The following table presents revenues for our North America segment by major products and activities for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,		Percentage Change
	2019	2018	2019-2018
	(U.S.$ in millions)		
Generic products	$ 966	$ 1,088	(11%)
COPAXONE	208	476	(56%)
BENDEKA / TREANDA	122	181	(33%)
ProAir	59	130	(55%)
QVAR	64	107	(41%)
AJOVY	20		NA
AUSTEDO	74	30	151%
Anda	379	331	14%
Other	155	188	(18%)
Total	$ 2,047	$ 2,531	(19%)

Generic products revenues in our North America segment in the first quarter of 2019 decreased by 11% to $966 million, compared to the first quarter of 2018, mainly due to market dynamics, price erosion in our U.S. generics business and portfolio optimization, partially offset by new generic product launches.

Among the most significant generic products we sold in North America in the first quarter of 2019 were albuterol sulfate inhalation aerosol (ProAir® HFA authorized generic of Teva s specialty product), daptomycin injection (the generic equivalent of Cubicin®), amphetamine salt tablets (the generic equivalent of Adderall IR®), methylphenidate extended-release tablets (Concerta® authorized generic) and lidocaine transdermal patch (the generic equivalent of Lidoderm Patch®).

In the first quarter of 2019, we led the U.S. generics market in total prescriptions and new prescriptions, with approximately 436 million total prescriptions (based on trailing twelve months), representing 12% of total U.S. generic prescriptions according to IQVIA data.

COPAXONE revenues in our North America segment in the first quarter of 2019 decreased by 56% to $208 million, compared to the first quarter of 2018, mainly due to generic competition in the United States.

COPAXONE revenues in the United States were $194 million in the first quarter of 2019.

Revenues of COPAXONE in our North America segment were 62% of global COPAXONE revenues in the first quarter of 2019, compared to 74% in the first quarter of 2018.

COPAXONE global sales accounted for approximately 8% of our global revenues in the first quarter of 2019 and a significantly higher percentage of our profits and cash flow from operations during this period.

The FDA approved generic versions of COPAXONE 40 mg/mL in October 2017 and February 2018 and a second generic version of COPAXONE 20 mg/mL in October 2017 in the United States. Hybrid versions of COPAXONE 20 mg/mL and 40 mg/mL were also approved in the European Union.

On October 12, 2018, the U.S. Court of Appeals for the Federal Circuit (CAFC) handed down its ruling in the consolidated appeal of decisions from the U.S. District Court and Patent Trial and Appeal Board, relating to patents covering COPAXONE 40 mg/ml. The CAFC found all claims at issue to be invalid and we are currently evaluating our options for further appeals. COPAXONE 40 mg/mL is protected by one European patent expiring in 2030. This patent is being challenged in Italy and Norway. The patent was upheld by the Opposition Division of the European Patent Office in April 2019. In October 2017, the U.K. High Court found this patent invalid and our application for permission to appeal this decision was rejected.

The market for MS treatments continues to develop, particularly with the recent approvals of generic versions of COPAXONE discussed above, as well as additional generic versions expected to be approved in the future. Oral treatments for MS, such as Tecfidera®, Gilenya® and Aubagio®, continue to present significant and increasing competition. COPAXONE also continues to face competition from existing injectable products, as well as from monoclonal antibodies.

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BENDEKA and **TREANDA** combined revenues in our North America segment in the first quarter of 2019 decreased by 33% to $122 million, compared to the first quarter of 2018, mainly due to lower volumes and lower pricing, resulting partly from the June 2018 launch of a ready-to-dilute bendamustine hydrochloride by Eagle Pharmaceuticals, Inc. (Eagle). In July 2018, our partner, Eagle, prevailed in its suit in the U.S. district court against the FDA to obtain seven years of orphan drug exclusivity in the United States for BENDEKA. The FDA has appealed the district court s decision, but barring a reversal by the appellate court, drug applications referencing BENDEKA, TREANDA or any other bendamustine product will not be approved by the FDA until the orphan drug exclusivity expires in December 2022. In April 2019, we signed an amendment to the license agreement with Eagle extending the royalty term applicable to the U.S. to the full period for which we sell BENDEKA and increasing the royalty rate. In addition, Eagle agreed to assume a portion of BENDEKA-related patent litigation expenses.

ProAir revenues in our North America segment in the first quarter of 2019 decreased by 55% to $59 million, compared to the first quarter of 2018, mainly due to lower volumes as well as lower net pricing. In January 2019, we launched our own ProAir authorized generic in the United States following the launch of a generic version of Ventolin® HFA, another albuterol inhaler. Revenues from our ProAir HFA authorized generic are included in generic products above. ProAir is the second-largest short-acting beta-agonist in the market, with an exit market share of 28.9% in terms of total number of prescriptions during the first quarter of 2019, compared to 46.1% in the first quarter of 2018. In the first quarter of 2019, the exit market share of our ProAir HFA authorized generic was 17.6%. In June 2014, we settled a patent challenge to ProAir HFA with Perrigo Pharmaceuticals (Perrigo) permitting Perrigo to launch its generic product in limited quantities once it receives FDA approval and without quantity limitations after June 2018. In November 2017, we settled another patent challenge to ProAir HFA with Lupin Pharmaceuticals, Inc. (Lupin), et al. permitting Lupin to launch its generic product on September 23, 2019, or earlier under certain circumstances. To date, no generic competition has been launched.

QVAR revenues in our North America segment in the first quarter of 2019 decreased by 41% to $64 million, compared to the first quarter of 2018. The decrease in sales in the first quarter of 2019 was mainly due to higher than normal volumes during the first quarter of 2018 in connection with the launch of QVAR® RediHaler and lower net pricing. QVAR maintained its second-place position in the inhaled corticosteroids category in the United States, with an exit market share of 21.1% in terms of total number of prescriptions during the first quarter of 2019, compared to 29.4% in the first quarter of 2018.

AJOVY revenues in our North America segment in the first quarter of 2019 were $20 million. AJOVY was approved by the FDA and launched in the United States in September 2018 for the preventive treatment of migraine in adults. In April 2019, the European Medicines Agency (EMA) granted a Marketing Authorization for AJOVY in the European Union in a centralized process.

On May 12, 2017, we entered into a license and collaboration agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka) providing Otsuka with an exclusive license to conduct phase 2 and 3 clinical trials for AJOVY in Japan and, once approved, to commercialize the product in Japan.

AJOVY is protected by patents expiring in 2026 in Europe and in 2027 in the United States, with possibility for extension in various markets. An additional patent relating to the use of AJOVY in the treatment of migraine is issued in the United States and will expire in 2035. This patent is also pending in other countries. AJOVY will also be protected by regulatory exclusivity for 12 years from marketing approval in the United States and 10 years from marketing approval in Europe.

We have filed a lawsuit in the United States District Court for the District of Massachusetts alleging that Eli Lilly & Co. s (Lilly) marketing and sale of its galcanezumab product for the treatment of migraine infringes nine Teva patents.

Lilly has also submitted IPR (inter partes review) petitions to the Patent Trial and Appeal Board, challenging the validity of the nine patents asserted against it in the litigation. In addition, we have entered into separate agreements with Alder Biopharmaceuticals and Lilly, resolving the European Patent Office oppositions that they filed against our AJOVY patents. The settlement agreement with Lilly also resolved Lilly s action to revoke the patent protecting AJOVY in the U.K.

AUSTEDO revenues in our North America segment in the first quarter of 2019 were $74 million, compared to $30 million in the first quarter of 2018.

AUSTEDO was approved by the FDA and launched in April 2017 in the United States for the treatment of chorea associated with Huntington disease. In August 2017, the FDA approved AUSTEDO for the treatment of tardive dyskinesia.

Anda revenues in our North America segment increased by 14% to $379 million in the first quarter of 2019, compared to the first quarter of 2018, mainly due to higher volumes. Anda, our distribution business in the United States, distributes generic, specialty and OTC pharmaceutical products from various third party manufacturers to independent retail pharmacies, pharmacy retail chains, hospitals and physician offices in the United States. Anda is able to compete in the secondary distribution market by maintaining high inventory levels for a broad offering of products, competitive pricing and offering next day delivery throughout the United States.

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Product Launches and Pipeline

In the first quarter of 2019, we launched the generic version of the following branded products in North America:

Product Name	Brand Name	Launch Date	Total Annual U.S. Branded Sales at Time of Launch (U.S.$ in millions (IQVIA))*
Vardenafil hydrochloride tablets, 2.5 mg, 5 mg, 10 mg & 20 mg	Levitra®	January	$ 88
Albuterol sulfate HFA inhalation aerosol with dose counter, 90 mcg**	ProAir®	January	$ 1,497
Vigabatrin tablets, USP, 500 mg	Sabril®	February	$ 183
ALYQ™ (tadalafil tablets), USP, 20 mg	Adcirca®	February	$ 475
Ketoconazole cream, 2%***	Nizoral®	February	$ 92
Clindamycin phosphate and benzoyl peroxide gel, 1.2%/2.5%	Acanya®	February	$ 21
Minocycline hydrochloride extended-release tablets, USP, 80 mg & 105 mg	SolodynER®	February	$ 173
Diclofenac epolamine topical patch, 1.3%	Flector®	March	$ 123
Cyclobenzaprine hydrochloride extended-release capsules, 15 mg & 30 mg**	Amrix®	March	$ 50
Deferasirox tablets, 125 mg, 250 mg & 500 mg	Exjade®	March	$ 134
Methylergonovine maleate tablets, USP, .2 mg	Methergine®	March	$ 62
Docosanol cream, 10%	Abreva®	March	$ 88

* The figures presented are for the twelve months ended in the calendar quarter immediately prior to our launch or re-launch.

** Authorized generic of a Teva specialty product.

*** Product was re-launched.

Our generic products pipeline in the United States includes, as of March 31, 2019, 284 product applications awaiting FDA approval, including 93 tentative approvals. This total reflects all pending ANDAs, supplements for product line extensions and tentatively approved applications and includes some instances where more than one application was submitted for the same reference product. Excluding overlaps, the branded products underlying these pending applications had U.S. sales for the twelve months ended December 31, 2018 exceeding $117 billion, according to IQVIA. Approximately 70% of pending applications include a paragraph IV patent challenge and we believe we are first to file with respect to 105 of these products, or 128 products including final approvals where launch is pending a settlement agreement or court decision. Collectively, these first to file opportunities represent over $75 billion in U.S.

brand sales for the twelve months ended December 31, 2018, according to IQVIA.

IQVIA 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 first quarter of 2019, we received tentative approvals for generic equivalents of the products listed in the table below, excluding overlapping applications. A tentative approval 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.

Generic Name	Brand Name	Total U.S. Annual Branded Market (U.S. $ in millions (IQVIA))*
Dapagliflozin tablets, 5 mg	Farxiga®	$ 1,688
Enzalutamide capsules, 40 mg	Xtandi®	$ 999
Everolimus tablets, 2.5 mg, 5 mg, 7.5 mg & 10 mg	Afinitor®	$ 770

* For the twelve months ended in the calendar quarter immediately prior to the receipt of tentative approval.

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Below is a description of key products in our specialty pipeline as of March 31, 2019:

Product	Potential Indication(s)	Route of Administration	Development Phase (date entered phase 3)	Comments
CNS, Neurology and Neuropsychiatry				
AUSTEDO (deutetrabenazine)	Tourette syndrome	Oral	3 (December 2017)	Teva and Nuvelution entered into a partnership agreement on September 19, 2017 to develop AUSTEDO for the treatment of tics associated with Tourette syndrome in pediatric patients in the United States. Nuvelution will fund and manage phase 3 clinical development, leading all operational aspects of the program. Teva will lead the regulatory process and be responsible for commercialization.
	Dyskinesia in cerebral palsy	Oral	3 (January 2019)	
TV-46000 (risperidone LAI)	Schizophrenia	LAI	3 (April 2018)	
Migraine and Pain				
fremanezumab (anti CGRP)	Episodic cluster headache	Subcutaneous	3 (November 2016)	Discontinued in April 2019, after a futility analysis of the phase 3 study showed that the primary endpoint is unlikely to be met.
	Post traumatic headache	Subcutaneous	2	
Fasinumab *A fully human monoclonal antibody that targets NGF, a protein that plays a central role in the regulation of pain signaling. There is evidence that NGF levels are elevated in*	Osteoarthritis pain	Subcutaneous	3 (March 2016)	Developed in collaboration with Regeneron Pharmaceuticals, Inc. (Regeneron). In August 2018, Regeneron and Teva

patients with chronic pain conditions.				announced positive topline phase 3 results in patients with chronic pain from osteoarthritis of the knee or hip with the remaining low dose 1mg every month (1mg4W) and 1mg every two months (1mg8W). Fasinumab is protected by patents expiring in 2028 and will also be protected by regulatory exclusivity of 12 years from marketing approval in the United States and 10 years from marketing approval in Europe.
	Chronic lower back pain	Subcutaneous	3 (December 2017)	
Respiratory				
CINQAIR/CINQAERO	Severe asthma with eosinophilia	Subcutaneous	3 (August 2015)	In January 2018, we announced that the phase 3 study did not meet its primary endpoint. We are reviewing the full data to determine next steps.
ProAir e-RespiClick	Bronchospasm and exercise induced bronchitis	Oral inhalation	Submitted to FDA (September 2017) Resubmitted to FDA (August 2018)	Following feedback from the FDA, changes in application were implemented resulting in a re-submission of the supplemental NDA to the FDA on August 30, 2018.
Oncology				
Truxima (formerly CT-P10)	(biosimilar to Rituxan® US)		Approved by FDA (November 2018) Approved in Canada (April 2019)	
Herzuma (formerly CT-P06)	(biosimilar to Herceptin® US)		Approved by FDA (December 2018)	

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North America Gross Profit

Gross profit from our North America segment in the first quarter of 2019 was $1,039 million, a decrease of 26% compared to $1,403 million in the first quarter of 2018. The decrease was mainly due to lower revenues from COPAXONE, as well as a decline in sales of certain other specialty products and generic products, partially offset by increases in sales of AUSTEDO and AJOVY.

Gross profit margin for our North America segment in the first quarter of 2019 decreased to 50.8%, compared to 55.5% in the first quarter of 2018. The decrease was mainly due to lower revenues from COPAXONE and certain other specialty products, partially offset by generic products and Anda.

North America R&D Expenses

R&D expenses relating to our North America segment in the first quarter of 2019 were $165 million, a decrease of 12% compared to $188 million in the first quarter of 2018.

For a description of our R&D expenses in the first quarter of 2019, see Teva Consolidated Results Research and Development (R&D) Expenses below.

North America S&M Expenses

S&M expenses relating to our North America segment in the first quarter of 2019 were $268 million, a decrease of 3% compared to $276 million in the first quarter of 2018. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

North America G&A Expenses

G&A expenses relating to our North America segment in the first quarter of 2019 were $112 million, a decrease of 11% compared to $126 million in the first quarter of 2018. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

North America Other Income

Other income from our North America segment in the first quarter of 2019 was $4 million, compared to $102 million in the first quarter of 2018. The higher other income in the first quarter of 2018 was mainly due to Section 8 recoveries from multiple cases in Canada.

North America Profit

Profit from our North America segment consists of gross profit less R&D expenses, S&M expenses, G&A expenses and any other income related to this segment. Segment profit does not include amortization and certain other items.

Profit from our North America segment in the first quarter of 2019 was $498 million, a decrease of 46% compared to $915 million in the first quarter of 2018. The decrease was mainly due to lower revenues from COPAXONE, as well as a decline in sales of certain other specialty products and generic products and lower other income, partially offset by cost reductions and efficiency measures as part of the restructuring plan.

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Europe Segment

The following table presents revenues, expenses and profit for our Europe segment for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,			
	2019		2018	
	(U.S.$ in millions / % of Segment Revenues)			
Revenues	1,264	100%	1,442	100%
Gross profit	730	57.8%	792	55.0%
R&D expenses	66	5.2%	73	5.1%
S&M expenses	215	17.0%	250	17.4%
G&A expenses	48	3.8%	91	6.3%
Other income	(1)	§	1	§
Segment profit*	403	31.9%	377	26.1%

* Segment profit does not include amortization and certain other items.

§ Represents an amount less than 0.5%.

Europe Revenues

Our Europe segment includes the European Union and certain other European countries. Revenues from our Europe segment in the first quarter of 2019 were $1,264 million, a decrease of 12%, or $178 million, compared to the first quarter of 2018. In local currency terms, revenues decreased by 5%, mainly due to a decline in COPAXONE revenues due to the entry of competing glatiramer acetate products, the termination of the PGT joint venture and the sale of our women s health business, partially offset by new generic product launches.

Revenues by Major Products and Activities

The following table presents revenues for our Europe segment by major products and activities for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,		Percentage Change 2018-2019
	2019	2018	
	(U.S.$ in millions)		
Generic products	$ 919	$ 997	(8%)
COPAXONE	114	153	(26%)
Respiratory products	91	113	(19%)
Other	140	179	(22%)
Total	$ 1,264	$ 1,442	(12%)

Generic products revenues in our Europe segment in the first quarter of 2019, including OTC products, decreased by 8% to $919 million, compared to the first quarter of 2018. In local currency terms, revenues were flat compared to the first quarter of 2018, mainly due to the loss of revenues from the termination of the PGT joint venture, partially offset by new generic product launches.

COPAXONE revenues in our Europe segment in the first quarter of 2019 decreased by 26% to $114 million, compared to the first quarter of 2018. In local currency terms, revenues decreased by 20%, mainly due to price reductions resulting from the entry of competing glatiramer acetate products.

Revenues of COPAXONE in our Europe segment were 34% of global COPAXONE revenues in the first quarter of 2019, compared to 24% in the first quarter of 2018.

For further information about COPAXONE, see North America Revenues Revenues by Major Product above.

Respiratory products revenues in our Europe segment in the first quarter of 2019 decreased by 19% to $91 million, compared to the first quarter of 2018. In local currency terms, revenues decreased by 13%, mainly due to lower volumes in the U.K.

Product Launches and Pipeline

As of March 31, 2019, our generic products pipeline in Europe included 191 generic approvals relating to 35 compounds in 62 formulations, and approximately 1,291 marketing authorization applications pending approval in 37 European countries, relating to 150 compounds in 315 formulations, including two applications pending with the EMA for one strength in 30 countries.

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For information regarding our specialty pipeline and launches in the first quarter of 2019, see North America Segment Product Launches and Pipeline.

Europe Gross Profit

Gross profit from our Europe segment in the first quarter of 2019 was $730 million, a decrease of 8% compared to $792 million in the first quarter of 2018. The decrease was mainly due to a decline in COPAXONE revenues, the loss of revenues from the sale of our women s health business and the impact of currency fluctuations, partially offset by new generic product launches and lower cost of goods sold.

Gross profit margin for our Europe segment in the first quarter of 2019 increased to 57.8%, compared to 55.0% in the first quarter of 2018. The increase was mainly due to lower cost of goods sold related to the termination of the PGT joint venture.

Europe R&D Expenses

R&D expenses relating to our Europe segment in the first quarter of 2019 were $66 million, a decrease of 10% compared to $73 million in the first quarter of 2018.

For a description of our R&D expenses in the first quarter of 2019, see Teva Consolidated Results Research and Development (R&D) Expenses below.

Europe S&M Expenses

S&M expenses relating to our Europe segment in the first quarter of 2019 were $215 million, a decrease of 14% compared to $250 million in the first quarter of 2018. The decrease was mainly due to cost reductions as part of the restructuring plan.

Europe G&A Expenses

G&A expenses relating to our Europe segment in the first quarter of 2019 were $48 million, a decrease of 47% compared to $91 million in the first quarter of 2018. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

Europe Profit

Profit of our Europe segment consists of gross profit less R&D expenses, S&M expenses, G&A expenses and any other income related to this segment. Segment profit does not include amortization and certain other items.

Profit from our Europe segment in the first quarter of 2019 was $403 million, an increase of 7% compared to $377 million in the first quarter of 2018. The increase was mainly due to lower cost of goods sold related to the termination of the PGT joint venture and cost reductions and efficiency measures as part of the restructuring plan.

International Markets Segment

The following table presents revenues, expenses and profit for our International Markets segment for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,			
	2019		2018	
	(U.S.$ in millions / % of Segment Revenues)			
Revenues	668	100%	750	100%
Gross profit	269	40.3%	313	41.8%
R&D expenses	22	3.3%	24	3.2%
S&M expenses	115	17.2%	134	17.9%
G&A expenses	36	5.3%	41	5.5%
Other income	(0)	§	(8)	(1.1%)
Segment profit*	97	14.5%	122	16.3%

* Segment profit does not include amortization and certain other items.

§ Represents an amount less than 0.5%.

International Markets Revenues

Our International Markets segment includes all countries other than those in our North America and Europe segments. Our key international markets are Israel, Japan and Russia. The countries in this category range from highly regulated, pure generic markets, such as Israel, to hybrid markets, such as Japan, to branded generics oriented markets, such as Russia and certain Commonwealth of Independent States (CIS), Latin American and Asia Pacific markets.

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Revenues from our International Markets segment in the first quarter of 2019 were $668 million, a decrease of $82 million, or 11%, compared to the first quarter of 2018. In local currency terms, revenues decreased 3% compared to the first quarter of 2018, mainly due to lower sales in Japan, partially offset by higher sales in Russia.

Revenues by Major Products and Activities

The following table presents revenues for our International Markets segment by major products and activities for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,		Percentage Change
	2019	2018	2018-2019
	(U.S.$ in millions)		
Generic products	$ 441	$ 488	(10%)
COPAXONE	13	16	(18%)
Distribution	151	153	(1%)
Other	62	93	(33%)
Total	$ 668	$ 750	(11%)

Generic products revenues in our International Markets segment in the first quarter of 2019, which include OTC products, decreased by 10% to $441 million, compared to the first quarter of 2018. In local currency terms, revenues decreased by 1%, mainly due to lower sales in Japan resulting from regulatory pricing reductions and generic competition to off-patented products, partially offset by higher sales in Russia.

COPAXONE revenues in our International Markets segment in the first quarter of 2019 decreased by 18% to $13 million, compared to the first quarter of 2018. In local currency terms, revenues increased by 3%.

For further information about COPAXONE, see North America Revenues Revenues by Major Product above.

Distribution revenues in our International Markets segment in the first quarter of 2019 decreased by 1% to $151 million, compared to the first quarter of 2018. In local currency terms, revenues increased by 4%.

International Markets Gross Profit

Gross profit from our International Markets segment in the first quarter of 2019 was $269 million, a decrease of 14% compared to $313 million in the first quarter of 2018.

Gross profit margin for our International Markets segment in the first quarter of 2019 decreased to 40.3%, compared to 41.8% in the first quarter of 2018. The decrease was mainly due to lower sales in Japan, partially offset by higher sales in Russia.

International Markets R&D Expenses

R&D expenses relating to our International Markets segment in the first quarter of 2019 were $22 million, a decrease of 8% compared to $24 million in the first quarter of 2018.

For a description of our R&D expenses in the first quarter of 2019, see Teva Consolidated Results Research and Development (R&D) Expenses below.

International Markets S&M Expenses

S&M expenses relating to our International Markets segment in the first quarter of 2019 were $115 million, a decrease of 14% compared to $134 million in the first quarter of 2018. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

International Markets G&A Expenses

G&A expenses relating to our International Markets segment in the first quarter of 2019 were $36 million, a decrease of 13% compared to $41 million in the first quarter of 2018. The decrease was mainly due to cost reductions as part of the restructuring plan.

International Markets Profit

Profit of our International Markets segment consists of gross profit less R&D expenses, S&M expenses, G&A expenses and any other income related to this segment. Segment profit does not include amortization and certain other items.

Profit from our International Markets segment in the first quarter of 2019 was $97 million, a decrease of 20% compared to $122 million in the first quarter of 2018. The decrease was mainly due to lower sales in Japan resulting from regulatory pricing reductions and generic competition to off-patent products, partially offset by higher sales in Russia and cost reductions and efficiency measures as part of the restructuring plan.

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Other Activities

We have other sources of revenues, primarily the sale of APIs to third parties, certain contract manufacturing services and an out-licensing platform offering a portfolio of products to other pharmaceutical companies through our affiliate Medis. Our other activities are not included in our North America, Europe or International Markets segments described above.

Our revenues from other activities in the first quarter of 2019 were $317 million, a decrease of 7% compared to the first quarter of 2018. In local currency terms, revenues decreased by 5%, mainly due to lower revenues from contract manufacturing services and Medis.

API sales to third parties in the first quarter of 2019 were $187 million, an increase of 4% compared to the first quarter of 2018. In local currency terms, revenues increased by 5%.

Teva Consolidated Results

Revenues

Revenues in the first quarter of 2019 were $4,295 million, a decrease of 15%, or 12% in local currency terms, compared to the first quarter of 2018, mainly due to generic competition to COPAXONE, as well as declines in revenues from our respiratory products and U.S. generics business. See North America Revenues, Europe Revenues, International Markets Revenues and Other Activities above.

Exchange rate movements during the first quarter of 2019 negatively impacted revenues by $177 million compared to the first quarter of 2018.

Gross Profit

Gross profit in the first quarter of 2019 was $1,856 million, a decrease of 20% compared to the first quarter of 2018. The decrease was mainly a result of the factors discussed above under North America Gross Profit, Europe Gross Profit and International Markets Gross Profit.

Gross profit as a percentage of revenues was 43.2% in the first quarter of 2019, compared to 45.7% in the first quarter of 2018.

The decrease in gross profit as a percentage of revenues was mainly due to lower profitability in North America, resulting mainly from a decline in COPAXONE revenues due to generic competition, as well as lower revenues of certain other specialty products, partially offset by lower amortization expenses and higher profitability in Europe, mainly due to the termination of the PGT joint venture.

Research and Development (R&D) Expenses

Net R&D expenses in the first quarter of 2019 were $261 million, a decrease of 18% compared to the first quarter of 2018.

Our R&D activities for generic products in each of our segments include both (i) direct expenses relating to product formulation, analytical method development, stability testing, management of bioequivalence and other clinical studies and regulatory filings; and (ii) indirect expenses, such as costs of internal administration, infrastructure and

personnel.

Our R&D activities for specialty products in each of our segments include costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, clinical trials and product registration costs. These expenditures are reported net of contributions received from collaboration partners. Our spending takes place throughout the development process, including (i) early-stage projects in both discovery and preclinical phases; (ii) middle-stage projects in clinical programs up to phase 3; (iii) late-stage projects in phase 3 programs, including where a new drug application is currently pending approval; (iv) life cycle management and post-approval studies for marketed products; and (v) 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.

In the first quarter of 2019, our R&D expenses were primarily related to generic products in our North America segment, as well as specialty product candidates in the pain, migraine, headache and respiratory therapeutic areas, with additional activities in selected other areas.

Our lower R&D expenses in the first quarter of 2019 compared to the first quarter of 2018 primarily resulted from pipeline optimization and project terminations, phase 3 studies that have ended and related headcount reductions.

R&D expenses as a percentage of revenues were 6.1% in the first quarter of 2019, compared to 6.3% in the first quarter of 2018.

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Selling and Marketing (S&M) Expenses

S&M expenses in the first quarter of 2019 were $648 million, a decrease of 12% compared to the first quarter of 2018. Our S&M expenses were primarily the result of the factors discussed above under North America Segment S&M Expenses, Europe Segment S&M Expenses and International Markets Segment S&M Expenses.

S&M expenses as a percentage of revenues were 15.1% in the first quarter of 2019, compared to 14.6% in the first quarter of 2018.

General and Administrative (G&A) Expenses

G&A expenses in the first quarter of 2019 were $292 million, a decrease of 11% compared to the first quarter of 2018. Our G&A expenses were primarily the result of the factors discussed above under North America Segment G&A Expenses, Europe Segment G&A Expenses and International Markets Segment G&A Expenses .

G&A expenses as a percentage of revenues were 6.8% in the first quarter of 2019, compared to 6.5% in the first quarter of 2018.

Identifiable Intangible Asset Impairments

We recorded expenses of $469 million for identifiable intangible asset impairments in the first quarter of 2019, compared to expenses of $206 million in the first quarter of 2018. See note 6 to our consolidated financial statements.

Goodwill Impairment

In the first quarter of 2019, there were no goodwill impairments recorded, compared to a goodwill impairment of $180 million in the first quarter of 2018. The goodwill impairment in the first quarter of 2018 was mainly attributable to goodwill associated with our Rimsa reporting unit (now included in International Markets reporting unit). See note 7 to our consolidated financial statements.

Other Assets Impairments, Restructuring and Other Items

We recorded an expense of $1 million for other assets impairments, restructuring and other items in the first quarter of 2019, compared to expenses of $501 million in the first quarter of 2018. See note 14 to our consolidated financial statements.

Significant regulatory events

In July 2018, the FDA completed an inspection of our manufacturing plant in Davie, Florida in the United States, and issued a Form FDA-483 to the site. In October 2018, the FDA notified us that the inspection of the site is classified as official action indicated (OAI). On February 5, 2019, we received a warning letter from the FDA that contains four enumerated concerns related to production, quality control and investigations at this site. We are working diligently to remediate the FDA s concerns in a manner consistent with current good manufacturing practice (CGMP) requirements as quickly and as thoroughly as possible. If we are unable to remediate the warning letter findings to the FDA s satisfaction, we may face additional consequences, including delays in FDA approval for future products from the site, financial implications due to loss of revenues, impairments, inventory write offs, customer penalties, idle capacity charges, costs of additional remediation and possible FDA enforcement action. We expect to generate approximately $240 million in revenues from this site for the remainder of 2019, assuming remediation or enforcement does not

cause any unscheduled slowdown or stoppage at the facility.

In July 2018, we announced the voluntary recall of valsartan and certain combination valsartan medicines in various countries due to the detection of trace amounts of a previously unknown impurity called NDMA found in valsartan API supplied to us by Zhejiang Huahai Pharmaceutical. Since July 2018, we have been actively engaged with regulatory agencies around the world in reviewing our valsartan and other sartan products for NDMA and other related impurities and, where necessary, have initiated additional voluntary recalls. The impact of this recall on our 2018 financial statements was $51 million, primarily related to inventory reserves. We expect to continue to experience loss of revenues and profits in connection with this matter. In addition, multiple lawsuits have been filed in connection with this matter. We may also incur additional customer penalties, impairments and litigation costs going forward.

Restructuring

In the first quarter of 2019, we recorded $32 million of restructuring expenses, compared to $247 million in the first quarter of 2018. The expenses in the first quarter of 2019 were primarily related to headcount reductions across all functions as part of the restructuring plan announced in 2017.

The two-year restructuring plan announced in 2017 is intended to reduce our total cost base by $3 billion by the end of 2019.

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Since the announcement, we reduced our global headcount by approximately 10,400 full-time-equivalent employees.

Legal Settlements and Loss Contingencies

Legal settlements and loss contingencies in the first quarter of 2019 amounted to an expense of $57 million, compared to an income of $1,278 million in the first quarter of 2018. The income in the first quarter of 2018 consisted primarily of the working capital adjustment with Allergan, the Rimsa settlement and the reversal of the reserve related to the carvedilol judgment.

Other Income

Other income in the first quarter of 2019 was $6 million, compared to $203 million in the first quarter of 2018. Other income in the first quarter of 2018 was primarily the result of higher Section 8 recoveries from multiple cases in Canada and a net gain related to the divestment of our women s health business.

Operating Income

Operating income was $134 million in the first quarter of 2019, compared to $1,525 million in the first quarter of 2018.

Operating income as a percentage of revenues was 3.1% in the first quarter of 2019, compared to 30.1% in the first quarter of 2018. The decrease was mainly due to legal settlements and loss contingencies expenses (compared to income in 2018), higher intangible asset impairments and lower profit in our North America segment, partially offset by lower other assets impairments and reduced expenses related to restructuring.

The following table presents a reconciliation of our segment profits to our consolidated operating income and to consolidated income (loss) before income taxes for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,	
	2019	2018
	(U.S.$ in millions)	
North America profit	$ 498	$ 915
Europe profit	403	377
International Markets profit	97	122
Total segment profit	998	1,414
Profit of other activities	21	21
	1,019	1,435
Amounts not allocated to segments:		
Amortization	283	310
Other assets impairments, restructuring and other items	1	501
Goodwill impairment		180
Intangible asset impairments	469	206

Gain on divestitures, net of divestitures related costs	§	(93)
Other R&D expenses	§	22
Costs related to regulatory actions taken in facilities	4	1
Legal settlements and loss contingencies	57	(1,278)
Other unallocated amounts	70	61
Consolidated operating income	134	1,525
Financial expenses, net	218	271
Consolidated (loss) income before income taxes	$ (84)	$ 1,254

§ Represents an amount less than $0.5 million.

Financial Expenses, Net

Financial expenses were $218 million in the first quarter of 2019, compared to $271 million in the first quarter of 2018. Financial expenses in the first quarter of 2019 were mainly comprised of interest expenses of $227 million. Financial expenses in the first quarter of 2018 were mainly comprised of interest expenses of $218 million and approximately $67 million resulting from early redemption of debt.

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Tax Rate

In the first quarter of 2019, we recognized a tax expense of $9 million, or 11%, on pre-tax loss of $84 million. In the first quarter of 2018, we recognized a tax expense of $46 million, or 4%, on pre-tax income of $1,254 million. Our tax rate for the first quarter of 2019 was mainly affected by impairments, amortization and interest disallowance as a result of the U.S. Tax Cuts and Jobs Act.

The statutory Israeli corporate tax rate is 23% in 2019. Our tax rate differs from the Israeli statutory tax rate mainly due to generation of profits in various jurisdictions in which tax rates are different than the Israeli tax rate, tax benefits in Israel and other countries, as well as infrequent or nonrecurring items.

Share in Losses of Associated Companies, Net

Share in losses of associated companies, net in the first quarter of 2019 was $4 million, compared to $74 million in the first quarter of 2018.

Net Income (Loss)

Net loss was $97 million in the first quarter of 2019, compared to net income of $1,134 million in the first quarter of 2018.

Diluted Shares Outstanding and Earnings (Loss) per Share

The weighted average diluted shares outstanding used for the fully diluted share calculation for the three months ended March 31, 2019 and 2018 were 1,090 million and 1,020 million shares, respectively.

In computing loss per share for the three months ended March 31, 2019, no account was taken of the potential dilution by the assumed exercise of employee stock options and non-vested RSUs granted under employee stock compensation plans and convertible senior debentures, since they had an anti-dilutive effect on loss per share.

Additionally, no account was taken of the potential dilution by the mandatory convertible preferred shares, amounting to 64 million shares (including shares that were issued due to unpaid dividends until that date) for the three months ended March 31, 2018, since they had an anti-dilutive effect on loss per share.

On December 17, 2018, the mandatory convertible preferred shares automatically converted into ADSs and all of the accumulated and unpaid dividends on the mandatory convertible preferred shares were paid in ADSs. As a result of this conversion, we issued 70.6 million ADSs in December 2018.

Diluted loss per share was $0.10 in the first quarter of 2019, compared to diluted earnings per share of $1.03 in the first quarter of 2018.

Share Count for Market Capitalization

We calculate 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 performance share units (PSUs) and the conversion of our convertible senior debentures, in each case, at period end.

As of March 31, 2019 and 2018, the fully diluted share count for purposes of calculating our market capitalization was approximately 1,107 million and 1,095 million, respectively.

Impact of Currency Fluctuations on Results of Operations

In the first quarter of 2019, approximately 49% of our revenues were denominated in currencies other than the U.S. dollar. Because our results are reported in U.S. dollars, we are subject to significant foreign currency risks. 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 euro, British pound, Japanese yen, Israeli shekel, Canadian dollar, Polish zloty, Argentinean peso, Turkish lira and Russian ruble) impact our results.

During the first quarter of 2019, the following main currencies relevant to our operations decreased in value against the U.S. dollar (each on a quarterly average compared to quarterly average basis): Argentinian peso by 49%, Turkish lira by 29%, Russian ruble by 14%, Hungarian forint by 10%, Polish zloty by 10%, Indian rupee by 9%, euro by 8%, British pound by 6%, Canadian dollar by 5%, Israeli shekel by 5%, Swiss franc by 5% and Japanese yen by 2%.

As a result, exchange rate movements during the first quarter of 2019 negatively impacted overall revenues by $177 million and our operating income by $49 million, in comparison with the first quarter of 2018.

Commencing in the third quarter of 2018, the cumulative inflation in Argentina exceeded 100% or more over a 3-year period. Although this triggered highly inflationary accounting treatment, it did not have a material impact on our results of operations.

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Liquidity and Capital Resources

Total balance sheet assets were $59,854 million as of March 31, 2019, compared to $60,683 million as of December 31, 2018.

Our working capital balance, which includes trade receivables net of SR&A, inventories, prepaid expenses and other current assets, trade payables, employee-related obligations, accrued expenses and other current liabilities, was $59 million as of March 31, 2019, compared to negative $186 million as of December 31, 2018.

Employee-related obligations, as of March 31, 2019, were $633 million, compared to $870 million as of December 31, 2018. The decrease in the first quarter of 2019 was mainly due to performance incentive payments to employees for 2018.

Investment in property, plant and equipment in the first quarter of 2019 was approximately $125 million, compared to $213 million in the fourth quarter of 2018. Depreciation in the first quarter of 2019 was $152 million, compared to $161 million in the fourth quarter of 2018.

Cash and cash equivalents and short-term and long-term investments as of March 31, 2019 were $2,040 million, compared to $1,846 million as of December 31, 2018, mainly due to cash generated during the quarter, partially offset by the repurchase and cancellation of $126 million of our $1,700 million 1.7% senior notes due July 2019.

Our cash on hand that is not used for ongoing operations is generally invested in bank deposits as well as liquid securities that bear fixed and floating rates.

Our principal sources of short-term liquidity are our existing cash investments, liquid securities and available credit facilities, primarily our revolving credit facility (RCF), which was replaced in April 2019, as well as internally generated funds.

In April 2019, we entered into a $2.3 billion unsecured syndicated revolving credit facility which replaced the previous $3 billion revolving credit facility. The revolving credit facility contains certain covenants, including certain limitations on incurring liens and indebtedness and maintenance of certain financial ratios, including a maximum leverage ratio, which becomes more restrictive over time. As of March 31, 2019, we did not have any outstanding debt under our then-applicable revolving credit facility, which was our only debt subject to a maximum leverage ratio, and met all financial covenants thereunder.

We expect that we will continue to have sufficient cash resources to support our debt service payments and all other financial obligations for at least twelve months from the date of this report.

Debt Balance and Movements

As of March 31, 2019, our debt was $28,624 million, compared to $28,916 million as of December 31, 2018. The decrease was mainly due to favorable exchange rates as well as repurchase and cancellation of $126 million of our $1,700 million 1.7% senior notes due July 2019.

During the first quarter of 2019, we repurchased and canceled approximately $126 million principal amount of our $1,700 million 1.7% senior notes due July 2019.

Our debt as of March 31, 2019 was effectively denominated in the following currencies: 66% in U.S. dollars, 31% in euros and 3% in Swiss francs.

The portion of total debt classified as short-term as of March 31, 2019 was 10%, compared to 8% as of December 31, 2018, due to a net increase in current maturities.

Our financial leverage was 64% as of March 31, 2019, a slight decrease compared to 65% as of December 31 2018.

Our average debt maturity was approximately 6.6 years as of March 31, 2019, compared to 6.8 years as of December 31 2018.

Total Equity

Total equity was $15,821 million as of March 31, 2019, flat compared to December 31, 2018.

Exchange rate fluctuations affected our balance sheet, as approximately 36% of our net assets in the first quarter of 2019 (including both non-monetary and monetary assets) were in currencies other than the U.S. dollar. When compared to December 31, 2018, changes in currency rates had a positive impact of $47 million on our equity as of March 31, 2019, mainly due to the changes in value against the U.S. dollar of: the euro by 2%, the Russian ruble by 6%, the British pound by 3%, the Canadian dollar by 2% and the Chilean peso by 2%. All comparisons are on a quarter-end to quarter-end basis.

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Cash Flow

Cash flow generated from operating activities during the first quarter of 2019 was $112 million, compared to $1,496 million in the first quarter of 2018. The higher cash flow in the first quarter of 2018 was mainly due to the proceeds from the working capital adjustment with Allergan and the legal settlement with Rimsa. In addition, the lower cash flow in the first quarter of 2019 was mainly due to lower revenues from COPAXONE, as well as a decline in sales of certain other specialty products and generic products and performance incentive payments to employees for 2018.

Cash flow generated from operating activities in the first quarter of 2019, net of cash used for capital investments and beneficial interest collected in exchange for securitized trade receivables, was $360 million, compared to $1,894 million in the first quarter of 2018. The decrease in cash flow was mainly due to less cash flow generated from operating activities and higher net capital investments.

Dividends

We have not paid dividends on our ordinary shares or ADSs since December 2017.

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 leases, royalty payments, contingent payments pursuant to acquisition agreements and participation in joint ventures associated with R&D activities.

In September 2016, we entered into an agreement to develop and commercialize Regeneron s pain medication product, fasinumab. We paid Regeneron $250 million upfront and will share equally with Regeneron in the global commercial benefits of this product, as well as ongoing associated R&D costs of approximately $1.0 billion. Milestone payments of $25 million, $35 million and $60 million were paid in the second quarter of 2017, the first quarter of 2018 and the fourth quarter of 2018, respectively.

In October 2016, we entered into an exclusive partnership with Celltrion to commercialize two of Celltrion s biosimilar products in development for the U.S. and Canadian markets. We paid Celltrion $160 million, of which up to $60 million is refundable or creditable under certain circumstances. We will share the profit from the commercialization of these products with Celltrion. These two products, Truxima and Herzuma, were approved by the FDA in November and December 2018, respectively.

In September 2017, we entered into a partnership agreement with Nuvelution for development of AUSTEDO for the treatment of Tourette syndrome in pediatric patients in the United States. Nuvelution will fund and manage clinical development, driving all operational aspects of the phase 3 program, and we will lead the regulatory process and be responsible for commercialization. Upon and subject to FDA approval of AUSTEDO for Tourette syndrome, we will pay Nuvelution a pre-agreed return.

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 (i) infringement or violation of intellectual property or other rights of such third party; or (ii) 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.

2019 Aggregated Contractual Obligations

There have not been any material changes in our assessment of material contractual obligations and commitments as set forth in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2018, other than as set forth below.

For a description of our new revolving credit facility entered into in April 2019, see Liquidity and Capital Resources above.

Supplemental Non-GAAP Income Data

We utilize 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, which is based on the non-GAAP presentation set forth below.

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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 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 such 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 scope;
- 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 changes in contingent consideration, integration costs, banker and other professional fees, inventory step-up and in-process R&D acquired in development arrangements;
- expenses related to our equity compensation;
- significant one-time financing costs and devaluation losses;
- deconsolidation charges;

unusual tax items;

other awards or settlement amounts, either paid or received;

other exceptional items that we believe are sufficiently large that their exclusion is important to facilitate an understanding of 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 related consulting costs, or other unusual events; and

corresponding tax effects of the foregoing items.

The following tables present supplemental non-GAAP data, in U.S. dollar, which we believe facilitates an understanding of the factors affecting our business. In these tables, we exclude the following amounts:

	Three Months Ended March 31,	
	2019	2018
	(U.S. $ in millions)	
Gain on divestitures, net of divestitures related costs	0	(93)
Amortization of purchased intangible assets	283	310
Restructuring expenses	32	247
Equity compensation expenses	34	30
Costs related to regulatory actions taken in facilities	4	1
Acquisition, integration and related expenses	2	2
Other R&D expenses	0	22
Contingent consideration	(71)	8
Legal settlements and loss contingencies	57	(1,278)
Goodwill impairment		180
Impairment of long-lived assets	489	432
Other non-GAAP items	54	49
Financial expense (income)	(2)	68
Minority interest	(8)	(8)
Impairments of equity investments		94
Corresponding tax effect	(177)	(165)
Unusual tax item	61	

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

	Three Months Ended March 31, 2019 U.S. $ and shares in millions (except per share amounts) Excluded for non GAAP measurement														
	GAAP	Amortization of purchased intangible assets	Legal settlements and loss contingencies	Impairments of long-lived assets	Acquisition, integration and related expenses	Restructuring costs	Costs related to regulatory actions taken	Equity compensation	Contingent consideration	Gain on sale of businesses	Other non GAAP items	Other items	Corresponding tax effect	Unusual tax item*	Non-GAAP
COGS	2,440	248					4	7			35				2,146
R&D	261							6			0				255
S&M	648	35						10							602
G&A	292							12			0				280
Other income	(6)									0					(6)
Legal settlements and loss contingencies	57		57												
Other assets impairments, restructuring and other items	1			20	2	32			(71)		19				
Intangible assets impairment	469			469											
Financial expenses	218											(2)			220
Income taxes	9												(177)	61	125
Share in losses of associated companies net	4														4
Net income attributable to non-controlling interests	8											(8)			16
Total reconciled items		283	57	489	2	32	4	34	(71)	0	54	(10)	(177)	61	
EPS Basic	(0.10)													0.70	0.60
EPS Diluted	(0.10)													0.70	0.60

* Interest disallowance as a result of the U.S. Tax Cuts and Jobs Act.

The non-GAAP diluted weighted average number of shares was 1,093 million for the three months ended March 31, 2019.

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Three Months Ended March 31, 2018
U.S. $ and shares in millions (except per share amounts)

		Excluded for non GAAP measurement												
	GAAP	Amortization of purchased intangible assets	Legal settlements and loss contingencies	Impairment of long-lived assets	Acquisition, integration and Related expenses	Other R&D expenses	Restructuring costs	Costs related to regulatory actions taken in facilitation	Equity compensation	Contingent consideration	Other non GAAP items	Other items	Corresponding tax effect	Non GAAP
COGS	2,750	264						1	6		32			2,447
R&D	317				22				5		1			289
S&M	738	46							9		1			682
G&A	329								10		(3)			322
Other income	(203)										(93)			(110)
Legal settlements and loss contingencies	(1,278)		(1,278)											
Impairments, restructuring and other	501			226		2	247			8	18			
Intangible assets impairment	206			206										
Goodwill impairment	180			180										
Financial expenses	271											68		203
Income taxes	46												(165)	211
Share in losses of associated companies net	74											94		(20)
Net income attributable to non-controlling interests	14											(8)		22
Total reconciled items		310	(1,278)	612	22	2	247	1	30	8	(44)	154	(165)	
EPS Basic	1.04												(0.10)	0.94
EPS Diluted	1.03												(0.09)	0.94

The non-GAAP diluted weighted average number of shares was 1,020 million for the three months ended March 31, 2018.

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Non-GAAP Tax Rate

Non-GAAP income taxes for the first quarter of 2019 were $125 million, or 16%, on pre-tax non-GAAP income of $799 million. Non-GAAP income taxes in the first quarter of 2018 were $211 million, or 17%, on pre-tax non-GAAP income of $1,232 million. Our non-GAAP tax rate for the first quarter of 2019 was mainly affected by the mix of products sold in different geographies and the enactment of the Tax Cuts and Jobs Act in the United States.

Off-Balance Sheet Arrangements

Except for securitization transactions, which are disclosed in note 16 (d) to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018, we do not have any material off-balance sheet arrangements.

Critical Accounting Policies

For a summary of our significant accounting policies, see note 1 to our consolidated financial statements and Critical Accounting Policies included in our Annual Report on Form 10-K for the year ended December 31, 2018.

Recently Issued Accounting Pronouncements

See note 2 to our consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has not been any material change in our assessment of material contractual obligations and commitments as set forth in Item 7A to our Annual Report on Form 10-K for the year ended December 31, 2018.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Teva maintains disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to provide reasonable assurance that information required to be disclosed in Teva s reports filed or submitted under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to Teva s management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective.

After evaluating the effectiveness of our disclosure controls and procedures as of March 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, Teva s disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2019, there were no changes in internal control over financial reporting that materially affected or are reasonably likely to materially affect Teva s internal control over financial reporting.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are subject to various litigation and other legal proceedings. For a discussion of these matters, see Commitments and Contingencies included in note 16 to the consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

ITEM 1A. RISK FACTORS

There are no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

There were no sales of unregistered equity securities during the three months ended March 31, 2019.

Repurchase of Shares

In December 2011, our Board of Directors authorized us to repurchase up to an aggregate amount of $3.0 billion of our ordinary shares or ADSs, of which $1.3 billion remained available for purchase, when in October 2014, the Board of Directors authorized us to increase our share repurchase program by $1.7 billion to $3.0 billion, of which $2.1 billion remained available as of March 31, 2019. We did not repurchase any of our shares during the three months ended March 31, 2019 and currently cannot do so due to our accumulated deficit. The repurchase program has no time limit. Repurchases may be commenced or suspended at any time, subject to applicable law.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

10.1	Senior Unsecured Revolving Credit Agreement, dated as of April 8, 2019, by and among Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Finance Netherlands III B.V., Teva Pharmaceutical Finance Netherlands II B.V., Bank of America, N.A. and the lenders party thereto (1)
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *
32	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 *
101.INS	XBRL Taxonomy Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

* Filed herewith.

1. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on April 10, 2019.

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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: May 2, 2019

By: /s/ Michael McClellan
Name: **Michael McClellan**
Title: **Executive Vice President,**

Chief Financial Officer

(Duly Authorized Officer)