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 June 30, 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	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification Number)**
5 Basel Street, Petach Tikva, ISRAEL	**4951033**
(Address of principal executive offices)	**(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 June 30, 2019, the registrant had 1,091,906,300 ordinary shares outstanding.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

INDEX

INTRODUCTION AND USE OF CERTAIN TERMS

Unless otherwise indicated, all references to the "Company," "we," "our" and "Teva" refer to Teva Pharmaceutical Industries Limited and its subsidiaries, and references to "revenues" refer to net revenues. References to "U.S. dollars," "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 "ADS(s)" are to Teva's American Depositary Share(s). 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 and terms of similar 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; implementation of a new enterprise resource planning system that, if deficient, could materially and adversely affect our operations and/or the effectiveness of our internal controls; 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;

- 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.

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)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,165	$ 1,782
Trade receivables	5,260	5,822
Inventories	4,850	4,731
Prepaid expenses	1,069	899
Other current assets	437	468
Assets held for sale	24	92
Total current assets	13,805	13,794
Deferred income taxes	317	368
Other non-current assets	721	731
Property, plant and equipment, net	6,732	6,868
Operating lease right-of-use assets	500	—
Identifiable intangible assets, net	12,435	14,005
Goodwill	24,913	24,917
Total assets	$ 59,424	$ 60,683
LIABILITIES AND EQUITY		
Current liabilities:		
Short-term debt	$ 2,771	$ 2,216
Sales reserves and allowances	6,054	6,711
Trade payables	1,806	1,853
Employee-related obligations	587	870
Accrued expenses	2,335	1,868
Other current liabilities	899	804
Total current liabilities	14,452	14,322
Long-term liabilities:		
Deferred income taxes	1,698	2,140
Other taxes and long-term liabilities	1,642	1,727
Senior notes and loans	25,955	26,700
Operating lease liabilities	426	—
Total long-term liabilities	29,721	30,567
Commitments and contingencies, see note 16		
Total liabilities	44,173	44,889
Equity:		
Teva shareholders' equity:		
Ordinary shares of NIS 0.10 par value per share; June 30, 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	27,258	27,210
Accumulated deficit	(6,752)	(5,958)
Accumulated other comprehensive loss	(2,312)	(2,459)
Treasury shares as of June 30, 2019 and December 31, 2018 — 107 million ordinary shares and 106 million ordinary shares, respectively	(4,128)	(4,142)
	14,122	14,707
Non-controlling interests	1,128	1,087
Total equity	15,251	15,794
Total liabilities and equity	$ 59,424	$ 60,683

Amounts may not add up due to rounding.
The accompanying notes are an integral part of the financial statements.

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

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Net revenues	$ 4,337	$ 4,701	$8,632	$ 9,766
Cost of sales	2,443	2,668	4,883	5,418
Gross profit	1,893	2,033	3,749	4,348
Research and development expenses	276	290	537	607
Selling and marketing expenses	666	682	1,313	1,420
General and administrative expenses	296	316	589	645
Intangible assets impairment	561	521	1,030	727
Goodwill impairment	—	120	—	300
Other assets impairments, restructuring and other items	101	194	103	695
Legal settlements and loss contingencies	646	20	703	(1,258)
Other income	(9)	(96)	(15)	(299)
Operating income (loss)	(644)	(14)	(510)	1,511
Financial expenses, net	206	236	425	507
Income (loss) before income taxes	(850)	(250)	(934)	1,004
Income taxes	(179)	(76)	(170)	(30)
Share in losses (income) of associated companies, net	—	(8)	4	66
Net income (loss)	(671)	(166)	(768)	968
Net income attributable to non-controlling interests	18	10	26	24
Net income (loss) attributable to Teva	(689)	(176)	(794)	944
Dividends on preferred shares	—	65	—	130
Net income (loss) attributable to ordinary shareholders	$ (689)	$ (241)	$ (794)	$ 814
Earnings (loss) per share attributable to ordinary shareholders:				
Basic	$ (0.63)	$ (0.24)	$ (0.73)	$ 0.80
Diluted	$ (0.63)	$ (0.24)	$ (0.73)	$ 0.80
Weighted average number of shares (in millions):				
Basic	1,092	1,018	1,091	1,018
Diluted	1,092	1,018	1,091	1,020

Amounts may not add up due to rounding.
The accompanying notes are an integral part of the financial statements.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(U.S. dollars in millions)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Net income (loss)	$ (671)	$ (166)	$ (768)	$ 968
Other comprehensive income (loss), net of tax:				
Currency translation adjustment	86	(711)	133	(472)
Unrealized gain (loss) from derivative financial instruments	(10)	100	37	56
Unrealized gain (loss) from available-for-sale securities	1	(1)	1	(1)
Unrealized loss on defined benefit plans	(1)	(2)	(1)	(1)
Total other comprehensive income (loss)	76	(614)	170	(418)
Total comprehensive income (loss)	(595)	(780)	(598)	550
Comprehensive income (loss) attributable to non-controlling interests	47	(51)	49	46
Comprehensive income (loss) attributable to Teva	$ (642)	$ (729)	$ (647)	$ 504

Amounts may not add up due to rounding.
The accompanying notes are an integral part of the financial statements.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
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 shareholders' equity	Non-controlling interests	Total equity
					(U.S. dollars in millions)					
Balance at March 31, 2018**	1,124	54	3,696	23,443	(2,688)	(1,735)	(4,149)	18,621	1,481	20,102
Comprehensive income (loss)					(176)	(554)		(730)	(51)	(780)
Stock-based compensation expense				47				47		47
Dividends to preferred shareholders			65	(65)				—	—	—
Balance at June 30, 2018	1,124	$ 54	$3,760	$ 23,426	$ (2,864)	$ (2,289)	$(4,149)	$ 17,938	$ 1,430	$ 19,368

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

	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 shareholders' equity	Non-controlling interests	Total equity
					(U.S. dollars in millions)					
Balance at March 31, 2019	1,198	56	—	27,234	(6,063)	(2,359)	(4,137)	14,732	1,089	15,821
Comprehensive income (loss)					(689)	47		(642)	47	(595)
Issuance of Shares		**								
Issuance of Treasury Shares				(6)			9	3		3
Stock-based compensation expense				32				32		32
Other				(2)				(2)		(2)
Transactions with non-controlling interests									(8)	(8)
Balance at June 30, 2019	1,198	$ 56	—	$ 27,258	$ (6,752)	$ (2,312)	$(4,128)	$ 14,122	$ 1,128	$ 15,251

* 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.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
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 shareholders' 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)					944	(441)		503	46	550
Dividends to preferred shareholders			129	(129)						
Stock-based compensation expense				77				77		77
Transactions with non-controlling interests									(2)	(2)
Balance at June 30, 2018	1,124	$ 54	$3,760	$ 23,426	$ (2,864)	$ (2,289)	$(4,149)	$ 17,938	$ 1,430	$ 19,368

* 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 shareholders' equity	Non-controlling interests	Total equity
	(U.S. dollars in millions)									
Balance at December 31, 2018	1,196	56	—	27,210	(5,958)	(2,459)	(4,142)	14,707	1,087	15,794
Comprehensive income (loss)					(794)	147		(647)	49	(598)
Issuance of Shares	2	**								
Issuance of Treasury Shares				(8)			14	6		6
Stock-based compensation expense				64				64		64
Transactions with non-controlling interests									(8)	(8)
Other				(8)				(8)		(8)
Balance at June 30, 2019	1,198	$ 56	—	$ 27,258	$ (6,752)	$ (2,312)	$(4,128)	$ 14,122	$ 1,128	$ 15,251

* 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.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in millions)
(Unaudited)

	Six months ended June 30,	
	2019	**2018**
Operating activities:		
Net income (loss)	$ (768)	$ 968
Adjustments to reconcile net income (loss) to net cash provided by operations:		
Net change in operating assets and liabilities	(1,056)	(1,268)
Impairment of long-lived assets	1,097	980
Depreciation and amortization	893	986
Deferred income taxes – net and uncertain tax positions	(362)	(489)
Stock-based compensation	64	77
Other items	11	44
Net gain from sale of long-lived assets and investments	6	(88)
Goodwill impairment	—	300
Impairment of equity investment	—	94
In process Research and development	—	54
Net cash provided by (used in) operating activities	(115)	1,658
Investing activities:		
Beneficial interest collected in exchange for securitized trade receivables	746	970
Purchases of property, plant and equipment	(237)	(299)
Proceeds from sales of business, investments and long-lived assets	134	841
Other investing activities	59	(11)
Purchases of investments and other assets	(1)	(56)
Net cash provided by investing activities	701	1,445
Financing activities:		
Repayment of senior notes and loans and other long-term liabilities	(157)	(6,289)
Tax withholding payments made on shares and dividends	(52)	(22)
Other financing activities	(13)	(10)
Net change in short-term debt	(2)	(261)
Proceeds from senior notes and loans, net of issuance costs	—	4,435
Net cash used in financing activities	(224)	(2,147)
Translation adjustment on cash and cash equivalents	21	(58)
Net change in cash and cash equivalents	383	898
Balance of cash and cash equivalents at beginning of period	1,782	963
Balance of cash and cash equivalents at end of period	$2,165	$1,861
Non-cash financing and investing activities:		
Beneficial interest obtained in exchange for securitized trade receivables	$ 770	$ 968

Amounts may not add up due to rounding.
The accompanying notes are an integral part of the financial statements.

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 six months ended June 30, 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 have material impact on 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, the Company's accounting for finance leases remained substantially unchanged. See note 20 for further discussion.

Recently issued accounting pronouncements, not yet adopted

In April 2019, the FASB issued ASU 2019-04 "Codification Improvements to Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Financial Instruments (Topic 825)." This ASU provides clarifications for three topics related to financial instruments accounting. The guidance will be effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

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.

Reclassifications of prior periods

During the fourth quarter of 2018, the Company changed its accounting policy for the presentation of royalty payments to third parties that are not involved in the production of products. Teva previously accounted for royalty payments to such third parties as S&M expenses. Royalties paid to a party that is involved in the production process are classified as cost of sales. The Company believes this change in accounting policy is preferable in order to be aligned with industry practice of classifying all royalty payments related to currently marketed products in cost of sales. The Company now reports all royalty payments as cost of sales. The Company has retrospectively adjusted prior periods to reflect this change and the impact of the change for the first and second quarters of 2018 was an increase in cost of sales of $33 million and $28 million, respectively, with a corresponding decrease in S&M expenses.

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.

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 June 30, 2019 and December 31, 2018:

	June 30, 2019	December 31, 2018
	(U.S. $ in millions)	
Property, plant and equipment, net	$ 30	$ 92
Goodwill	—	51
Adjustments of assets held for sale to fair value	(6)	(51)
Total assets of the disposal group classified as held for sale in the consolidated balance sheets	$ 24	$ 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 United Kingdom.

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 United States 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.

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 U.S. Food and Drug Administration ("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.

NOTE 4 – Inventories:

Inventories, net of reserves, consisted of the following:

	June 30, 2019	December 31, 2018
	(U.S. $ in millions)	
Finished products	$2,643	$ 2,665
Raw and packaging materials	1,393	1,328
Products in process	638	590
Materials in transit and payments on account	176	148
Total	$4,850	$ 4,731

NOTE 5 – Property, plant and equipment:

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

	June 30, 2019	December 31, 2018
	(U.S. $ in millions)	
Machinery and equipment	$ 5,713	$ 5,691
Buildings	3,092	3,143
Computer equipment and other assets	2,129	2,097
Payments on account	526	514
Land	370	351
	11,830	11,796
Less—accumulated depreciation	(5,099)	(4,928)
Total	$ 6,732	$ 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	
	June 30, 2019	December 31, 2018	June 30, 2019	December 31, 2018	June 30, 2019	December 31, 2018
	(U.S. $ in millions)					
Product rights	$ 19,995	$ 20,361	$ 10,043	$ 9,565	$ 9,952	$ 10,796
Trade names	604	606	109	91	496	515
In process research and development	1,988	2,694	—	—	1,988	2,694
Total	$22,587	$ 23,661	$10,152	$ 9,656	$12,435	$ 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 $285 million and $302 million in the three months ended June 30, 2019 and 2018, respectively.

Amortization of intangible assets amounted to $568 million and $612 million in the six months ended June 30, 2019 and 2018, respectively.

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) – $1,730 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 three months ended June 30, 2019, Teva reclassified $19 million of products from IPR&D to product rights following regulatory approval.

In the first six months of 2019, Teva reclassified $256 million of products from IPR&D to product rights following regulatory approval, mainly $174 million in connection with methylphenidate ER.

Intangible assets impairment

Impairments of long-lived intangible assets for the three months ended on June 30, 2019 and 2018 were $561 million and $521 million, respectively. Impairments in the second quarter of 2019 consisted of:

a) Identifiable product rights of $365 million, mainly due to updated market assumptions regarding price and volume of products acquired from Actavis Generics and primarily marketed in the United States.

b) IPR&D assets of $196 million, mainly due to: (i) $137 million of generic pipeline 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) in the United States and (ii) $59 million related to a change in the assumption of the future market share of few products within Teva's Actavis Generics related pipeline in Europe.

Impairments of long-lived intangible assets for the six months ended on June 30, 2019 and 2018 were $1,030 million and $727 million, respectively. Impairments in the first six months of 2019 consisted of:

a) Identifiable product rights of $569 million, mainly due to updated market assumptions regarding price and volume of products acquired from Actavis Generics and primarily marketed in the United States.

b) IPR&D assets of $461 million, due to: (i) $277 million of generic pipeline 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) in the United States and (ii) $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 (iii) $59 million related to a change in the assumption of the future market share of few products within Teva's Actavis Generics related pipeline in Europe.

NOTE 7 – Goodwill:

The changes in the carrying amount of goodwill for the period ended June 30, 2019 were as follows:

	North America	Europe	International Markets	Other	Total
	(U.S. $ in millions)				
Balance as of January 1, 2019 (1)	$11,098	$8,653	$ 2,479	$2,687	$24,917
Changes during the period:					
Goodwill disposal	(23)	(5)	—	—	(28)
Goodwill adjustments	(13)	—	—	—	(13)
Translation differences	16	(32)	53	—	37
Balance as of June 30, 2019 (1)	$11,078	$8,616	$ 2,532	$2,687	$24,913

(1) Accumulated goodwill impairment as of June 30, 2019 and January 1, 2019 was approximately $21.0 billion.

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. 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 believed that its fair value assessment was reasonably supported by Teva's market capitalization. Based on this assessment, management concluded that it was not more likely than not that the fair value of any of the reporting units was below its carrying value as of March 31, 2019 and, therefore, no quantitative assessments were performed.

In the second quarter of 2019, the Company completed its long-range planning ("LRP") process. The LRP is part of Teva's internal financial planning and budgeting processes and is discussed and reviewed by Teva's management and its board of directors. Certain events and changes in circumstances, reflected in the LRP, indicated that it was more likely than not that the carrying value of certain reporting units may exceed their fair value. The following analysis was performed based upon the June 30, 2019 assessment:

International Markets

Management noted a further decrease in the profitability projections in the Japanese market related to new price regulation and further generic competition. Consequently, management conducted a quantitative analysis to its International Markets reporting unit, which resulted in no impairment.

The percentage difference between estimated fair value and estimated carrying value for the International Markets reporting unit is 4%.

The Company used a terminal growth rate of 2.3% and a discount rate of 10.74%. If Teva holds all other assumptions constant, a reduction in the terminal value growth rate of 0.4% or an increase in discount rate of 0.3% would result in an impairment related to its International Markets reporting unit.

North America

Management believes that the sharp decline in the Company's share price, which commenced May 2019, was mainly a result of events related to increased publicity surrounding certain litigations in the United States. Management considered the sharp decline in share price as an indication that it was more likely than not that the carrying value of its North America reporting unit exceeded its fair value.

Consequently, management conducted a quantitative analysis to its North America reporting unit, which resulted in no impairment.

The percentage difference between estimated fair value and estimated carrying value for the North America reporting unit is 9%.

The Company used a terminal growth rate of 2.0% and a discount rate of 10.0%. If Teva holds all other assumptions constant, a reduction in the terminal value growth rate of 0.9% or an increase in discount rate of 0.6% would result in an impairment related to its North America reporting unit.

Remaining reporting units

After assessing the totality of relevant events and circumstances, Teva determined that it is not more likely than not that the fair value of its remaining reporting units is less than their carrying amount.

The percentage difference between estimated fair value and estimated carrying value for the Europe, Medis and TAPI reporting units is 22%, 45% and 15%, respectively.

Market Capitalization

Teva analyzed the aggregate fair value of its reporting units as compared to its market capitalization in order to assess the reasonableness of the results of its cash flow projections used for its goodwill impairment analysis.

During the second quarter of 2019, Teva noted its market capitalization was significantly below management's assessment of the aggregate fair value of its reporting units. Management analyzed the difference and the underlying factors:

- Based on research analysts' reports reviewed by management and responses from certain analysts to Teva's inquiries, management noted a gap in the sales projections of AJOVY in the Europe and International Markets reporting units. Management concluded that the majority of analysts do not focus on these markets in preparing their financial models and, as a result, have not attributed value to the launch potential in these reporting units. Management believes that its fair value assessment relies on more accurate information and therefore no adjustment was incorporated to the fair value.
- Management also noted a difference with regard to sales projections of AUSTEDO in North America resulting in higher fair value as analyzed by management compared to Teva's market capitalization. Management believes that it has more accurate information based on its knowledge of the market and its growth through the remainder of 2019 and therefore no adjustment was incorporated to the fair value.
- Management believes that the remaining difference in fair value is attributable to market concerns regarding certain litigation risks, namely from the opioid and price fixing litigations, and concern surrounding the company's cash flow and overall liquidity. Management believes that these concerns led to an acute reaction, which resulted in further decline in the share price. Although ultimately the outcome of the relevant cases will not be known in the near term, developments in these cases, likely to occur through the end of 2019, are expected to clarify the outlook with regards to the opioid litigation, which may result in a share price recovery. Consequently, management believes that this disparity results from a market value not reflective of the underlying fair value of its reporting units and therefore it would be inappropriate to record an impairment charge in the second quarter of 2019 related thereto.

Management will continue to monitor business conditions and potential events or circumstances that could have a negative effect on the estimated fair value of the Company.

Based on assumptions in place at this time, if Teva's share price does not recover in the near term, this may lead to a goodwill impairment charge of up to an aggregated amount of approximately $5,000 million in its North America and International Markets reporting units. Future impairment charges, if any, reflecting conditions at that time may be materially different.

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 June 30, 2019 and 2018, no account was taken of the potential dilution of 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, in the three months ended June 30, 2018, no account was taken of the potential dilution by the mandatory convertible preferred shares, amounting to 63 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.

In computing the diluted loss per share for the six months ended June 30, 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 six months ended June 30, 2018 take 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 six months ended June 30, 2018, no account was taken of the potential dilution by the mandatory convertible preferred shares, amounting to 65 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.

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 June 30, 2019				
	North America	Europe	International Markets	Other activities	Total
	(U.S. $ in millions)				
Sale of goods	1,686	1,173	526	204	3,588
Licensing arrangements	35	10	2	1	48
Distribution	351	§	164	—	515
Other	—	§	49	137	186
	$ 2,071	$1,183	$ 741	$ 342	4,337

§ Represents an amount less than $1 million.

	Three months ended June 30, 2018				
	North America	Europe	International Markets	Other activities	Total
	(U.S. $ in millions)				
Sale of goods	1,913	1,317	573	186	3,989
Licensing arrangements	30	8	1	2	41
Distribution	320	3	154	—	477
Other	—	—	61	133	194
	$ 2,263	$1,328	$ 789	$ 321	$4,701

	Six months ended June 30, 2019				
	North America	Europe	International Markets	Other activities	Total
	(U.S. $ in millions)				
Sale of goods	3,324	2,433	994	390	7,141
Licensing arrangements	65	15	2	3	85
Distribution	729	§	315	—	1,044
Other	—	§	97	264	362
	$ 4,118	$2,448	$ 1,409	$ 657	$8,632

§ Represents an amount less than $1 million.

	Six months ended June 30, 2018				
	North America	Europe	International Markets	Other activities	Total
	(U.S. $ in millions)				
Sale of goods	4,081	2,746	1,092	365	8,284
Licensing arrangements	62	18	21	4	105
Distribution	651	6	307	—	964
Other	—	—	119	294	413
	$ 4,794	$2,770	$ 1,539	$ 663	$9,766

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 June 30, 2019, with the remaining balance primarily in Canada and Germany. The changes in SR&A for third-party sales for the six months ended June 30, 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 SR&A	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	229	2,651	548	4,822	148	213	8,427	8,656
Provisions related to sales made in prior periods	—	7	—	(5)	3	(4)	1	1
Credits and payments	(242)	(2,975)	(739)	(4,936)	(196)	(206)	(9,052)	(9,294)
Translation differences	—	4	—	2	2	4	12	12
Balance at June 30, 2019	$ 162	$ 2,693	$ 1,170	$ 1,413	$ 595	$ 183	$ 6,054	$ 6,261

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	(495)	—	42	—	(453)
Amounts reclassified to the statements of income	—	(1)	14	1	14
Net other comprehensive income (loss) before tax	(495)	(1)	56	1	(439)
Corresponding income tax	—	—	—	(2)	(2)
Net other comprehensive income (loss) after tax**	(495)	(1)	56	(1)	(441)
Balance as of June 30, 2018	$ (1,811)	$ —	$ (386)	$ (92)	$(2,289)

* 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 $23 million gain from foreign currency translation adjustments attributable to non-controlling interests.

	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, 2018	$ (2,055)	$ 1	$ (327)	$ (78)	$(2,459)
Other comprehensive income (loss) before reclassifications	111	—	22	—	133
Amounts reclassified to the statements of income	—	—	15	—	15
Net other comprehensive income (loss) before tax	111	—	37	—	148
Corresponding income tax	—	—	—	(1)	(1)
Net other comprehensive income (loss) after tax*	111	—	37	(1)	147
Balance as of June 30, 2019	$ (1,944)	$ 1	$ (290)	$ (79)	$(2,312)

* Amounts do not include a $24 million gain from foreign currency translation adjustments attributable to non-controlling interests.

NOTE 11 – Debt obligations:

a. Short-term debt:

	Weighted average interest rate as of June 30, 2019	Maturity	June 30, 2019	December 31, 2018
			(U.S. $ in millions)	
Bank and financial institutions	4.25%	—	$ 1	$ 2
Convertible debentures	0.25%	2026	514	514
Current maturities of long-term liabilities			2,256	1,700
Total short-term debt			$2,771	$ 2,216

Long-term debt:

	Weighted average interest rate as of June 30, 2019	Maturity	June 30, 2019	December 31, 2018
			(U.S. $ in millions)	
Senior notes EUR 1,660 million	0.38%	2020	$ 1,886	$ 1,897
Senior notes EUR 1,500 million	1.13%	2024	1,697	1,707
Senior notes EUR 1,300 million	1.25%	2023	1,472	1,480
Senior notes EUR 900 million	4.50%	2025	1,023	1,029
Senior notes EUR 750 million	1.63%	2028	846	850
Senior notes EUR 700 million	3.25%	2022	796	801
Senior notes EUR 700 million	1.88%	2027	794	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 1,556 million (1)	1.70%	2019	1,556	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	858	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	619	621
Senior notes USD 588 million	3.65%	2021	587	587
Senior notes CHF 350 million	0.50%	2022	359	356
Senior notes CHF 350 million	1.00%	2025	359	356
Fair value hedge accounting adjustments			9	(9)
Total senior notes			28,313	28,483
Other long-term debt	1.15%	2026	1	12
Less current maturities			(2,256)	(1,700)
Derivative instruments			(9)	9
Less debt issuance costs			(94)	(104)
Total senior notes and loans			$25,955	$ 26,700

(1) During the first six months of 2019, Teva repurchased and canceled approximately $144 million principal amount of its $1,700 million 1.7% senior notes due in July 2019. In July 2019, Teva repaid at maturity $1,556 million of its 1.7% senior notes.

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, if any.

Long-term debt as of June 30, 2019 is effectively denominated (taking into consideration cross currency swap agreements) in the following currencies: U.S. dollar 62%, euro 35% and Swiss franc 3%.

Teva's principal sources of short-term liquidity are its cash on hand, 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 RCF, 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 the requirement to maintain compliance with a net debt to EBITDA ratio, which becomes more restrictive over time. The net debt to EBITDA ratio limit is 6.25x through December 31, 2019, gradually declines to 5.75x in the third and fourth quarters of 2020, and continues to gradually decline over the remaining term of the RCF.

The RCF can be used for general corporate purposes, including repaying existing debt. As of June 30, 2019, no amounts were outstanding under the RCF. As of the date of this report, $500 million was outstanding under the RCF. Based on current and forecasted results, the Company expects that it will not exceed the financial covenant thresholds set forth in the RCF within one year from the date that these financial statements are issued.

Under specified circumstances, including non-compliance with any of the covenants described above and the unavailability of any waiver, amendment or other modification thereto, the Company will not be able to borrow under the RCF. Additionally, violations of the covenants, under the above-mentioned circumstances, would result in an event of default in all borrowings under the RCF and, when greater than a specified threshold amount as set forth in each series of senior notes is outstanding, could lead to an event of default under the Company's senior notes due to cross acceleration provisions.

Teva expects that it will continue to have sufficient cash resources to support its debt service payments and all other financial obligations within one year from the date that these financial statements are issued.

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 six months of 2019.

Financial items carried at fair value as of June 30, 2019 and December 31, 2018 are classified in the tables below in one of the three categories described above:

	June 30, 2019			
	Level 1	Level 2	Level 3	Total
	(U.S. $ in millions)			
Cash and cash equivalents:				
Money markets	$ 401	$ —	$ —	$ 401
Cash, deposits and other	1,764	—	—	1,764
Investment in securities:				
Equity securities	48	—	—	48
Other, mainly debt securities	5	—	13	18
Derivatives:				
Asset derivatives—options and forward contracts	—	14	—	14
Asset derivatives—interest rate and cross-currency swaps		85	—	85
Liability derivatives—options and forward contracts	—	(55)	—	(55)
Liability derivatives—interest rate and cross-currency swaps	—	(37)	—	(37)
Contingent consideration*	—	—	(403)	(403)
Total	$2,218	$ 7	$ (390)	$1,835

	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—interest rate and cross-currency swaps	—	58	—	58
Liability derivatives—options and forward contracts	—	(26)	—	(26)
Liability 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 United States 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:

	Six months ended June 30, 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	101
Eagle transaction	(54)
Settlement of contingent consideration:	
Eagle transaction	57
Fair value at the end of the period	$ (390)

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:

	Fair value*	
	June 30, 2019	December 31, 2018
	(U.S. $ in millions)	
Senior notes included under senior notes and loans	$22,770	$ 23,560
Senior notes and convertible senior debentures included under short-term debt	2,719	2,140
Total	$25,489	$ 25,700

* The fair value was based on quoted market price.

NOTE 13 – Derivative instruments and hedging activities:

a. Foreign exchange risk management:

In the first six months 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.

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:

	June 30, 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	
Reported under	June 30, 2019	December 31, 2018	June 30, 2019	December 31, 2018
	(U.S. $ in millions)			
Asset derivatives:				
Other current assets:				
Option and forward contracts	$ —	$ —	$ 14	$ 18
Other non-current assets:				
Cross-currency swaps—cash flow hedge	76	58	—	—
Senior notes and loans:				
Interest rate swaps—fair value hedge	9	—	—	—
Liability derivatives:				
Other current liabilities:				
Option and forward contracts	—	—	(55)	(26)
Cross-currency swaps—net investment hedge	(37)	—	—	—
Other taxes and long-term liabilities:				
Cross-currency swaps—net investment hedge	—	(41)	—	—
Senior notes and loans:				
Interest rate swaps—fair value hedge	—	(9)	—	—

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

	Financial expenses, net		Other comprehensive income	
	Three month ended,		Three month ended,	
Reported under	June 30, 2019	June 30, 2018**	June 30, 2019	June 30, 2018**
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	$ 206	$ 236	$ (76)	$ 614
Cross-currency swaps—cash flow hedge (1)	(1)	*	4	(28)
Cross-currency swaps—net investment hedge (2)	(7)	(9)	14	(59)
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.

Reported under	Financial expenses, net Six month ended, June 30, 2019	Financial expenses, net Six month ended, June 30, 2018**	Other comprehensive income Six month ended, June 30, 2019	Other comprehensive income Six month ended, June 30, 2018**
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	$ 425	$ 507	$ (170)	$ 418
Cross-currency swaps—cash flow hedge (1)	(1)	(1)	(15)	(11)
Cross-currency swaps—net investment hedge (2)	(15)	(16)	(6)	(29)
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 pre-tax (gains) losses from derivatives not designated as hedging instruments:

Reported under	Financial expenses, net Three month ended, June 30, 2019	Financial expenses, net Three month ended, June 30, 2018	Net revenues Three month ended, June 30, 2019	Net revenues Three month ended, June 30, 2018
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	$ 206	$ 236	$ (4,337)	$ (4,701)
Option and forward contracts (4)	34	(24)	—	—
Option and forward contracts Economic hedge	—	—	4	(1)

Reported under	Financial expenses, net Six month ended, June 30, 2019	Financial expenses, net Six month ended, June 30, 2018	Net revenues Six month ended, June 30, 2019	Net revenues Six month ended, June 30, 2018
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	$ 425	$ 507	$ (8,632)	$ (9,766)
Option and forward contracts (4)	(7)	(5)	—	—
Option and forward contracts Economic hedge	—	—	4	(1)

(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 accumulated other comprehensive income 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).

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 June 30, 2019 and 2018, and losses of $15 million and $14 million were recognized under financial expenses, net for the six months ended June 30, 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 June 30, 2019 and 2018, and gains of $3 million were recognized under financial expenses, net for the six months ended June 30, 2019 and 2018.

NOTE 14 – Other assets impairments, restructuring and other items:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	(U.S. $ in millions)			
Impairments of long-lived tangible assets (1)	$ 48	$ 27	$ 68	$ 253
Contingent consideration	24	47	(47)	55
Restructuring	47	107	79	354
Other	(18)	13	3	33
Total	$ 101	$ 194	$ 103	$ 695

(1) Including impairments related to exit and disposal activities

Impairments

Impairments of property, plant and equipment for the three months ended on June 30, 2019 and 2018 were $48 million and $27 million, respectively.

Impairments of property, plant and equipment for the six months ended on June 30, 2019 and 2018 were $68 million and $253 million, respectively.

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 June 30, 2019, Teva recorded an expense of $24 million for contingent consideration, compared to an expense of $47 million in the three months ended June 30, 2018. The expenses in the second quarter of 2019 mainly related to an increase in the expected future royalty payments to Eagle Pharmaceuticals, Inc. due to the orphan drug status granted to BENDEKA and the expected royalty payments in connection with lenalidomide (generic equivalent of Revlimid®) which was part of the Actavis acquisition.

In the six months ended June 30, 2019, Teva recorded $47 million of contingent consideration income, compared to $55 million expense in the six months ended June 30, 2018. The income in the first six months 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.

Restructuring

In the three months ended June 30, 2019, Teva recorded $47 million of restructuring expenses, compared to $107 million in the three months ended June 30, 2018.

In the six months ended June 30, 2019, Teva recorded $79 million of restructuring expenses, compared to $354 million in the six months ended June 30, 2018.

Since the announcement of its restructuring plan, Teva reduced its global headcount by approximately 11,145 full-time-equivalent employees.

During the three months ended June 30, 2019 and 2018, Teva recorded impairments of property, plant and equipment related to restructuring costs of $21 million and $8 million, respectively.

During the six months ended June 30, 2019 and 2018, Teva recorded impairments of property, plant and equipment related to restructuring costs of $21 million and $155 million, respectively.

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 June 30,	
	2019	2018
	(U.S. $ in millions)	
Restructuring		
Employee termination	$ 36	$ 90
Other	11	17
Total	$ 47	$ 107

	Six months ended June 30,	
	2019	2018
	(U.S. $ in millions)	
Restructuring		
Employee termination	$ 56	$ 318
Other	23	36
Total	$ 79	$ 354

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	(56)	(23)	(79)
Utilization and other*	67	45	112
Balance as of June 30, 2019	$ (193)	$ (7)	$(200)

* 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 $142 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 as of June 30, 2019 on Teva's financial statements was $55 million, primarily related to inventory reserves and returns. 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.

NOTE 15 – Legal settlements and loss contingencies:

In the second quarter of 2019, Teva recorded an expense of $646 million in legal settlements and loss contingencies, compared to $20 million in the second quarter of 2018. The expense in the second quarter of 2019 was mainly related to the $85 million settlement paid in the opioid litigation brought by the Oklahoma Attorney General and an estimated provision made for certain other opioid cases.

In the first six months of 2019, Teva recorded an expense of $703 million in legal settlements and loss contingencies, compared to income of $1,258 million in the first six months of 2018. The expense in the first six months of 2019 was mainly related to the $85 million settlement paid in the opioid litigation brought by the Oklahoma Attorney General and an estimated provision made for certain other opioid cases.

As of June 30, 2019 and December 31, 2018, Teva's provision for legal settlements and loss contingencies recorded under accrued expenses was $1,149 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.

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. A hearing is scheduled for September 4, 2019. 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, and oral argument in that appeal is scheduled for September 9, 2019. 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 U.S. District Court for the District 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 U.S. 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 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 District Court for the District of New Jersey also found the patent to be invalid. Teva launched its generic 250mg product in November 2018. On May 14, 2019, the U.S. Court of Appeals affirmed that Janssen's patent is invalid. That decision became final on June 20, 2019. Janssen may seek U.S. Supreme Court review of this decision. 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.

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 U.S. 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 reached a settlement with 48 state attorneys general, which was approved by the court on November 7, 2016, and on July 23, 2019, reached a settlement with the State of California, which is pending court approval.

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 Modafinil 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 U.S. 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 U.S. Court of Appeals for 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 appeals court granted the defendants' petition for immediate appellate review and the district court has stayed the litigation pending the outcome of the 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.

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. On July 23, 2019 Teva and the State of California reached a settlement agreement.

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 U.S. Court of Appeals for 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.

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. 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.

In January 2019, generic manufacturer Cipla Limited filed a lawsuit against Amgen in Delaware federal court, alleging, among other things, that a January 2, 2019 settlement agreement between Amgen and Teva, resolving patent litigation over cinacalcet (generic Sensipar®), violated the antitrust laws. In March 2019, Cipla Limited amended its complaint to name Teva as an additional defendant, and putative classes of direct-purchaser and end-payer plaintiffs have also filed antitrust lawsuits in U.S. federal district court against Amgen and Teva related to the January 2, 2019 settlement. Both Cipla Limited and the putative class plaintiffs seek damages and injunctive relief. Annual sales of Sensipar® in the United States were approximately $1.4 billion at the time Teva launched its generic version of Sensipar® in December 2018, and at the time of the January 2, 2019 settlement.

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 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.

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. Trial is scheduled to commence on August 19, 2019 and a provision was included in the financial statements.

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 2,000 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 (including various putative class actions of individuals) 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, approximately 350 complaints 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 and certain plaintiffs specify multiple billions of dollars in the aggregate as alleged damages. In many of these cases, plaintiffs are seeking joint and several damages among all defendants. An adverse resolution of any of these lawsuits or investigations may involve large monetary penalties, damages, and/or other forms of monetary and non-monetary relief and could have a material and adverse effect on Teva's reputation, business, results of operations and cash flows. 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 overruled defendants' objections to the Report & Recommendation. 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. On June 13, 2019, the District Court adopted the two Report & Recommendations in all respects except those regarding the plaintiffs' negligence per se claims, for which the District Court overruled the Report & Recommendation and held that Plaintiffs cannot state a claim for negligence per se pursuant to the statutes that the plaintiffs identified. Motions to dismiss in additional similar cases remain pending. Discovery in the MDL Opioid Proceeding for the first track of cases is closed and motions for summary judgment were filed in June 2019. Trial is scheduled for October 2019. Other cases remain pending in various states. In some jurisdictions, such as Illinois, New York, Pennsylvania, South Carolina, Texas and Utah, certain state court cases have been transferred to a single court within their respective state court systems for coordinated pretrial proceedings. Trials are expected to proceed in several states in 2020. In May 2019, Teva settled the Oklahoma litigation brought by the Oklahoma Attorney General (State of Oklahoma, ex. rel. Mike Hunter, Attorney General of Oklahoma vs. Purdue Pharma L.P., et. al.) for $85 million. The settlement did not include any admission of violation of law for any of the claims or allegations made. Management believes that the Oklahoma settlement amount is not likely indicative of the settlement of the other opioid-related litigation due to a variety of distinguishing factors. There is a wide range of potential outcomes given the state governments, subdivisions and other private party suits have made claims for large recoveries, the breadth of the litigation, novel legal theories and numerous defenses raised versus Teva's willingness to potentially settle for a small fraction of such claimed amounts. As the Company demonstrated a willingness to settle part of the litigation, for accounting purposes, management considered a portion of opioid-related cases as probable and, as such, recorded an estimated provision. Given the relatively early status of the cases, management viewed no amount within the range to be the most likely outcome. Therefore, management recorded a provision for the reasonably estimable minimum amount in the assessed range for such opioid-related cases in accordance with Accounting Standards Codification 450 "Accounting for Contingencies." 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.

In addition, several jurisdictions in Canada have initiated litigation regarding opioids alleging similar claims as those in the United States. The cases in Canada are likely to be consolidated and are in their early stages.

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. That complaint was later amended to add new states as named plaintiffs, as well as new allegations and new state law claims, and on June 18, 2018, the attorneys general of 49 states plus Puerto Rico and the District of Columbia filed a consolidated amended complaint against Actavis and Teva, as well as other companies and individuals. On May 10, 2019, most (though not all) of these same attorneys general filed yet another antitrust complaint against Actavis and Teva, plus other companies and individuals, alleging price-fixing and market allocation as concerns additional generic products. The complaint alleges that Teva was at the center of a conspiracy in the generic pharmaceutical industry, and asserts that Teva and others fixed prices, rigged bids, and allocated customers and market share with respect to certain additional products, many of which were not previously at issue in the Pennsylvania MDL. In the various complaints described above, 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. All such complaints have been transferred to the generic drug multidistrict litigation in the Eastern District of Pennsylvania ("Pennsylvania MDL").

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. 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.

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. The 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 June 2019, fourteen 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. On June 21, 2019, the Employees' Retirement System of the City of St. Petersburg, Florida filed a putative securities class action in the U.S. District Court for the Eastern District of Pennsylvania purportedly on behalf of purchasers of Teva's securities between August 4, 2017 and May 10, 2019 seeking unspecified damages, legal fees, interest, and costs. The complaint alleges similar claims to 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 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.

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.

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 June 30, 2019		
	North America	Europe	International Markets
	(U.S. $ in millions)		
Revenues	$ 2,071	$1,183	$ 741
Gross profit	1,067	674	312
R&D expenses	175	70	24
S&M expenses	269	216	119
G&A expenses	117	70	34
Other (income) expense	2	1	(1)
Segment profit	$ 504	$ 316	$ 136

	Three months ended June 30, 2018		
	North America	Europe	International Markets
	(U.S. $ in millions)		
Revenues	$ 2,263	$1,328	$ 789
Gross profit	1,179	727	328
R&D expenses	182	73	25
S&M expenses	272	233	130
G&A expenses	103	78	37
Other (income) expense	(100)	(3)	(3)
Segment profit	$ 722	$ 346	$ 139

	Six months ended June 30, 2019		
	North America	Europe	International Markets
	(U.S. $ in millions)		
Revenues	$ 4,118	$2,448	$ 1,409
Gross profit	2,107	1,404	582
R&D expenses	340	136	46
S&M expenses	537	431	234
G&A expenses	230	119	70
Other (income) expense	(2)	(1)	(1)
Segment profit	$ 1,001	$ 719	$ 233

	Six months ended June 30, 2018		
	North America	Europe	International Markets
	(U.S. $ in millions)		
Revenues	$ 4,794	$2,770	$ 1,539
Gross profit	2,582	1,519	641
R&D expenses	370	146	49
S&M expenses	548	483	264
G&A expenses	229	169	78
Other (income) expense	(202)	(2)	(11)
Segment profit	$ 1,637	$ 723	$ 261

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	(U.S. $ in millions)		(U.S. $ in millions)	
North America profit	$ 504	$ 722	$1,001	$ 1,637
Europe profit	316	346	719	723
International Markets profit	136	139	233	261
Total segment profit	956	1,207	1,954	2,621
Profit of other activities	55	31	76	52
	1,011	1,238	2,029	2,673
Amounts not allocated to segments:				
Amortization	285	302	568	612
Other assets impairments, restructuring and other items	101	194	103	695
Goodwill impairment	—	120	—	300
Intangible asset impairments	561	521	1,030	727
(Gain) loss on divestitures, net of divestitures related costs	(9)	10	(9)	(83)
Other R&D expenses	§	—	§	22
Costs related to regulatory actions taken in facilities	12	4	16	5
Legal settlements and loss contingencies	646	20	703	(1,258)
Other unallocated amounts	59	81	129	142
Consolidated operating income (loss)	(644)	(14)	(510)	1,511
Financial expenses, net	206	236	425	507
Consolidated income (loss) before income taxes	$ (850)	$ (250)	$ (934)	$ 1,004

§ Represents an amount less than $1 million.

b. Segment revenues by major products and activities:

The following tables present revenues by major products and activities for the three months and the six months ended June 30, 2019 and 2018:

	Three months ended June 30,	
	2019	2018
	(U.S. $ in millions)	
North America		
Generic products	$ 946	$ 947
COPAXONE	274	464
TREANDA/BENDEKA	115	160
ProAir*	65	115
QVAR	60	30
AJOVY	23	—
AUSTEDO	96	44
Anda	351	320
Other	141	183
Total	$ 2,071	$ 2,263

* Does not include sales of ProAir authorized generic, which are included under generics.

	Six months ended June 30,	
	2019	2018
	(U.S. $ in millions)	
North America		
Generic products	$1,913	$2,035
COPAXONE	482	940
TREANDA/BENDEKA	229	341
ProAir*	123	245
QVAR	124	137
AJOVY	43	—
AUSTEDO	171	74
Anda	729	651
Other	305	372
Total	$4,118	$4,794

* Does not include sales of ProAir authorized generic, which are included under generics.

	Three months ended June 30,	
	2019	2018
	(U.S. $ in millions)	
Europe		
Generic products	$ 844	$ 907
COPAXONE	107	140
Respiratory products	89	106
Other	143	175
Total	$ 1,183	$ 1,328

	Six months ended June 30,	
	2019	2018
	(U.S. $ in millions)	
Europe		
Generic products	$ 1,763	$ 1,904
COPAXONE	221	293
Respiratory products	181	219
Other	283	354
Total	$ 2,448	$ 2,770

	Three months ended June 30,	
	2019	2018
	(U.S. $ in millions)	
International markets		
Generic products	$ 489	$ 537
COPAXONE	13	22
Distribution	164	154
Other	75	76
Total	$ 741	$ 789

	Six months ended June 30,	
	2019	2018
	(U.S. $ in millions)	
International markets		
Generic products	$ 930	$ 1,025
COPAXONE	27	38
Distribution	315	307
Other	137	168
Total	$ 1,409	$ 1,539

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 June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	(U.S. $ in millions)		(U.S. $ in millions)	
Gain (loss) on divestitures, net of divestitures related costs (1)	$ 9	(10)	$ 9	83
Section 8 and similar payments (2)	—	95	—	194
Gain (loss) on sale of assets	(5)	1	(4)	9
Other, net	5	10	11	13
Total other income	$ 9	$ 96	$ 15	$ 299

(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.

NOTE 19 – Income taxes:

In the second quarter of 2019, Teva recognized a tax benefit of $179 million, or 21%, on pre-tax loss of $850 million. In the second quarter of 2018, Teva recognized a tax benefit of $76 million, or 30%, on pre-tax loss of $250 million. Teva's tax rate for the second quarter of 2019 was mainly affected by impairments, amortization and interest disallowance as a result of the U.S. Tax Cuts and Jobs Act.

In the first six months of 2019, Teva recognized a tax benefit of $170 million, or 18%, on pre-tax loss of $934 million. In the first six months of 2018, Teva recognized a tax benefit of $30 million on pre-tax income of $1,004 million. Teva's tax rate for the first six months 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 six months ended June 30, 2018 and the 12 months ended December 31, 2018, was $90 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.

Some of Teva's 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 operating lease cost for the three months ended and six months ended June 30, 2019 were as follows:

	Three months ended June 30, 2019	Six months ended June 30, 2019
	(U.S. $ in millions)	
Operating lease cost:		
Fixed payments and variable payments that depend on an index or rate	$ 36	$ 78
Variable lease payments not included in the lease liability	2	4
Short-term lease cost	1	3
Total operating lease cost	$ 39	$ 85

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

	Six months ended June 30, 2019
	(U.S. $ in millions)
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 79
Right-of-use assets obtained in exchange for lease obligations (non-cash):	
Operating leases	$ 46

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

	June 30, 2019
	(U.S. $ in millions)
Operating leases:	
Operating lease ROU assets	$ 500
Other current liabilities	120
Operating lease liabilities	426
Total operating lease liabilities	$ 546

	June 30, 2019
Weighted average remaining lease term	
Operating leases	7.7 years
Weighted average discount rate	
Operating leases	5.9%

Maturities of operating lease liabilities were as follows:

	June 30, 2019
	(U.S. $ in millions)
2019 (excluding the six months ended June 30, 2019)	$ 87
2020	124
2021	100
2022	78
2023	58
2024 and thereafter	266
Total operating lease payments	$ 713
Less: imputed interest	167
Present value of lease liabilities	$ 546

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

As of June 30, 2019, Teva has additional operating leases for office space, which have yet to commence, with undiscounted future payments of $94 million. These operating leases will commence during fiscal year 2020 with lease terms of 9 to 12 years.

As of June 30, 2019, Teva's total finance lease assets and finance lease liabilities are $78 million and $27 million, respectively. The difference between those amounts is mainly due to prepaid payments.

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 second quarter of 2019 included:

- Revenues in the second quarter of 2019 were $4,337 million, a decrease of 8%, or 5% in local currency terms, compared to the second quarter of 2018, mainly due to generic competition to COPAXONE®, as well as declines in revenues from TREANDA®/BENDEKA®, certain other specialty products in the United States, our Europe segment and Japan, partially offset by higher revenues from AUSTEDO®, AJOVY® and QVAR® in the United States.
- Our North America segment generated revenues of $2,071 million and profit of $504 million in the second quarter of 2019. Revenues decreased by 8% compared to the second quarter of 2018, mainly due to a decline in revenues from COPAXONE, TREANDA/BENDEKA and certain other specialty products, partially offset by higher revenues from our Anda business, QVAR, AUSTEDO and AJOVY. Profit decreased by 30%, mainly due to the changes in revenues described above and the non-recurrence of other income, as well as cost reductions and efficiency measures as part of the restructuring plan.
- Our Europe segment generated revenues of $1,183 million and profit of $316 million in the second quarter of 2019. Revenues decreased by 11%, or 5% in local currency terms, compared to the second quarter of 2018, mainly due to a decline in COPAXONE revenues due to the entry of competing glatiramer acetate products and the termination of the PGT joint venture, partially offset by new generic product launches. Profit decreased by 9%, mainly due to the changes in revenues and the impact of currency fluctuations, partially offset by cost reductions and efficiency measures as part of the restructuring plan.
- Our International Markets segment generated revenues of $741 million and profit of $136 million in the second quarter of 2019. Revenues decreased by 6%, or 2% in local currency terms, and profit decreased by 2% compared to the second quarter of 2018. The decrease in revenues and profit was mainly due to lower sales in Japan resulting from 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.
- Intangible asset impairments were $561 million in the second quarter of 2019, compared to $521 million in the second quarter of 2018. The impairment expenses in the second quarter of 2019 were related to identifiable product rights of $365 million and IPR&D assets of $196 million. The impairments were mainly related to products acquired from Actavis Generics.
- Operating loss was $644 million in the second quarter of 2019, compared to $14 million in the second quarter of 2018. The increase in operating loss was mainly due to lower profit from our operating segments and an increase in legal settlements and loss contingencies expenses.
- Exchange rate movements between the second quarter of 2019 and the second quarter of 2018 negatively impacted revenues by $125 million and operating income by $41 million.

- As of June 30, 2019, our debt was $28,726 million, compared to $28,624 million as of March 31, 2019. The increase was mainly due to exchange rates fluctuations.
- Cash flow used in operating activities during the second quarter of 2019 was $227 million, compared to cash flow generated from operating activities of $162 million in the second quarter of 2018. The decrease in cash flow in the second quarter of 2019 was mainly due to lower revenues, timing of certain customer payments and credits and payments of U.S. customer rebates paid this quarter, primarily related to managed care and Medicaid.
- Cash flow generated from operating activities in the second quarter of 2019, net of cash received for capital investments and beneficial interest collected in exchange for securitized trade receivables, was $168 million, compared to $559 million in the second quarter of 2018. The decrease in cash flow was mainly due to the reasons mentioned above.

Results of Operations

Comparison of Three Months Ended June 30, 2019 to Three Months Ended June 30, 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 June 30,		Percentage Change
	2019	2018	2019 - 2018
	%	%	%
Net revenues	100	100	(8)
Gross profit	44	43	(7)
Research and development expenses	6	6	(5)
Selling and marketing expenses	15	15	(2)
General and administrative expenses	7	7	(6)
Intangible assets impairment	13	11	8
Goodwill impairment	—	3	(100)
Other assets impairments, restructuring and other items	2	4	(48)
Legal settlements and loss contingencies	15	§	—
Other income	§	(2)	—
Operating income	(15)	§	—
Financial expenses, net	5	5	(13)
Income (loss) before income taxes	(20)	(5)	240
Income taxes	(4)	(2)	135
Share in losses (income) of associated companies, net	§	§	—
Net income attributable to non-controlling interests	§	§	—
Net income (loss) attributable to Teva	(16)	(4)	292
Dividends on preferred shares	—	1	(100)
Net income (loss) attributable to ordinary shareholders	(16)	(5)	186

§ 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 June 30, 2019 and 2018:

	Three months ended June 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 2,071	100.0%	$ 2,263	100.0%
Gross profit	1,067	51.5%	1,179	52.1%
R&D expenses	175	8.5%	182	8.0%
S&M expenses	269	13.0%	272	12.0%
G&A expenses	117	5.6%	103	4.6%
Other (income) expense	2	§	(100)	(4.4%)
Segment profit*	$ 504	24.3%	$ 722	31.9%

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

§ Represents an amount less than 0.5%.

North America Revenues

Our North America segment includes the United States and Canada. Revenues from our North America segment in the second quarter of 2019 were $2,071 million, a decrease of $192 million, or 8%, compared to the second quarter of 2018, mainly due to a decline in revenues of COPAXONE, TREANDA/BENDEKA and certain other specialty products, partially offset by higher revenues from our Anda business, QVAR, 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 June 30, 2019 and 2018:

	Three months ended June 30,		Percentage Change 2019-2018
	2019	2018	
	(U.S. $ in millions)		
Generic products	$ 946	$ 947	§
COPAXONE	274	464	(41%)
TREANDA/BENDEKA	115	160	(28%)
ProAir*	65	115	(44%)
QVAR	60	30	103%
AJOVY	23	—	NA
AUSTEDO	96	44	117%
Anda	351	320	10%
Other	141	183	(23%)
Total	$ 2,071	$ 2,263	(8%)

* Does not include sales of ProAir authorized generic, which are included under generics.

§ Represents an amount less than 0.5%.

Generic products revenues in our North America segment in the second quarter of 2019 were $946 million flat compared to the second quarter of 2018, mainly due to new generic product launches, offset by market dynamics, including product mix and price erosion in our U.S. generics business.

Among the most significant generic products we sold in North America in the second quarter of 2019 were epinephrine injection (the generic equivalent of EpiPen®), solifenacin succinate tablets (the generic equivalent of Vesicare®), albuterol sulfate inhalation aerosol (ProAir® HFA authorized generic of Teva's specialty product), amphetamine salt tablets (the generic equivalent of Adderall IR®), and lidocaine transdermal patch (the generic equivalent of Lidoderm Patch®).

In the second quarter of 2019, we led the U.S. generics market in total prescriptions and new prescriptions, with approximately 404 million total prescriptions (based on trailing twelve months), representing 11% of total U.S. generic prescriptions according to IQVIA data.

COPAXONE revenues in our North America segment in the second quarter of 2019 decreased by 41% to $274 million, compared to the second quarter of 2018, mainly due to generic competition in the United States.

COPAXONE revenues in the United States were $260 million in the second quarter of 2019.

Revenues of COPAXONE in our North America segment were 69% of global COPAXONE revenues in the second quarter of 2019, compared to 74% in the second quarter of 2018.

COPAXONE global sales accounted for approximately 9% of our global revenues in the second 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.

COPAXONE 40 mg/mL is protected by one European patent expiring in 2030. This patent is being challenged in various jurisdictions. In October 2017, the U.K. High Court found this patent invalid and our application for permission to appeal this decision was rejected. The patent was upheld by the Opposition Division of the European Patent Office in April 2019.

The market for MS treatments continues to develop, particularly with the 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.

BENDEKA and **TREANDA** combined revenues in our North America segment in the second quarter of 2019 decreased by 28% to $115 million, compared to the second 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, 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 United States 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 second quarter of 2019 decreased by 44% to $65 million, compared to the second 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 25.3% (45.8% including our ProAir HFA authorized generic) in terms of total number of prescriptions for albuterol inhalers during the second quarter of 2019, compared to 44.4% in the second quarter of 2018. In June 2014, we settled a patent challenge to ProAir HFA with Perrigo Pharmaceuticals ("Perrigo"), under which Perrigo is now permitted to launch its generic product. 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 second quarter of 2019 increased by 103% to $60 million, compared to the second quarter of 2018, which was a transition period due to the launch of QVAR® RediHaler™. QVAR maintained its second-place position in the inhaled corticosteroids category in the United States, with an exit market share of 20.2% in terms of total number of prescriptions during the second quarter of 2019, compared to 24.2% in the second quarter of 2018.

AJOVY revenues in our North America segment in the second quarter of 2019 were $23 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 is 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 U.S. 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, and as a result the litigation in the district court has been stayed pending resolution of the IPRs. 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 United Kingdom.

AUSTEDO revenues in our North America segment in the second quarter of 2019 increased by 117%, to $96 million, compared to $44 million in the second 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 10% to $351 million in the second quarter of 2019, compared to the second 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.

Product Launches and Pipeline

In the second 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))*
Fluoxetine tablets, USP 20 mg	—	April	$ 56
Testosterone gel, metered 1.62% CIII	AndroGel® 1.62% [CIII]	April	$ 755
Solifenacin succinate tablets, 5 mg & 10 mg	Vesicare®	April	$ 946
Ambrisentan tablets, 5 mg & 10 mg	Letairis®	May	$ 254
Erlotinib tablets, 100 mg & 150 mg	Tarceva®	May	$ 188
Mesalamine delayed-release capsules, 400 mg	Delzicol®	May	$ 130
Ranolazine extended-release tablets, 500 mg & 1000 mg	Ranexa®	May	$ 950
Aspirin and extended-release dipyridamole capsules, 25 mg/200 mg **	Aggrenox®	June	$ 168
Desmopressin acetate injection, USP, 4 mcg/mL**	DDAVP®	June	$ 58
Albendazole tablets, USP, 200 mg	Albenza®	June	$ 85
Bosentan tablets, 62.5 mg & 125 mg	Tracleer®	June	$ 84
Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets, 10 mg/10 mg	Diclegis®	June	$ 151
Penicillamine capsules, USP, 250 mg	Cuprimine®	June	$ 130
1% Sodium hyaluronate injection	***	June	$ —

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

** Product was re-launched.

*** Approved via 515(d)(1)(B)(ii) regulatory pathway for medical devices; not equivalent to a brand product.

Our generic products pipeline in the United States includes, as of June 30, 2019, 256 product applications awaiting FDA approval, including 86 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 March 31, 2019 exceeding $111 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 101 of these products, or 123 products including final approvals where launch is pending a settlement agreement or court decision. Collectively, these first to file opportunities represent over $74 billion in U.S. brand sales for the twelve months ended March 31, 2019, 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 second 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))*
Icatibant injection, 30 mg/3 mL	Firazyr®	$ 318
Sorafenib tablets, 200 mg	Nexavar®	$ 55

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

Below is a description of key products in our specialty pipeline as of June 30, 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)	Post traumatic headache	Subcutaneous	2	
Fasinumab	Osteoarthritis pain	Subcutaneous	3 (March 2016)	Developed in collaboration with Regeneron Pharmaceuticals, Inc. ("Regeneron"). In August 2018, Regeneron and Teva 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	Approved by FDA (December 2018)	
AirDuo® Digihaler™	Treatment of asthma in patients aged 12 years and older	Oral inhalation	Approved by FDA (July 2019)	
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)	

North America Gross Profit

Gross profit from our North America segment in the second quarter of 2019 was $1,067 million, a decrease of 9%, compared to $1,179 million in the second 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, partially offset by increases in sales of AUSTEDO, QVAR and AJOVY.

Gross profit margin for our North America segment in the second quarter of 2019 decreased to 51.5%, compared to 52.1% in the second quarter of 2018. The decrease was mainly due to lower revenues from COPAXONE and certain other specialty products, partially offset by improved gross profit margin of generic products.

North America R&D Expenses

R&D expenses relating to our North America segment in the second quarter of 2019 were $175 million, a decrease of 4%, compared to $182 million in the second quarter of 2018.

For a description of our R&D expenses in the second 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 second quarter of 2019 were $269 million, a decrease of 1%, compared to $272 million in the second quarter of 2018. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan, partially offset by increased expenses related to AJOVY.

North America G&A Expenses

G&A expenses relating to our North America segment in the second quarter of 2019 were $117 million, an increase of 14%, compared to $103 million in the second quarter of 2018. The increase was mainly due to legal expenses, partially offset by cost reductions and efficiency measures as part of the restructuring plan.

North America Other Income (Expense)

Other expenses from our North America segment in the second quarter of 2019 was $2 million, compared to other income of $100 million in the second quarter of 2018. The income in the second quarter of 2018 was mainly due to legal recovery of lost profits, where U.S. patent infringement litigation had previously prevented a product's sales.

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 second quarter of 2019 was $504 million, a decrease of 30%, compared to $722 million in the second 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 the non-recurrence of other income, partially offset by increases in sales of AUSTEDO and QVAR, as well as cost reductions and efficiency measures as part of the restructuring plan.

ERP Implementation

Teva is in the process of implementing a company-wide enterprise resource planning ("ERP") system in the U.S. to upgrade certain operational and financial processes. ERP implementation is a complex and time-consuming project. As with any new information system we implement, this application, along with the internal controls over financial reporting included in this process, has required testing for effectiveness and management has made appropriate efforts in this regard. In connection with this ERP implementation, we are updating our internal controls over financial reporting, as necessary, to accommodate modifications to our business processes and accounting procedures. We do not expect that the ERP implementation will have an adverse effect on our business. However, if the design or implementation of our new ERP system is deficient, it could adversely affect our operations, such as manufacturing or distribution, and/or the effectiveness of our internal controls.

Europe Segment

The following table presents revenues, expenses and profit for our Europe segment for the three months ended June 30, 2019 and 2018:

	Three months ended June 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 1,183	100.0%	$ 1,328	100.0%
Gross profit	674	56.9%	727	54.7%
R&D expenses	70	5.9%	73	5.5%
S&M expenses	216	18.3%	233	17.5%
G&A expenses	70	5.9%	78	5.9%
Other (income) expense	1	§	(3)	§
Segment profit*	$ 316	26.7%	$ 346	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 second quarter of 2019 were $1,183 million, a decrease of 11% or $145 million, compared to the second 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 and the termination of the PGT joint venture, 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 June 30, 2019 and 2018:

	Three months ended June 30,		Percentage Change 2018-2019
	2019	2018	
	(U.S. $ in millions)		
Generic products	$ 844	$ 907	(7%)
COPAXONE	107	140	(24%)
Respiratory products	89	106	(16%)
Other	143	175	(18 %)
Total	$ 1,183	$ 1,328	(11%)

Generic products revenues in our Europe segment in the second quarter of 2019, including OTC products, decreased by 7% to $844 million, compared to the second quarter of 2018. In local currency terms, revenues decreased by 1% compared to the second quarter of 2018, mainly due to the loss of revenues from the termination of the PGT joint venture and volume decline due to specific market conditions in various European Union countries, partially offset by new generic product launches.

COPAXONE revenues in our Europe segment in the second quarter of 2019 decreased by 24% to $107 million, compared to the second quarter of 2018. In local currency terms, revenues decreased by 19%, mainly due to price reductions resulting from the entry of competing glatiramer acetate products.

Revenues of COPAXONE in our Europe segment were 27% of global COPAXONE revenues in the second quarter of 2019, compared to 22% in the second 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 second quarter of 2019 decreased by 16% to $89 million, compared to the second quarter of 2018. In local currency terms, revenues decreased by 11%, mainly due to lower sales in the United Kingdom.

Product Launches and Pipeline

As of June 30, 2019, our generic products pipeline in Europe included 384 generic approvals relating to 49 compounds in 101 formulations, and approximately 1,326 marketing authorization applications pending approval in 37 European countries, relating to 144 compounds in 296 formulations in 30 countries.

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

Europe Gross Profit

Gross profit from our Europe segment in the second quarter of 2019 was $674 million, a decrease of 7% compared to $727 million in the second quarter of 2018. The decrease was mainly due to a decline in COPAXONE revenues and the impact of currency fluctuations, partially offset by new generic product launches.

Gross profit margin for our Europe segment in the second quarter of 2019 increased to 56.9%, compared to 54.7% in the second quarter of 2018. The increase was mainly due to lower cost of goods sold related to the termination of the PGT joint venture and network optimization.

Europe R&D Expenses

R&D expenses relating to our Europe segment in the second quarter of 2019 were $70 million, a decrease of 4% compared to $73 million in the second quarter of 2018.

For a description of our R&D expenses in the second 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 second quarter of 2019 were $216 million, a decrease of 7% compared to $233 million in the second quarter of 2018. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

Europe G&A Expenses

G&A expenses relating to our Europe segment in the second quarter of 2019 were $70 million, a decrease of 10% compared to $78 million in the second 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 second quarter of 2019 was $316 million, a decrease of 9% compared to $346 million in the second quarter of 2018. The decrease was mainly due to lower revenues and the impact of currency fluctuations, partially offset by impact of 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 June 30, 2019 and 2018:

	Three months ended June 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$741	100.0%	$789	100.0%
Gross profit	312	42.1%	328	41.5%
R&D expenses	24	3.2%	25	3.2%
S&M expenses	119	16.1%	130	16.4%
G&A expenses	34	4.7%	37	4.7%
Other (income) expense	(1)	§	(3)	§
Segment profit*	$136	18.3%	$139	17.6%

* 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.

Revenues from our International Markets segment in the second quarter of 2019 were $741 million, a decrease of $48 million, or 6%, compared to the second quarter of 2018. In local currency terms, revenues decreased 2% compared to the second 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 June 30, 2019 and 2018:

	Three months ended June 30,		Percentage Change
	2019	2018	2018-2019
	(U.S. $ in millions)		
Generic products	$ 489	$ 537	(9%)
COPAXONE	13	22	(40%)
Distribution	164	154	6%
Other	75	76	(1%)
Total	$ 741	$ 789	(6%)

Generic products revenues in our International Markets segment in the second quarter of 2019, which include OTC products, decreased by 9% to $489 million, compared to the second quarter of 2018. In local currency terms, revenues decreased by 4%, mainly due to lower sales in Japan resulting from generic competition to off-patented products, partially offset by higher sales in Russia.

COPAXONE revenues in our International Markets segment in the second quarter of 2019 decreased by 40% to $13 million, compared to the second quarter of 2018. In local currency terms, revenues decreased by 28%.

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

Distribution revenues in our International Markets segment in the second quarter of 2019 increased by 6% to $164 million, compared to the second quarter of 2018. In local currency terms, revenues increased by 7%.

International Markets Gross Profit

Gross profit from our International Markets segment in the second quarter of 2019 was $312 million, a decrease of 5% compared to $328 million in the second quarter of 2018.

Gross profit margin for our International Markets segment in the second quarter of 2019 increased to 42.1%, compared to 41.5% in the second quarter of 2018. The increase was mainly due to lower cost of goods and portfolio optimization, mainly in Russia and Israel.

International Markets R&D Expenses

R&D expenses relating to our International Markets segment in the second quarter of 2019 were $24 million, a decrease of 6% compared to $25 million in the second quarter of 2018.

For a description of our R&D expenses in the second 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 second quarter of 2019 were $119 million, a decrease of 8% compared to $130 million in the second 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 second quarter of 2019 were $34 million, a decrease of 7% compared to $37 million in the second quarter of 2018. The decrease was mainly due to cost reductions and efficiency measures 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 second quarter of 2019 was $136 million, a decrease of 2% compared to $139 million in the second quarter of 2018. The decrease was mainly due to lower sales in Japan resulting from 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.

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 second quarter of 2019 were $342 million, an increase of 6% compared to the second quarter of 2018. In local currency terms, revenues increased by 10%, mainly due to higher revenues from API sales to third parties.

API sales to third parties in the second quarter of 2019 were $204 million, an increase of 10%, in both U.S. dollar and local currency terms, compared to the second quarter of 2018.

Teva Consolidated Results

Revenues

Revenues in the second quarter of 2019 were $4,337 million, a decrease of 8%, or 5% in local currency terms, compared to the second quarter of 2018, mainly due to generic competition to COPAXONE, as well as declines in revenues from TREANDA/BENDEKA, certain other specialty products in the United States, our Europe segment and Japan, partially offset by higher revenues from AUSTEDO, AJOVY and QVAR in the United States. See "—North America Revenues," "—Europe Revenues," "—International Markets Revenues" and "—Other Activities" above.

Exchange rate movements during the second quarter of 2019 negatively impacted revenues by $125 million compared to the second quarter of 2018.

Gross Profit

Gross profit in the second quarter of 2019 was $1,893 million, a decrease of 7% compared to the second 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 43.7% in the second quarter of 2019, compared to 43.2% in the second quarter of 2018.

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

Research and Development (R&D) Expenses

Net R&D expenses in the second quarter of 2019 were $276 million, a decrease of 5% compared to the second 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 second 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 second quarter of 2019 compared to the second quarter of 2018 primarily resulted from pipeline optimization and project terminations and related headcount reductions.

R&D expenses as a percentage of revenues were 6.4% in the second quarter of 2019, compared to 6.2% in the second quarter of 2018.

Selling and Marketing (S&M) Expenses

S&M expenses in the second quarter of 2019 were $666 million, a decrease of 2% compared to the second 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 15.4% in the second quarter of 2019, compared to 14.5% in the second quarter of 2018.

General and Administrative (G&A) Expenses

G&A expenses in the second quarter of 2019 were $296 million, a decrease of 6% compared to the second 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 second quarter of 2019, compared to 6.7% in the second quarter of 2018.

Intangible Asset Impairments

We recorded expenses of $561 million for identifiable intangible asset impairments in the second quarter of 2019, compared to expenses of $521 million in the second quarter of 2018. See note 6 to our consolidated financial statements.

Goodwill Impairment

In the second quarter of 2019, there were no goodwill impairments recorded, compared to a goodwill impairment of $120 million in the second quarter of 2018. The goodwill impairment in the second quarter of 2018 was mainly attributable to goodwill associated with our Rimsa reporting unit (now included in our International Markets reporting unit). See note 7 to our consolidated financial statements.

Other Assets Impairments, Restructuring and Other Items

We recorded expenses of $101 million for other assets impairments, restructuring and other items in the second quarter of 2019, compared to expenses of $194 million in the second 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 $142 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 as of June 30, 2019 on our financial statements was $55 million, primarily related to inventory reserves and returns. 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 second quarter of 2019, we recorded $47 million of restructuring expenses, compared to $107 million in the second quarter of 2018. The expenses in the second 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.

Since the announcement, we reduced our global headcount by approximately 11,145 full-time-equivalent employees.

Legal Settlements and Loss Contingencies

In the second quarter of 2019, we recorded an expense of $646 million in legal settlements and loss contingencies, compared to $20 million in the second quarter of 2018. The expense in the second quarter of 2019 was mainly related to the $85 million settlement paid in the opioid litigation brought by the Oklahoma Attorney General and an estimated provision made for certain other opioid cases. See note 16 to our consolidated financial statements.

Other Income

Other income in the second quarter of 2019 was $9 million, compared to $96 million in the second quarter of 2018. Other income in the second quarter of 2018 was primarily the result of legal recovery of lost profits, where U.S. patent infringement litigation had previously prevented a product's sales.

Operating Income (Loss)

Operating loss was $644 million in the second quarter of 2019, compared to $14 million in the second quarter of 2018.

Operating loss as a percentage of revenues was 14.8% in the second quarter of 2019, compared to 0.3% in the second quarter of 2018. The increase was mainly due to legal settlements and loss contingencies expenses, lower profit in our North America segment and higher intangible asset impairments, partially offset by goodwill impairment in the second quarter of 2018 which did not recur in the second quarter of 2019 and lower other assets impairments, restructuring and other items.

Financial Expenses, Net

Financial expenses were $206 million in the second quarter of 2019, compared to $236 million in the second quarter of 2018. Financial expenses in the second quarter of 2019 were mainly comprised of interest expenses of $226 million. Financial expenses in the second quarter of 2018 were mainly comprised of interest expenses of $231 million.

The following table presents a reconciliation of our segment profits to our consolidated operating income (loss) and to consolidated income (loss) before income taxes for the three months ended June 30, 2019 and 2018:

	Three months ended June 30,	
	2019	2018
	(U.S. $ in millions)	
North America profit	$ 504	$ 722
Europe profit	316	346
International Markets profit	136	139
Total segment profit	956	1,207
Profit of other activities	55	31
	1,011	1,238
Amounts not allocated to segments:		
Amortization	285	302
Other assets impairments, restructuring and other items	101	194
Goodwill impairment	—	120
Intangible asset impairments	561	521
Gain on divestitures, net of divestitures related costs	(9)	10
Other R&D expenses	§	—
Costs related to regulatory actions taken in facilities	12	4
Legal settlements and loss contingencies	646	20
Other unallocated amounts	59	81
Consolidated operating income (loss)	(644)	(14)
Financial expenses, net	206	236
Consolidated income (loss) before income taxes	$ (850)	$ (250)

§ Represents an amount less than $1 million.

Tax Rate

In the second quarter of 2019, we recognized a tax benefit of $179 million, or 21%, on pre-tax loss of $850 million. In the second quarter of 2018, we recognized a tax benefit of $76 million, or 30%, on pre-tax loss of $250 million. Our tax rate for the second 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 (Income) of Associated Companies, Net

We had no share in income of associated companies, net in the second quarter of 2019, compared to $8 million in the second quarter of 2018.

Net Income (Loss)

Net loss attributable to Teva was $689 million in the second quarter of 2019, compared to $176 million in the second quarter of 2018.

Net loss attributable to ordinary shareholders was $689 million in the second quarter of 2019, compared to net loss of $241 million in the second 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 June 30, 2019 and 2018 were 1,092 million and 1,018 million shares, respectively.

In computing loss per share for the three months ended June 30, 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 63 million shares (including shares that were issued due to unpaid dividends until that date) for the three months ended June 30, 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 $0.63 in the second quarter of 2019, compared to diluted loss per share of $0.24 in the second 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 June 30, 2019 and 2018, the fully diluted share count for purposes of calculating our market capitalization was approximately 1,107 million and 1,109 million, respectively.

Impact of Currency Fluctuations on Results of Operations

In the second quarter of 2019, approximately 50% 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 second 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 47%, Turkish lira by 26%, Hungarian forint by 8%, euro by 6%, British pound by 6%, Polish zloty by 6%, Russian ruble by 4%, Indian rupee by 4%, Canadian dollar by 4%, Swiss franc by 2%, Israeli shekel by 1% and Japanese yen by 1%.

As a result, exchange rate movements during the second quarter of 2019 negatively impacted overall revenues by $125 million and our operating income by $41 million, in comparison with the second quarter of 2018.

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

Comparison of Six Months Ended June 30, 2019 to Six Months Ended June 30, 2018

The factors used to explain quarterly changes on a year-over-year basis are also generally relevant to a comparison of the results for the six months ended June 30, 2019 and 2018. Additional factors affecting the six months comparison are described below.

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

	Percentage of Net Revenues Six Months Ended June 30,		Percentage Change
	2019	2018	2019 - 2018
	%	%	%
Net revenues	100.0	100.0	(12)
Gross profit	43.4	44.5	(14)
Research and development expenses	6.2	6.2	(12)
Selling and marketing expenses	15.2	14.5	(7)
General and administrative expenses	6.8	6.6	(9)
Other asset impairments, restructuring and other items	1.2	7.1	(85)
Goodwill impairment	—	3	—
Legal settlements and loss contingencies	8.1	(12.9)	—
Other income	(0.2)	(3.1)	(95)
Operating income (loss)	(5.9)	15.6	—
Financial expenses, net	4.9	5.2	(16)
Income (loss) before income taxes	(10.8)	10.4	—
Tax benefit	(2.0)	(0.3)	466
Share in (profits) losses of associated companies, net	§	0.7	—
Net income (loss) attributable to non-controlling interests	(0.3)	0.2	—
Net income (loss) attributable to Teva	(9.2)	9.7	—
Dividends on preferred shares	—	1.3	—
Net income (loss) attributable to ordinary shareholders	(9.2)	8.3	—

§ 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 six months ended June 30, 2019 and 2018:

	Six months ended June 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 4,118	100.0%	$ 4,794	100.0%
Gross profit	2,107	51.2%	2,582	53.9%
R&D expenses	340	8.3%	370	7.7%
S&M expenses	537	13.0%	548	11.4%
G&A expenses	230	5.6%	229	4.8%
Other (income) expense	(2)	§	(202)	(4.2%)
Segment profit*	$ 1,001	24.3%	$ 1,637	34.1%

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

§ Represents an amount less than 0.5%.

North America Revenues

Our North America segment includes the United States and Canada. Revenues from our North America segment in the first six months of 2019 were $4,118 million, a decrease of $676 million, or 14%, compared to the first six months of 2018.

Revenues by Major Products and Activities

The following table presents revenues for our North America segment by major products and activities for the six months ended June 30, 2019 and 2018:

	Six months ended June 30,		Percentage Change
	2019	2018	2018-2019
	(U.S. $ in millions)		
Generic products	$1,913	$2,035	(6%)
COPAXONE	482	940	(49%)
TREANDA/BENDEKA	229	341	(33%)
ProAir*	123	245	(50%)
QVAR	124	137	(10%)
AJOVY	43	—	N/A
AUSTEDO	171	74	130%
Anda	729	651	12%
Other	305	372	(18%)
Total	$4,118	$4,794	(14%)

* Does not include sales of ProAir authorized generic, which are included under generics.

North America Gross Profit

Gross profit from our North America segment in the first six months of 2019 was $2,107 million, a decrease of 18%, compared to $2,582 million in the first six months of 2018.

Gross profit margin for our North America segment in the first six months of 2019 decreased to 51.2% from 53.9% in the first six months of 2018.

North America R&D Expenses

R&D expenses relating to our North America segment in the first six months of 2019 were $340 million, a decrease of 8%, compared to $370 million in the first six months of 2018.

North America S&M Expenses

S&M expenses relating to our North America segment in the first six months of 2019 were $537 million, a decrease of 2%, compared to $548 million in the first six months of 2018.

North America G&A Expenses

G&A expenses relating to our North America segment in the first six months of 2019 were $230 million, flat compared to the first six months of 2018.

North America Other Income

Other income from our North America segment in the first six months of 2019 was $2 million, compared to $202 million in the first six months of 2018.

North America Profit

Profit from our North America segment in the first six months of 2019 was $1,001 million, a decrease of 39%, compared to $1,637 million in the first six months of 2018.

Europe Segment

The following table presents revenues, expenses and profit for our Europe segment for the six months ended June 30, 2019 and 2018:

	Six months ended June 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 2,448	100%	$ 2,770	100%
Gross profit	1,404	57.4%	1,519	54.9%
R&D expenses	136	5.5%	146	5.3%
S&M expenses	431	17.6%	483	17.5%
G&A expenses	119	4.8%	169	6.1%
Other (income) expense	(1)	§	(2)	§
Segment profit*	$ 719	29.4%	$ 723	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 six months of 2019 were $2,448 million, a decrease of 12% or $322 million, compared to the first six months of 2018. In local currency terms, revenues decreased by 5% compared to the first six months of 2018.

Revenues by Major Products and Activities

The following table presents revenues for our Europe segment by major products and activities for the six months ended June 30, 2019 and 2018:

	Six months ended June 30,		Percentage Change
	2019	2018	2018-2019
	(U.S. $ in millions)		
Generic products	$1,763	$1,904	(7%)
COPAXONE	221	293	(25%)
Respiratory products	181	219	(18%)
Other	283	354	(20%)
Total	$2,448	$2,770	(12%)

Europe Gross Profit

Gross profit from our Europe segment in the first six months of 2019 was $1,404 million, a decrease of 8% compared to $1,519 million in the first six months of 2018.

Gross profit margin for our Europe segment in the first six months of 2019 increased to 57.4% from 54.9% in the first six months of 2018.

Europe R&D Expenses

R&D expenses relating to our Europe segment in the first six months of 2019 were $136 million, a decrease of 7% compared to $146 million in the first six months of 2018.

Europe S&M Expenses

S&M expenses relating to our Europe segment in the first six months of 2019 were $431 million, a decrease of 11% compared to $483 million in the first six months of 2018.

Europe G&A Expenses

G&A expenses relating to our Europe segment in the first six months of 2019 were $119 million, a decrease of 30% compared to $169 million in the first six months of 2018.

Europe Profit

Profit from our Europe segment in the first six months of 2019 was $719 million, flat compared to the first six months of 2018.

International Markets Segment

The following table presents revenues, expenses and profit for our International Markets segment for the six months ended June 30, 2019 and 2018:

	Six months ended June 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$1,409	100.0%	$1,539	100.0%
Gross profit	582	41.3%	641	41.6%
R&D expenses	46	3.2%	49	3.2%
S&M expenses	234	16.6%	264	17.2%
G&A expenses	70	5.0%	78	5.1%
Other (income) expense	(1)	§	(11)	(0.7%)
Segment profit*	$ 233	16.5%	$ 261	17.0%

* 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. Revenues from our International Markets segment in the first six months of 2019 were $1,409 million, a decrease of $130 million, or 8%, compared to the first six months of 2018. In local currency terms, revenues decreased by 3% compared to the first six months of 2018.

Revenues by Major Products and Activities

The following table presents revenues for our International Markets segment by major products and activities for the six months ended June 30, 2019 and 2018:

	Six months ended June 30,		Percentage Change
	2019	2018	2018-2019
	(U.S. $ in millions)		
Generic products	$ 930	$1,025	(9%)
COPAXONE	27	38	(31%)
Distribution	315	307	3%
Other	137	168	(19%)
Total	$1,409	$1,539	(8%)

International Markets Gross Profit

Gross profit from our International Markets segment in the first six months of 2019 was $582 million, a decrease of 9% compared to $641 million in the first six months of 2018.

Gross profit margin for our International Markets segment in the first six months of 2019 decreased to 41.3%, from 41.6% in the first six months 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 six months of 2019 were $46 million, a decrease of 7% compared to $49 million in the first six months of 2018.

International Markets S&M Expenses

S&M expenses relating to our International Markets segment in the first six months of 2019 were $234 million, a decrease of 11% compared to $264 million in the first six months of 2018.

International Markets G&A Expenses

G&A expenses relating to our International Markets segment in the first six months of 2019 were $70 million, a decrease of 10% compared to $78 million in the first six months of 2018.

International Markets Profit

Profit from our International Markets segment in the first six months of 2019 was $233 million, compared to $261 million in the first six months of 2018.

Other Activities

Our revenues from other activities in the first six months of 2019 decreased by 1% to $658 million, compared to the first six months of 2018. In local currency terms, revenues increased by 2%.

API sales to third parties in the first six months of 2019 increased by 7%, in both U.S. dollar and local currency terms, to $390 million, compared to the first six months of 2018.

Teva Consolidated Results

Revenues

Revenues in the first six months of 2019 were $8,632 million, a decrease of 12% or 9% in local currency terms, compared to the first six months of 2018.

Exchange rate movements during the first six months of 2019 compared to the first six months of 2018 negatively impacted revenues by $301 million.

Gross Profit

Gross profit in the first six months of 2019 was $3,749 million, a decrease of $599 million compared to the first six months of 2018.

Gross profit as a percentage of revenues was 43.4% in the first six months of 2019, compared to 44.5% in the first six months of 2018.

Research and Development (R&D) Expenses

Net R&D expenses in the first six months of 2019 were $537 million, a decrease of 12% compared to the first six months of 2018.

R&D expenses as a percentage of revenues were 6.2% in the first six months of 2019, flat compared to the first six months of 2018.

Selling and Marketing (S&M) Expenses

S&M expenses in the first six months of 2019 were $1,313 million, a decrease of 7% compared to the first six months of 2018.

S&M expenses as a percentage of revenues were 15.2% in the first six months of 2019, compared to 14.5% in the first six months of 2018.

General and Administrative (G&A) Expenses

G&A expenses in the first six months of 2019 were $589 million, a decrease of 9% compared to the first six months of 2018.

G&A expenses as a percentage of revenues were 6.8% in the first six months of 2019, compared to 6.6% in the first six months of 2018.

Intangible Asset Impairments

We recorded expenses of $1,030 million for identifiable intangible asset impairments in the first six months of 2019, compared to expenses of $727 million in the first six months of 2018. See note 6 to our consolidated financial statements.

Goodwill Impairment

In the first six months of 2019, there were no goodwill impairments recorded, compared to a $300 million goodwill impairment charge recorded in the first six months of 2018. See note 7 to our consolidated financial statements.

Other Asset Impairments, Restructuring and Other Items

We recorded expenses of $103 million for other asset impairments, restructuring and other items in the first six months of 2019, compared to expenses of $695 million in the first six months of 2018. See note 14 to our consolidated financial statements.

Legal Settlements and Loss Contingencies

In the first six months of 2019, we recorded an expense of $703 million in legal settlements and loss contingencies, compared to an income of $1,258 million in the first six months of 2018. The expense in the first six months of 2019 was mainly related to the $85 million settlement paid in the opioid litigation brought by the Oklahoma Attorney General and an estimated provision made for certain other opioid cases. See note 16 to our consolidated financial statements.

Other Income

Other income in the first six months of 2019 was $15 million, compared to $299 million in the first six months of 2018.

Other income as a percentage of revenues was 0.2% in the first six months of 2019, compared to 3.1% in the first six months of 2018.

Operating Income (Loss)

Operating loss was $510 million in the first six months of 2019, compared to an operating income of $1,511 million in the first six months of 2018.

Financial Expenses, Net

Financial expenses were $425 million in the first six months of 2019, compared to $507 million in the first six months of 2018.

Financial expenses in the first six months of 2019 were mainly comprised of interest expenses of $454 million, partially offset by $27 million of interest income. Financial expenses in the first six months of 2018 were mainly comprised of interest expenses of $449 million and $60 million of early redemption charges and accelerated amortization related to the repayment of senior notes and term loans in the first quarter of 2018.

The following table presents a reconciliation of our segment profits to our consolidated operating income (loss) and to consolidated income (loss) before income taxes for the six months ended June 30, 2019 and 2018:

	Six months ended June 30,	
	2019	2018
	(U.S. $ in millions)	
North America profit	$1,001	$ 1,637
Europe profit	719	723
International Markets profit	233	261
Total segment profit	1,954	2,621
Profit of other activities	76	52
	2,029	2,673
Amounts not allocated to segments:		
Amortization	568	612
Other asset impairments, restructuring and other items	103	695
Goodwill impairment	—	300
Intangible asset impairments	1,030	727
Gain on divestitures, net of divestitures related costs	(9)	(83)
Other R&D expenses	§	22
Costs related to regulatory actions taken in facilities	16	5
Legal settlements and loss contingencies	703	(1,258)
Other unallocated amounts	129	142
Consolidated operating income (loss)	(510)	1,511
Financial expenses, net	425	507
Consolidated income (loss) before income taxes	$ (934)	$ 1,004

§ Represents an amount less than $1 million.

Tax Rate

In the first six months of 2019, we recognized a tax benefit of $170 million, on pre-tax loss of $934 million. In the first six months of 2018, we recognized a tax benefit of $30 million, on pre-tax income of $1,004 million. Our tax rate for the first six months of 2019 was mainly affected by impairments, amortization and interest disallowance as a result of the U.S. Tax Cuts and Jobs Act.

Share in Losses (Income) of Associated Companies, Net

Share in losses of associated companies, net in the first six months of 2019 was $4 million, compared to share in losses of $66 million in the first six months of 2018.

Net Income (Loss)

Net loss attributable to Teva was $794 million in the first six months of 2019, compared to net income attributable to Teva of $944 million in the first six months of 2018.

Net loss attributable to ordinary shareholders was $794 million in the first six months of 2019, compared to net income of $814 million in the first six months 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 six months ended June 30, 2019 and 2018 were 1,091 million and 1,020 million shares, respectively.

In computing diluted loss per share for the six months ended June 30, 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 six months ended June 30, 2018 take 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, no account was taken of the potential dilution by the mandatory convertible preferred shares, amounting to 65 million shares (including shares that may be issued due to unpaid dividends to date) for the six months ended June 30, 2018, since they had an anti-dilutive effect on loss per share.

Diluted loss per share was $0.73 in the first six months of 2019, compared to diluted earnings per share of $0.80 in the first six months of 2018.

Impact of Currency Fluctuations on Results of Operations

In the first six months 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 and, accordingly, changes in the exchange rate between the U.S. dollar and local currencies in the markets in which we operate (primarily the euro, British pound, Japanese yen, Polish zloty, Argentinean peso, Turkish lira and Russian ruble) impact our results. During the first six months of 2019, the following main currencies relevant to our operations decreased in value against the U.S. dollar: Argentinean peso by 48%, Turkish lira by 27%, Russian ruble by 9%, Hungarian forint by 9%, Polish zloty by 8%, euro by 7%, British pound by 6%, Indian rupee by 6%, Canadian dollar by 4%, new Israeli shekel by 3% and Japanese yen by 1% (all compared on a six-monthly average basis).

As a result, exchange rate movements during the first six months of 2019 negatively impacted overall revenues by $301 million and our operating income by $91 million, in comparison to the first six months of 2018.

Liquidity and Capital Resources

Total balance sheet assets were $59,424 million as of June 30, 2019, compared to $59,854 million as of March 31, 2019.

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 $65 million as of June 30, 2019, compared to $59 million as of March 31, 2019.

Trade receivables as of June 30, 2019 were $5,260 million, compared to $5,108 million as of March 31, 2019. The increase in the second quarter of 2019 was mainly due to timing of sales within the quarter and timing of issuance of credit memos to customers. SR&A as of June 30, 2019 was $6,054 million, compared to $6,200 million as of March 31, 2019. The reduction in the second quarter of 2019 is attributable to the payout of certain rebates, primarily managed care and Medicaid for prior periods. Payments exceed new provisions for the current period due to a decline in sales resulting in overall reduction to the liability.

Accrued expenses as of June 30, 2019, were $2,335 million, compared to $1,869 million as of March 31, 2019. The increase in the second quarter of 2019 was mainly due to provisions made under legal settlements and loss contingencies.

Investment in property, plant and equipment in the second quarter of 2019 was approximately $112 million, compared to $125 million in the first quarter of 2019. Depreciation in the second quarter of 2019 was $153 million, compared to $152 million in the first quarter of 2019.

Cash and cash equivalents and short-term and long-term investments as of June 30, 2019 were $2,232 million, compared to $2,040 million as of March 31, 2019. The increase in the second quarter of 2019 was mainly due to cash generated during the quarter.

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 cash on hand, existing cash investments, liquid securities and available credit facilities, primarily our $2.3 billion revolving credit facility ("RCF").

In April 2019, we entered into a $2.3 billion unsecured syndicated RCF, 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 the requirement to maintain compliance with a net debt to EBITDA ratio, which becomes more restrictive over time. The net debt to EBITDA ratio limit is 6.25x through December 31, 2019, gradually declines to 5.75x in the third and fourth quarters of 2020, and continues to gradually decline over the remaining term of the RCF.

The RCF can be used for general corporate purposes, including repaying existing debt. As of June 30, 2019, no amounts were outstanding under the RCF. As of the date of this report, $500 million was outstanding under the RCF. Based on current and forecasted results, we expect that we will not exceed the financial covenant thresholds set forth in the RCF within one year from the date that the financial statements are issued.

Under specified circumstances, including non-compliance with any of the covenants described above and the unavailability of any waiver, amendment or other modification thereto, we will not be able to borrow under the RCF. Additionally, violations of the covenants, under the above-mentioned circumstances, would result in an event of default in all borrowings under the RCF and, when greater than a specified threshold amount as set forth in each series of senior notes is outstanding, could lead to an event of default under our senior notes due to cross acceleration provisions.

We expect that we will continue to have sufficient cash resources to support our debt service payments and all other financial obligations within one year from the date that the financial statements are issued.

Debt Balance and Movements

As of June 30, 2019, our debt was $28,726 million, compared to $28,624 million as of March 31, 2019. The increase was mainly due to exchange rates fluctuations.

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.

During the second quarter of 2019, we repurchased and canceled approximately $18 million principal amount of our $1,574 million 1.7% senior notes due July 2019.

In July 2019, we repaid at maturity our $1,556 million 1.7% senior notes.

Our debt as of June 30, 2019 was effectively denominated in the following currencies: 66% in U.S. dollars, 32% in euros and 2% in Swiss francs.

The portion of total debt classified as short-term as of June 30, 2019 was 10%, similar to March 31, 2019.

Our financial leverage was 65% as of June 30, 2019, a slight increase compared to 64% as of March 31, 2019.

Our average debt maturity was approximately 6.3 years as of June 30, 2019, compared to 6.6 years as of March 31, 2019.

Total Equity

Total equity was $15,251 million as of June 30, 2019, compared to $15,821 million as of March 31, 2019. The decrease was mainly due to net loss of $671 million, partially offset by $86 million in exchange rate fluctuations in the second quarter of 2019.

Exchange rate fluctuations affected our balance sheet, as approximately 36% of our net assets in the second quarter of 2019 (including both non-monetary and monetary assets) were in currencies other than the U.S. dollar. When compared to March 31, 2019, changes in currency rates had a positive impact of $86 million on our equity as of June 30, 2019, mainly due to the changes in value against the U.S. dollar of: the Japanese yen by 3%, the euro by 1%, the Russian ruble by 4%, the British pound by 3%, the Canadian dollar by 2% and the Polish zloty by 3%. All comparisons are on a quarter-end to quarter-end basis.

Cash Flow

Cash flow used in operating activities during the second quarter of 2019 was $227 million, compared to cash flow generated from operating activities of $162 million in the second quarter of 2018. The decrease in cash flow in the second quarter of 2019 was mainly due to lower revenues, timing of certain customer payments and credits and payments of U.S. customer rebates paid this quarter, primarily related to managed care and Medicaid.

Cash flow generated from operating activities in the second quarter of 2019, net of cash received for capital investments and beneficial interest collected in exchange for securitized trade receivables, was $168 million, compared to $559 million in the second quarter of 2018. The decrease in cash flow was mainly due to the reasons mentioned above.

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.

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 June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	(U.S. $ in millions)			
Gain on divestitures, net of divestitures related costs	(9)	10	(9)	(83)
Amortization of purchased intangible assets	285	302	568	612
Restructuring expenses	47	107	79	354
Equity compensation expenses	35	47	69	77
Costs related to regulatory actions taken in facilities	12	4	16	5
Acquisition, integration and related expenses	—	3	2	5
Other R&D expenses	—	—	—	22
Contingent consideration	24	47	(47)	55
Legal settlements and loss contingencies	646	20	703	(1,258)
Goodwill impairment	—	120	—	300
Impairment of long-lived assets	609	548	1,097	980
Other non-GAAP items	6	44	60	93
Financial expense (income)	8	(2)	6	66
Minority interest	(8)	(12)	(16)	(20)
Impairments of equity investments	—	—	—	94
Corresponding tax effect	(312)	(203)	(429)	(368)

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

	Three months ended June 30, 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	Impairment of long-lived assets	Restructuring costs	Costs related to regulatory actions taken in facilities	Equity compensation	Contingent consideration	Gain on sale of business	Other non-GAAP items	Other items	Corresponding tax effect	Non-GAAP
Cost of Sales	2,443	249				12	7			26			2,149
R&D expenses	276						6			—			271
S&M expenses	666	35					10						621
G&A expenses	296						12			(2)			286
Other (income) expenses	(9)								(9)				(0)
Legal settlements and loss contingencies	646		646										—
Other assets impairments, restructuring and other items	101			48	47			24		(18)			—
Intangible assets impairment	561			561									—
Financial expenses, net	206										8		198
Income taxes	(179)											(312)	134
Net income (loss) attributable to non-controlling interests	18										(8)		26
Total reconciled items		285	646	609	47	12	35	24	(9)	6	(0)	(312)	
EPS—Basic	(0.63)											1.23	0.60
EPS—Diluted	(0.63)											1.23	0.60

The non-GAAP diluted weighted average number of shares was 1,093 million for the three months ended June 30, 2019.

	Three months ended June 30, 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	Restructuring costs	Costs related to regulatory actions taken in facilities	Equity compensation	Contingent consideration	Other non-GAAP items	Other items	Corresponding tax effect	Non-GAAP
Cost of Sales	2,668	261					4	9		32			2,362
R&D expenses	290							9		—			281
S&M expenses	682	41						12		(5)			634
G&A expenses	316							17		7			292
Other (income) expenses	(96)									10			(106)
Legal settlements and loss contingencies	20		20										—
Other assets impairments, restructuring and other items	194			27	3	107			47	10			—
Intangible assets impairment	521			521									—
Goodwill impairment	120			120									—
Financial expenses, net	236										(2)		238
Income taxes	(76)											(203)	127
Share in losses (income) of associated companies, net	(8)										—		(8)
Net income (loss) attributable to non-controlling interests	10										(12)		22
Total reconciled items		302	20	668	3	107	4	47	47	54	(14)	(203)	
EPS—Basic	(0.24)											1.02	0.78
EPS—Diluted	(0.24)											1.02	0.78

The non-GAAP diluted weighted average number of shares was 1,021 million for the three months ended June 30, 2018.

	Six months ended June 30, 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	Impairment of long-lived assets	Acquisition, integration and related expenses	Restructuring costs	Costs related to regulatory actions taken in facilities	Equity compensation	Contingent consideration	Gain on sale of business	Other non-GAAP items	Other items	Corresponding tax effect	Unusual tax item*	Non-GAAP
Cost of Sales	4,883	497					16	14			61				4,294
R&D expenses	537							11			0				525
S&M expenses	1,313	71						20			—				1,223
G&A expenses	589							24			(1)				566
Other (income) expenses	(15)									(9)					(6)
Legal settlements and loss contingencies	703		703												—
Other assets impairments, restructuring and other items	103			68	2	79			(47)		1				(0)
Intangible assets impairment	1,030			1,030											—
Financial expenses, net	425											6			419
Corresponding tax effect	(170)												(490)	61	259
Share in losses (income) of associated companies, net	4											—			4
Net income (loss) attributable to non-controlling interests	26											(16)			42
Total reconciled items		568	703	1,098	2	79	16	69	(47)	(9)	60	(10)	(490)	61	
EPS—Basic	(0.73)													1.93	1.20
EPS—Diluted	(0.73)													1.93	1.20

* 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 six months ended June 30, 2019.

	Six months ended June 30, 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	Other R&D expenses	Acquisition, integration and related expenses	Restructuring costs	Costs related to regulatory actions taken in facilities	Equity compensation	Contingent consideration	Other non-GAAP items	Other items	Corresponding tax effect	Non-GAAP
Cost of Sales	5,418	525						5	15		64			4,809
R&D expenses	607				22				14		1			570
S&M expenses	1,420	87							21		(4)			1,316
G&A expenses	645								27		4			614
Other (income) expenses	(299)										(83)			(216)
Legal settlements and loss contingencies	(1,258)		(1,258)											—
Other assets impairments, restructuring and other items	695			253		5	354			55	28			—
Intangible assets impairment	727			727										—
Goodwill impairment	300			300										—
Financial expenses, net	507											66		441
Corresponding tax effect	(30)												(368)	338
Share in losses (income) of associated companies, net	66											94		(28)
Net income (loss) attributable to non-controlling interests	24											(20)		44
Total reconciled items		612	(1,258)	1,280	22	5	354	5	77	55	10	140	(368)	
EPS—Basic	0.80												0.92	1.72
EPS—Diluted	0.80												0.91	1.71

The non-GAAP diluted weighted average number of shares was 1,020 million for the six months ended June 30, 2018.

Non-GAAP Tax Rate

Non-GAAP income taxes for the second quarter of 2019 were $134 million, or 16%, on pre-tax non-GAAP income of $812 million. Non-GAAP income taxes in the second quarter of 2018 were $127 million, or 13%, on pre-tax non-GAAP income of $1,000 million. Our non-GAAP tax rate for the second 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.

Non-GAAP income taxes for the first six months of 2019 were $259 million, or 16%, on pre-tax non-GAAP income of $1,611 million. Non-GAAP income taxes in the first six months of 2018 were $338 million, or 15% on pre-tax non-GAAP income of $2,232 million.

We expect our annual non-GAAP tax rate for 2019 to be 16%, which is higher than our previous projection. This is due to changes in the geographical mix of income we expect to earn this year. Our non-GAAP tax rate for 2018 was 14%.

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 market risk 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 June 30, 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 June 30, 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.

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 June 30, 2019. We did not repurchase any of our shares during the three months ended June 30, 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.

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.

SIGNATURES

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

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

Date: August 7, 2019

By: /s/ Michael McClellan
Name: **Michael McClellan**
Title: **Executive Vice President,**
Chief Financial Officer
(Duly Authorized Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Kåre Schultz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Teva Pharmaceutical Industries Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. disclosed in this report any change in the company's internal control over financial reporting that occurred during the company's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 7, 2019

/s/ Kåre Schultz

Kåre Schultz
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Michael McClellan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Teva Pharmaceutical Industries Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. disclosed in this report any change in the company's internal control over financial reporting that occurred during the company's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 7, 2019

/s/ Michael McClellan

Michael McClellan
Executive Vice President, Chief Financial Officer

Exhibit 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

In connection with the Quarterly Report of Teva Pharmaceutical Industries Limited (the "Company") on Form 10-Q for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Kåre Schultz, President and Chief Executive Officer of the Company, and Michael McClellan, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 7, 2019

/s/ Kåre Schultz
Kåre Schultz
President and Chief Executive Officer

/s/ Michael McClellan
Michael McClellan
Executive Vice President, Chief Financial Officer