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 September 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 September 30, 2019, the registrant had 1,092,089,421 ordinary shares outstanding.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

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INTRODUCTION AND USE OF CERTAIN TERMS

Unless otherwise indicated, all references to the "Company," "we," "our" and "Teva" refer to Teva Pharmaceutical 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, including changes to our senior management team; 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: our ability to reach a final resolution of the remaining opioid-related litigation; 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)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,241	$ 1,782
Trade receivables	5,254	5,822
Inventories	4,636	4,731
Prepaid expenses	976	899
Other current assets	416	468
Assets held for sale	18	92
Total current assets	12,542	13,794
Deferred income taxes	331	368
Other non-current assets	727	731
Property, plant and equipment, net	6,643	6,868
Operating lease right-of-use assets	468	—
Identifiable intangible assets, net	11,878	14,005
Goodwill	24,657	24,917
Total assets	$ 57,246	$ 60,683
LIABILITIES AND EQUITY		
Current liabilities:		
Short-term debt	$ 3,130	$ 2,216
Sales reserves and allowances	6,137	6,711
Trade payables	1,688	1,853
Employee-related obligations	583	870
Accrued expenses	1,748	1,868
Other current liabilities	820	804
Total current liabilities	14,107	14,322
Long-term liabilities:		
Deferred income taxes	1,462	2,140
Other taxes and long-term liabilities	2,546	1,727
Senior notes and loans	23,812	26,700
Operating lease liabilities	394	—
Total long-term liabilities	28,215	30,567
Commitments and contingencies, see note 16		
Total liabilities	42,322	44,889
Equity:		
Teva shareholders' equity:		
Ordinary shares of NIS 0.10 par value per share; September 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	27,293	27,210
Accumulated deficit	(7,066)	(5,958)
Accumulated other comprehensive loss	(2,365)	(2,459)
Treasury shares as of September 30, 2019 and December 31, 2018 — 106 million ordinary shares	(4,128)	(4,142)
	13,790	14,707
Non-controlling interests	1,134	1,087
Total equity	14,925	15,794
Total liabilities and equity	$ 57,246	$ 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 September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net revenues	$ 4,264	$ 4,529	$12,896	$14,295
Cost of sales	2,435	2,552	7,318	7,970
Gross profit	1,830	1,977	5,579	6,325
Research and development expenses	240	311	778	918
Selling and marketing expenses	595	699	1,908	2,119
General and administrative expenses	285	309	873	954
Intangible assets impairment	177	519	1,206	1,246
Goodwill impairment	—	—	—	300
Other assets impairments, restructuring and other items	160	139	263	834
Legal settlements and loss contingencies	468	19	1,171	(1,239)
Other income	(14)	(35)	(29)	(334)
Operating income (loss)	(81)	16	(591)	1,527
Financial expenses, net	211	229	635	736
Income (loss) before income taxes	(292)	(213)	(1,226)	791
Income taxes (benefit)	11	(26)	(159)	(56)
Share in losses of associated companies, net	4	10	8	76
Net income (loss)	(307)	(197)	(1,076)	771
Net income attributable to non-controlling interests	7	11	33	35
Net income (loss) attributable to Teva	(314)	(208)	(1,108)	736
Dividends on preferred shares	—	65	—	195
Net income (loss) attributable to ordinary shareholders	$ (314)	$ (273)	$ (1,108)	$ 541
Earnings (loss) per share attributable to ordinary shareholders:				
Basic	$ (0.29)	$ (0.27)	$ (1.02)	$ 0.53
Diluted	$ (0.29)	$ (0.27)	$ (1.02)	$ 0.53
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 September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net income (loss)	$ (307)	$ (197)	$(1,076)	$ 771
Other comprehensive income (loss), net of tax:				
Currency translation adjustment	(138)	(105)	(5)	(577)
Unrealized gain from derivative financial instruments	87	19	124	75
Unrealized gain (loss) from available-for-sale securities	(2)	1	(1)	—
Unrealized gain (loss) on defined benefit plans	—	1	(1)	—
Total other comprehensive income (loss)	(53)	(84)	117	(502)
Total comprehensive income (loss)	(360)	(281)	(959)	269
Comprehensive income (loss) attributable to non-controlling interests	7	(26)	56	20
Comprehensive income (loss) attributable to Teva	$ (367)	$ (255)	$ (1,015)	$ 249

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 comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	(U.S. dollars in millions)									
Balance at June 30, 2018	1,124	54	3,760	23,426	(2,864)	(2,289)	(4,149)	17,938	1,430	19,368
Comprehensive loss					(208)	(46)		(255)	(26)	(281)
Issuance of Shares	1	**								**
Issuance of Treasury Shares				(1)			3	2		2
Stock-based compensation expense				44				44		44
Dividends to preferred shareholders			65	(65)						—
Balance at September 30, 2018	1,125	$ 54	$3,825	$ 23,404	$ (3,072)	$ (2,335)	$(4,146)	$ 17,730	$ 1,404	$ 19,134

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

	Teva shareholders' equity									
	Ordinary shares									
	Number of shares (in millions)	Stated value	MCPS *	Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	(U.S. dollars in millions)									
Balance at June 30, 2019	1,198	56	—	27,258	(6,752)	(2,312)	(4,128)	14,122	1,128	15,251
Comprehensive income (loss)					(314)	(53)		(367)	7	(360)
Issuance of Shares	**	**								**
Stock-based compensation expense				35				35		35
Balance at September 30, 2019	1,198	$ 56	—	$ 27,293	$ (7,066)	$ (2,365)	$(4,128)	$ 13,790	$ 1,134	$ 14,925

* 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 comprehensive (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)					736	(487)		249	20	269
Issuance of Treasury Shares				(1)			3	2		2
Dividends to preferred shareholders			194	(194)						—
Issuance of shares	1	**								**
Stock-based compensation expense				120				120		120
Transactions with non-controlling interests									(2)	(2)
Balance at September 30, 2018	1,125	$ 54	$3,825	$ 23,404	$ (3,072)	$ (2,335)	$(4,146)	$ 17,730	$ 1,404	$ 19,134

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

	Teva shareholders' equity									
	Ordinary shares									
	Number of shares (in millions)	Stated value	MCPS *	Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other comprehensive (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)					(1,108)	94		(1,015)	56	(959)
Issuance of Shares	2	**								**
Issuance of Treasury Shares				(8)			14	6		6
Stock-based compensation expense				99				99		99
Transactions with non-controlling interests									(8)	(8)
Other				(8)				(8)		(8)
Balance at September 30, 2019	1,198	$ 56	—	$ 27,293	$ (7,066)	$ (2,365)	$(4,128)	$ 13,790	$ 1,134	$ 14,925

* 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)

	Nine months ended September 30,	
	2019	**2018**
Operating activities:		
Net income (loss)	$(1,076)	$ 771
Adjustments to reconcile net income (loss) to net cash provided by operations:		
Depreciation and amortization	1,306	1,460
Impairment of long-lived assets	1,302	1,501
Net change in operating assets and liabilities	(784)	(1,521)
Deferred income taxes – net and uncertain tax positions	(652)	(650)
Stock-based compensation	99	122
Net loss (gain) from sale of long-lived assets and investments	10	(53)
Other items	5	(8)
Goodwill impairment	—	300
Impairment of equity investment	—	103
In process research and development	—	54
Net cash provided by operating activities	210	2,079
Investing activities:		
Beneficial interest collected in exchange for securitized trade receivables	1,108	1,372
Purchases of property, plant and equipment	(406)	(438)
Proceeds from sales of business, investments and long-lived assets	169	880
Other investing activities	59	34
Purchases of investments and other assets	(5)	(56)
Net cash provided by investing activities	925	1,792
Financing activities:		
Repayment of senior notes and loans and other long-term liabilities	(1,715)	(6,989)
Net change in short-term debt	96	(262)
Tax withholding payments made on shares and dividends	(52)	(22)
Other financing activities	(14)	(13)
Proceeds from senior notes and loans, net of issuance costs	—	4,434
Net cash used in financing activities	(1,685)	(2,852)
Translation adjustment on cash and cash equivalents	9	(107)
Net change in cash and cash equivalents	(541)	912
Balance of cash and cash equivalents at beginning of period	1,782	963
Balance of cash and cash equivalents at end of period	$1,241	$1,875
Non-cash financing and investing activities:		
Beneficial interest obtained in exchange for securitized trade receivables	$ 1,123	$ 1,345

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 nine months ended September 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) effective as of January 1, 2019, 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, second and third quarters of 2018 was an increase in cost of sales of $33 million, $28 million and $44 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 September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
	(U.S. $ in millions)	
Property, plant and equipment, net	24	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	$ 18	$ 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:

	September 30, 2019	December 31, 2018
	(U.S. $ in millions)	
Finished products	$ 2,517	$ 2,665
Raw and packaging materials	1,338	1,328
Products in process	621	590
Materials in transit and payments on account	160	148
Total	$ 4,636	$ 4,731

NOTE 5 – Property, plant and equipment:

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

	September 30, 2019	December 31, 2018
	(U.S. $ in millions)	
Machinery and equipment	$ 5,678	$ 5,691
Buildings	3,037	3,143
Computer equipment and other assets	2,120	2,097
Payments on account	616	514
Land	364	351
	11,816	11,796
Less—accumulated depreciation	(5,172)	(4,928)
Total	$ 6,643	$ 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	
	September 30, 2019	December 31, 2018	September 30, 2019	December 31, 2018	September 30, 2019	December 31, 2018
	(U.S. $ in millions)					
Product rights	$ 19,698	$ 20,361	$ 10,182	$ 9,565	$ 9,516	$ 10,796
Trade names	596	606	117	91	479	515
In process research and development	1,883	2,694	—	—	1,883	2,694
Total	$ 22,177	$ 23,661	$ 10,299	$ 9,656	$ 11,878	$ 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 $255 million and $297 million in the three months ended September 30, 2019 and 2018, respectively.

Amortization of intangible assets amounted to $823 million and $909 million in the nine months ended September 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) – $1,626 million; various generic products (Rimsa) – $46 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 September 30, 2019, Teva reclassified $15 million of products from IPR&D to product rights following regulatory approval.

In the first nine months of 2019, Teva reclassified $271 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 September 30, 2019 and 2018 were $177 million and $519 million, respectively. Impairments in the third quarter of 2019 consisted of:

a) Identifiable product rights of $99 million, mainly due to supply challenges in connection with products primarily marketed in Hong Kong.

b) IPR&D assets of $78 million, mainly related to 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.

Impairments of long-lived intangible assets for the nine months ended September 30, 2019 and 2018 were $1,206 million and $1,246 million, respectively. Impairments in the first nine months of 2019 consisted of:

a) Identifiable product rights of $667 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 $539 million, mainly related to: (i) $355 million of various 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, (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 and (iii) $59 million related to a change in assumptions concerning the future market share of a number of products within Teva's Actavis Generics pipeline in Europe.

NOTE 7 – Goodwill:

The changes in the carrying amount of goodwill for the period ended September 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)
Translation differences	11	(300)	57	—	(232)
Balance as of September 30, 2019 (1)	$11,086	$8,348	$ 2,536	$2,687	$24,657

(1) Accumulated goodwill impairment as of September 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.

During the third 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 the Company's reporting units was below its carrying amount. 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 October 2019, Teva reached a settlement with two counties in Ohio and confirmed that it had reached an agreement in principle with a group of attorneys general for a global settlement framework in connection with the remaining opioids litigations. These events did not result in a material change in share price compared to the share price used in the market capitalization analysis performed in the second quarter of 2019. Although Teva's fair value assessment is significantly higher than its market capitalization as of September 30, 2019, management still believes that its fair value assessment is reasonably supported.

Based on this assessment, management has concluded that it is not more likely than not that the fair value of any of the reporting units is below its carrying value as of September 30, 2019 and, therefore, no quantitative assessments were performed.

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 diluted loss per share for the three months ended September 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 September 30, 2018, no account was taken of the potential dilution by the mandatory convertible preferred shares, amounting to 66 million shares (including shares issued due to unpaid dividends up to 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 nine months ended September 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 nine months ended September 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 68 million shares (including shares issued due to unpaid dividends up to that date) for the nine months ended September 30, 2018, as well as for the convertible senior debentures, since both had an anti-dilutive effect on earnings 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 September 30, 2019				
	North America	Europe	International Markets	Other activities	Total
			(U.S. $ in millions)		
Sale of goods	1,674	1,153	511	176	3,514
Licensing arrangements	26	7	1	1	36
Distribution	351	1	176	—	528
Other	§	2	48	136	186
	$ 2,051	$1,163	$ 736	$ 314	4,264

§ Represents an amount less than $1 million.

	Three months ended September 30, 2018				
	North America	Europe	International Markets	Other activities	Total
			(U.S. $ in millions)		
Sale of goods	1,902	1,210	525	166	3,803
Licensing arrangements	29	1	—	2	32
Distribution	333	1	149	—	483
Other	1	—	52	158	211
	$ 2,265	$1,212	$ 726	$ 326	$ 4,529

	Nine months ended September 30, 2019				
	North America	Europe	International Markets	Other activities	Total
			(U.S. $ in millions)		
Sale of goods	4,997	3,586	1,505	566	10,653
Licensing arrangements	92	22	3	4	121
Distribution	1,080	1	491	—	1,572
Other	§	2	145	402	549
	$ 6,169	$3,611	$ 2,145	$ 972	$12,896

§ Represents an amount less than $1 million.

	Nine months ended September 30, 2018				
	North America	Europe	International Markets	Other activities	Total
			(U.S. $ in millions)		
Sale of goods	5,983	3,956	1,617	526	12,082
Licensing arrangements	91	19	21	6	137
Distribution	984	7	456	—	1,447
Other	1	—	171	457	629
	$ 7,059	$3,982	$ 2,265	$ 989	$14,295

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 82% of the Company's total SR&A as of September 30, 2019, with the remaining balance primarily in Canada and Germany. The changes in SR&A for third-party sales for the nine months ended September 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	334	4,004	760	7,196	195	308	12,463	12,797
Provisions related to sales made in prior periods	3	(28)	(2)	(1)	23	(7)	(15)	(12)
Credits and payments	(356)	(4,276)	(882)	(7,299)	(251)	(295)	(13,003)	(13,359)
Translation differences	—	(14)	(4)	(1)	(1)	1	(19)	(19)
Balance at September 30, 2019	$ 156	2,692	$ 1,233	$ 1,425	$ 604	$ 183	$ 6,137	$ 6,293

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**	(562)	—	54	—	(508)
Amounts reclassified to the statements of income	—	—	21	2	23
Net other comprehensive income (loss) before tax	(562)	—	75	2	(485)
Corresponding income tax	—	—	—	(2)	(2)
Net other comprehensive income (loss) after tax	(562)	—	75	—	(487)
Balance as of September 30, 2018	$ (1,878)	$ 1	$ (367)	$ (91)	$(2,335)

* 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 $15 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*	(28)	(1)	103	**	74
Amounts reclassified to the statements of income	—	—	21	—	21
Net other comprehensive income (loss) before tax	(28)	(1)	124	**	95
Corresponding income tax	—	—	—	**	**
Net other comprehensive income (loss) after tax	(28)	(1)	124	(1)	94
Balance as of September 30, 2019	$ (2,083)	$ —	$ (203)	$ (79)	$(2,365)

* Amounts do not include a $23 million gain from foreign currency translation adjustments attributable to non-controlling interests.
** Represents an amount less than $0.5 million.

NOTE 11 – Debt obligations:

a. Short-term debt:

	Weighted average interest rate as of September 30, 2019	Maturity	September 30, 2019	December 31, 2018
			(U.S. $ in millions)	
Bank and financial institutions	—	—	$ —	$ 2
Revolving Credit Facility	LIBOR+1.6%	—	100	—
Convertible debentures	0.25%	2026	514	514
Current maturities of long-term liabilities			2,516	1,700
Total short-term debt			$ 3,130	$ 2,216

Long-term debt:

	Weighted average interest rate as of September 30, 2019	Maturity	September 30, 2019	December 31, 2018
			(U.S. $ in millions)	
Senior notes EUR 1,660 million	0.38%	2020	$ 1,816	$ 1,897
Senior notes EUR 1,500 million	1.13%	2024	1,633	1,707
Senior notes EUR 1,300 million	1.25%	2023	1,416	1,480
Senior notes EUR 900 million	4.50%	2025	985	1,029
Senior notes EUR 750 million	1.63%	2028	814	850
Senior notes EUR 700 million	3.25%	2022	766	801
Senior notes EUR 700 million	1.88%	2027	764	798
Senior notes USD 3,500 million	3.15%	2026	3,494	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	—	1,700
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	857	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	354	356
Senior notes CHF 350 million	1.00%	2025	354	356
Fair value hedge accounting adjustments			—	(9)
Total senior notes			26,417	28,483
Other long-term debt	0.96%	2026	1	12
Less current maturities			(2,516)	(1,700)
Derivative instruments			—	9
Less debt issuance costs			(89)	(104)
Total senior notes and loans			$ 23,812	$ 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 September 30, 2019 is effectively denominated (taking into consideration cross currency swap agreements) in the following currencies: U.S. dollar 68%, euro 29% 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 September 30, 2019, $100 million was outstanding under the RCF. As of the date of this quarterly report on Form 10-Q, no amounts are 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 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 material transfers between Level 1, Level 2 and Level 3 during the first nine months of 2019.

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

	September 30, 2019			
	Level 1	Level 2	Level 3	Total
	(U.S. $ in millions)			
Cash and cash equivalents:				
Money markets	$ 176	$ —	$ —	$ 176
Cash, deposits and other	1,065	—	—	1,065
Investment in securities:				
Equity securities	45	—	—	45
Other, mainly debt securities	2	—	12	14
Derivatives:				
Asset derivatives—options and forward contracts	—	40	—	40
Asset derivatives—cross-currency swaps		105	—	105
Liability derivatives—options and forward contracts	—	(18)	—	(18)
Contingent consideration*	—	—	(430)	(430)
Total	$1,288	$ 127	$(418)	$ 997

	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:

	Nine months ended September 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	96
Eagle transaction	(100)
Settlement of contingent consideration:	
Eagle transaction	80
Fair value at the end of the period	$ (418)

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*	
	September 30, 2019	December 31, 2018
	(U.S. $ in millions)	
Senior notes included under senior notes and loans	$ 19,097	$ 23,560
Senior notes and convertible senior debentures included under short-term debt	2,933	2,140
Total	$ 22,030	$ 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 nine months of 2019, approximately 50% 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 within the Teva 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:

	September 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
	$ 1,588	$ 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	September 30, 2019	December 31, 2018	September 30, 2019	December 31, 2018
	(U.S. $ in millions)			
Asset derivatives:				
Other current assets:				
Option and forward contracts	$ —	$ —	$ 40	$ 18
Other non-current assets:				
Cross-currency swaps—cash flow hedge	103	58	—	—
Cross-currency swaps—net investment hedge	2	—	—	—
Liability derivatives:				
Other current liabilities:				
Option and forward contracts	—	—	(18)	(26)
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 months ended,		Three months ended,	
Reported under	September 30, 2019	September 30, 2018**	September 30, 2019	September 30, 2018**
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	$ 211	$ 229	$ 53	$ 84
Cross-currency swaps—cash flow hedge[1]	(1)	(1)	(33)	(4)
Cross-currency swaps—net investment hedge[2]	(7)	(6)	(39)	$ (7)
Interest rate swaps—fair value hedge[3]	$ *	$ *	$ —	$ —

* Represents an amount less than $0.5 million.

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

	Financial expenses, net		Other comprehensive income	
	Nine months ended,		Nine months ended,	
Reported under	September 30, 2019	September 30, 2018**	September 30, 2019	September 30, 2018**
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	$ 635	$ 736	$ (117)	$ 502
Cross-currency swaps—cash flow hedge[1]	(2)	(1)	(49)	(18)
Cross-currency swaps—net investment hedge[2]	(22)	(22)	(46)	$ (36)
Interest rate swaps—fair value hedge[3]	$ 2	$ *	$ —	$ —

* 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:

	Financial expenses, net		Net revenues	
	Three months ended,		Three months ended,	
Reported under	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	211	229	(4,264)	(4,529)
Option and forward contracts[4]	$ (35)	$ (6)	$ —	$ —
Option and forward contracts Economic hedge[5]	—	—	(4)	1

	Financial expenses, net		Net revenues	
	Nine months ended,		Nine months ended,	
Reported under	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	635	736	(12,896)	(14,295)
Option and forward contracts[4]	$ (42)	$ (11)	$ —	$ —
Option and forward contracts Economic hedge[5]	—	—	*	*

* Represents an amount less than $0.5 million.

(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. In the third quarter of 2019, Teva terminated this interest rate swap agreement. The settlement of these transactions resulted in a gain position of $10 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.

(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.

(5) Teva entered into option and forward contracts designed to limit the exposure of foreign exchange fluctuations on the euro (EUR), the British pound (GBP), the Russian ruble (RUB) and some other currencies denominated revenues with respect to the quarter for which such instruments are purchased. These derivative instruments do not meet the criteria for hedge accounting, however, they are accounted for as economic hedge. These derivative instruments are recognized on the balance sheet at their fair value, with changes in the fair value recognized under the same line item in the statements of income as the underlying exposure being hedged. The cash flows associated with these derivatives are reflected as cash flows from operating activities in the consolidated statements of cash flows.

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 September 30, 2019 and 2018, and losses of $22 million and $21 million were recognized under financial expenses, net for the nine months ended September 30, 2019 and 2018, respectively.

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 were 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, terminated in 2016 and in 2019 as described above, gains of $3 million and $2 million were recognized under financial expenses, net for the three months ended September 30, 2019 and 2018, respectively, and gains of $6 million and $5 million were recognized under financial expenses, net for the nine months ended September 30, 2019 and 2018, respectively.

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
	(U.S. $ in millions)			
Impairments of long-lived tangible assets[1]	$ 28	$ 2	$ 96	$ 255
Contingent consideration	51	29	4	84
Restructuring	61	88	140	442
Other	21	20	24	53
Total	$ 160	$ 139	$ 263	$ 834

(1) Including impairments related to exit and disposal activities

Impairments

Impairments of long-lived tangible assets for the three months ended September 30, 2019 and 2018 were $28 million and $2 million, respectively.

Impairments of long-lived tangible assets for the nine months ended September 30, 2019 and 2018 were $96 million and $255 million, respectively.

Teva may record additional impairments in the future, to the extent it changes its plans on any given asset and/or the assumptions underlying such plans as a result of its plant rationalization plan.

Contingent consideration

In the three months ended September 30, 2019, Teva recorded an expense of $51 million for contingent consideration, compared to an expense of $29 million in the three months ended September 30, 2018. The expenses in the third quarter of 2019 were mainly related to a change in the estimated future royalty payments from Eagle Pharmaceuticals, Inc. (“Eagle”) in connection with bendamustine sales.

In the nine months ended September 30, 2019, Teva recorded an expense of $4 million for contingent consideration, compared to an expense of $84 million in the nine months ended September 30, 2018. The expense in the first nine months of 2019 were mainly related to a change in the estimated future royalty payments from Eagle in connection with bendamustine sales and an increase in the expected future royalty payments to Eagle due to the orphan drug status granted to BENDEKA®, offset by the change in the future royalty payments in connection with lenalidomide (generic equivalent of Revlimid®), which was part of the Actavis Generics acquisition.

Restructuring

In the three months ended September 30, 2019, Teva recorded $61 million of restructuring expenses, compared to $88 million in the three months ended September 30, 2018.

In the nine months ended September 30, 2019, Teva recorded $140 million of restructuring expenses, compared to $442 million in the nine months ended September 30, 2018.

Since the announcement of its restructuring plan, Teva reduced its global headcount by 11,554 full-time-equivalent employees.

During the three months ended September 30, 2019 and 2018, Teva recorded impairments of property, plant and equipment related to restructuring costs of $8 million and $2 million, respectively.

During the nine months ended September 30, 2019 and 2018, Teva recorded impairments of property, plant and equipment related to restructuring costs of $29 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 September 30,	
	2019	2018
	(U.S. $ in millions)	
Restructuring		
Employee termination	$ 49	$ 62
Other	11	26
Total	$ 61	$ 88

	Nine months ended September 30,	
	2019	2018
	(U.S. $ in millions)	
Restructuring		
Employee termination	$ 105	$ 380
Other	34	62
Total	$ 140	$ 442

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	(105)	(34)	(140)
Utilization and other*	108	56	164
Balance as of September 30, 2019	$ (201)	$ (7)	$(208)

* 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 $63 million in revenues from this site in the remainder of 2019 and approximately $230 million in 2020, 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. As of September 30, 2019, the accumulated impact of this recall 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 third quarter of 2019, Teva recorded an expense of $468 million in legal settlements and loss contingencies, compared to $19 million in the third quarter of 2018. The expense in the third quarter of 2019 was mainly related to an increase in the estimated settlement provision recorded in connection with the remaining opioid cases.

In the first nine months of 2019, Teva recorded an expense of $1,171 million in legal settlements and loss contingencies, compared to income of $1,239 million in the first nine months of 2018. The expense in the first nine months of 2019 was mainly related to an estimated settlement provision recorded in connection with the remaining opioid cases.

As of September 30, 2019 and December 31, 2018, Teva's provision for legal settlements and loss contingencies recorded under accrued expenses was $1,601 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. The provision that was originally included in the financial statements following the damages verdict in this matter was reversed following the opinion overturning the verdict as the exposure was no longer considered probable. On May 25, 2018, both parties filed an appeal. A hearing was held on September 4, 2019 and Teva awaits the Court's decision. 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.

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, which was denied by the appellate court on November 4, 2019. Janssen and Millennium may apply for a leave to appeal to the Canadian Supreme Court. If the decision is ultimately overturned, 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. Teva and Helsinn agreed on a settlement in principle to settle their dispute regarding palonosetron, pending completion of final documentation. A provision with respect to the settlement in principle was included in the financial statements.

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 did not seek U.S. Supreme Court review of this decision so this matter is considered closed.

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 final court approval, and is fully covered by the settlement fund explained below.

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. The remaining balance of the settlement fund after consideration of the settlement with the State of California noted above is approximately $19 million. 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 non-financial 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"), from which Teva later acquired certain assets and liabilities, 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 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 also settled with most of the retailer plaintiffs in April 2019. 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 are now proceeding as individual plaintiffs, and trial on their claims has been scheduled to begin in February 2020. In addition, in August 2019, certain other direct-purchaser plaintiffs (who would have been members of the direct purchaser class, had it been certified) filed their own claims in federal court in Philadelphia, challenging (in one complaint) both the September 2006 settlement between Watson and Solvay referenced above, as well as Teva's December 2011 settlement with AbbVie involving AndroGel® and TriCor®, referenced below. The defendants have moved the Philadelphia court to transfer all of these claims to the same Georgia federal court that has been presiding over the multidistrict litigation, and that motion remains pending. 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 August 2019, the district court certified the direct-purchaser class, although the court has yet to rule on the indirect purchaser' pending motion for class certification. 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 also reached a settlement agreement. On September 16, 2019, end-payers Blue Cross Blue Shield of Michigan and Blue Care Network of Michigan filed their own lawsuit against Watson, and other defendants, in Michigan state court. That lawsuit was subsequently removed to federal court and remains pending.

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, but on October 8, 2019, the district court dismissed, with prejudice, the direct purchasers' claims against the generic manufacturers (including Teva, Actavis, and Watson). 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 federal court in Philadelphia alleging that they violated the antitrust laws when they entered into a December 2011settlement 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 August 2019, two groups of direct-purchaser plaintiffs filed similar claims against AbbVie and Teva, in the same federal court in Philadelphia where the FTC's claims had been pending. The first group is challenging Teva's December 2011 settlement with AbbVie, while the second group is challenging that settlement, as well as the September 2006 AndroGel® settlement between Watson and Solvay, referenced above. The defendants have moved to transfer the second group's claims to the Georgia federal court that is presiding over the multidistrict litigation related to the September 2006 settlement between Watson and Solvay. That motion remains pending.

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. In August 2019, the court denied the indirect purchasers' motion for class certification, and they filed a petition for immediate appellate review, which remains pending. The court granted the direct purchasers' motion for class certification in September 2019. 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 (since consolidated in federal court in Delaware) against Amgen and Teva related to the January 2, 2019 settlement. Both Cipla Limited and the putative class plaintiffs seek damages and injunctive relief and the defendants moved to dismiss their claims on October 15, 2019. Those motions remain pending. 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. Teva has reached an agreement in principle to resolve relators' claims, for which an estimated provision was included in the financial statements for the second quarter of 2019 with the remainder of such provisions recorded in the third quarter of 2019. Pending the parties' efforts to finalize the settlement agreement and related matters and obtain necessary approvals, the court adjourned the previously scheduled trial date of August 19, 2019 until January 6, 2020.

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. On September 27, 2019, the Court granted the DOJ's motion to dismiss.

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, more than 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, tribes 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. 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. Absent resolutions, trials are expected to proceed in several states in 2020. 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.

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. 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 in the second quarter of 2019. Given the relatively early stage 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 October 21, 2019, Teva reached a settlement with the two plaintiffs in the MDL Opioid Proceeding that was scheduled for trial for the Track One case, Cuyahoga and Summit Counties of Ohio. Under the terms of the settlement, Teva will provide the two counties with opioid treatment medication, buprenorphine naloxone (sublingual tablets), known by the brand name Suboxone®, with a value of $25 million at wholesale acquisition cost and distributed over three years to help in the care and treatment of people suffering from addiction, and a cash payment in the amount of $20 million, to be paid in four payments over three years.

Also on October 21, 2019, Teva and certain other defendants reached an agreement in principle with a group of Attorneys General from North Carolina, Pennsylvania, Tennessee and Texas for a nationwide settlement framework. The framework is designed to provide a mechanism by which the Company attempts to seek resolution of remaining potential and pending opioid claims by both the U.S. states and political subdivisions (i.e., counties, tribes and other plaintiffs) thereof. Under this agreement, Teva would provide buprenorphine naloxone (sublingual tablets) with an estimated value of up to approximately $23 billion at wholesale acquisition cost over a ten year period. In addition, Teva would also provide cash payments of up to $250 million over a ten year period. The Company cannot predict if the nationwide settlement framework will be finalized.

Following these developments, the Company considered a range of potential settlement outcomes. No single outcome in the range was considered to be more likely than any other outcome; accordingly, Teva accrued to the new low end of the range, resulting in an increase in our previously recorded estimated liability.

Separately, on April 27, 2018, Teva received subpoena requests from the DOJ seeking documents relating to the manufacture, marketing and sale of opioids. In August 2019, Teva received a grand jury subpoena from the United States Attorney's Office for the Eastern District of New York for documents related to the Company's anti-diversion policies and procedures and distribution of its opioid medications, in what the Company understands to be part of a broader investigation into manufacturers' and distributors' monitoring programs and reporting under the Controlled Substances Act. In September 2019, Teva received subpoenas from the New York State Department of Financial Services (NYDFS) as part of an industry-wide inquiry into the effect of opioid prescriptions on New York health insurance premiums. The Company is cooperating with NYDFS's inquiry and producing documents in response to the various subpoenas and requests for information. Currently, Teva cannot predict how the nationwide settlement framework agreement (if finalized) will affect these investigations. 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 their 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. On July 18, 2019, certain individual plaintiffs commenced a civil action in the Pennsylvania Court of Common Pleas of Philadelphia County against many of the defendants in the Pennsylvania MDL, including Teva and Actavis, but no complaint has been filed.

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. On September 25, 2019, the court denied in substantial part and granted in part the defendants' motions to dismiss. The court has yet to establish a pre-trial schedule.

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. Following the September 25, 2019 decision on the motions to dismiss in the Ontario Teachers Securities Litigation, Teva is awaiting the court's pre-trial schedule for this case.

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. Following the September 25, 2019 decision on the motions to dismiss in the Ontario Teachers Securities Litigation, Teva is awaiting the court's a pre-trial schedule for this case.

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. Following the September 25, 2019 decision on the motions to dismiss in the Ontario Teachers Securities Litigation, Teva is awaiting the court's pre-trial schedule for this case.

Between August 2018 and July 2019, sixteen 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 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. Teva is awaiting the court's pre-trial schedule for the cases filed in, or transferred to, the District of Connecticut.

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. Teva has filed a motion to transfer the case to the United States District Court for the District of Connecticut, which motion remains pending.

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 from time to time. 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 September 30, 2019		
	North America	Europe	International Markets
		(U.S. $ in millions)	
Revenues	$ 2,051	$1,163	$ 736
Gross profit	1,048	662	295
R&D expenses	156	63	21
S&M expenses	219	206	114
G&A expenses	112	56	32
Other income	(5)	(4)	(1)
Segment profit	$ 565	$ 341	$ 130

	Three months ended September 30, 2018		
	North America	Europe	International Markets
		(U.S. $ in millions)	
Revenues	$ 2,265	$1,212	$ 726
Gross profit	1,196	676	301
R&D expenses	158	62	21
S&M expenses	265	242	120
G&A expenses	128	74	37
Other (income) expense	(4)	1	—
Segment profit	$ 649	$ 297	$ 123

	Nine months ended September 30, 2019		
	North America	Europe	International Markets
		(U.S. $ in millions)	
Revenues	$ 6,169	$3,611	$ 2,145
Gross profit	3,155	2,066	877
R&D expenses	497	199	66
S&M expenses	756	637	348
G&A expenses	342	175	102
Other income	(6)	(5)	(2)
Segment profit	$ 1,566	$1,060	$ 363

	Nine months ended September 30, 2018		
	North America	Europe	International Markets
		(U.S. $ in millions)	
Revenues	$ 7,059	$3,982	$ 2,265
Gross profit	3,778	2,195	942
R&D expenses	528	208	70
S&M expenses	813	725	384
G&A expenses	357	243	115
Other income	(206)	(1)	(11)
Segment profit	$ 2,286	$1,020	$ 384

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
	(U.S. $ in millions)		(U.S. $ in millions)	
North America profit	$ 565	$ 649	$ 1,566	$ 2,286
Europe profit	341	297	1,060	1,020
International Markets profit	130	123	363	384
Total segments profit	1,036	1,069	2,989	3,690
Profit of other activities	16	35	92	87
	1,051	1,104	3,081	3,777
Amounts not allocated to segments:				
Amortization	255	297	823	909
Other assets impairments, restructuring and other items	160	139	263	834
Goodwill impairment	—	—	—	300
Intangible asset impairments	177	519	1,206	1,246
Gain on divestitures, net of divestitures related costs	(3)	(31)	(12)	(114)
Other R&D expenses (income)	(7)	60	(7)	82
Costs related to regulatory actions taken in facilities	11	1	28	6
Legal settlements and loss contingencies	468	19	1,171	(1,239)
Other unallocated amounts	72	84	201	226
Consolidated operating income (loss)	(81)	16	(591)	1,527
Financial expenses, net	211	229	635	736
Consolidated income (loss) before income taxes	$ (292)	$ (213)	$(1,226)	$ 791

b. Segment revenues by major products and activities:

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

	Three months ended September 30,	
	2019	2018
	(U.S. $ in millions)	
North America		
Generic products	$ 914	$ 922
COPAXONE	271	463
BENDEKA/TREANDA	124	161
ProAir*	71	107
QVAR	60	36
AJOVY	25	—
AUSTEDO	105	62
Anda	351	333
Other	131	182
Total	$ 2,051	$ 2,265

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

	Nine months ended September 30,	
	2019	2018
	(U.S. $ in millions)	
North America		
Generic products	$ 2,826	$ 2,957
COPAXONE	753	1,403
BENDEKA/TREANDA	353	502
ProAir*	194	352
QVAR	183	173
AJOVY	68	—
AUSTEDO	276	136
Anda	1,080	984
Other	436	554
Total	$6,169	$7,059

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

	Three months ended September 30,	
	2019	2018
	(U.S. $ in millions)	
Europe		
Generic products	$ 836	$ 845
COPAXONE	106	124
Respiratory products	87	93
Other	134	150
Total	$ 1,163	$ 1,212

	Nine months ended September 30,	
	2019	2018
	(U.S. $ in millions)	
Europe		
Generic products	$2,599	$2,749
COPAXONE	327	417
Respiratory products	267	312
Other	417	504
Total	$3,611	$3,982

	Three months ended September 30,	
	2019	2018
	(U.S. $ in millions)	
International markets		
Generic products	$ 474	$ 498
COPAXONE	20	14
Distribution	176	149
Other	66	65
Total	$ 736	$ 726

	Nine months ended September 30,	
	2019	2018
	(U.S. $ in millions)	
International markets		
Generic products	$1,404	$1,523
COPAXONE	46	52
Distribution	491	456
Other	204	233
Total	$2,145	$2,265

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 September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
	(U.S. $ in millions)		(U.S. $ in millions)	
Gain on divestitures, net of divestitures related costs (1)	$ 3	31	$ 12	114
Section 8 and similar payments (2)	—	1	—	195
Gain (loss) on sale of assets	3	1	(1)	9
Other, net	8	2	19	16
Total other income	$ 14	$ 35	$ 29	$ 334

(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 third quarter of 2019, Teva recognized a tax expense of $11 million, on pre-tax loss of $292 million. In the third quarter of 2018, Teva recognized a tax benefit of $26 million, or 12%, on pre-tax loss of $213 million. Teva's tax rate for the third quarter of 2019 was mainly affected by impairments, amortization, legal settlements with low corresponding tax effect and interest disallowance as a result of the U.S. Tax Cuts and Jobs Act.

In the first nine months of 2019, Teva recognized a tax benefit of $159 million, or 13%, on pre-tax loss of $1,226 million. In the first nine months of 2018, Teva recognized a tax benefit of $56 million on pre-tax income of $791 million. Teva's tax rate for the first nine months of 2019 was mainly affected by impairments, amortization, legal settlements with low corresponding tax effect 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, as well as infrequent or nonrecurring items.

Teva filed a claim seeking the refund of withholding taxes paid to the Indian tax authorities in 2012. Trial in this case is scheduled to begin in November 2019. A final and binding decision against Teva in this case may lead to an impairment in the amount of $146 million.

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 nine months ended September 30, 2018 and the 12 months ended December 31, 2018, was $131 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.

The new Lease 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 nine months ended September 30, 2019 were as follows:

	Three months ended September 30, 2019	Nine months ended September 30, 2019
	(U.S. $ in millions)	
Operating lease cost:		
Fixed payments and variable payments that depend on an index or rate	$ 45	$ 123
Variable lease payments not included in the lease liability	—	4
Short-term lease cost	1	4
Total operating lease cost	$ 46	$ 131

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

	Nine months ended September 30, 2019 (U.S. $ in millions)
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 130
Right-of-use assets obtained in exchange for lease obligations (non-cash):	
Operating leases	$ 70

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

	September 30, 2019 (U.S. $ in millions)
Operating leases:	$
Operating lease ROU assets	468
Other current liabilities	116
Operating lease liabilities	394
Total operating lease liabilities	$ 510

	September 30, 2019
Weighted average remaining lease term	
Operating leases	7.4 years
Weighted average discount rate	
Operating leases	5.9%

Maturities of operating lease liabilities were as follows:

	September 30, 2019 (U.S. $ in millions)
2019 (excluding the nine months ended September 30, 2019)	$ 38
2020	128
2021	98
2022	73
2023	51
2024 and thereafter	253
Total operating lease payments	$ 641
Less: imputed interest	131
Present value of lease liabilities	$ 510

	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 September 30, 2019, Teva has additional operating leases for office space which have yet to commence, with undiscounted future payments of $92 million. These operating leases will commence during fiscal year 2020 with lease terms of 9 to 12 years.

On October 10, 2019, Teva entered into an agreement to sell and lease back the land and building of its distribution center in Israel. Net proceeds from the asset sale amounted to $128 million.

As of September 30, 2019, Teva's total finance lease assets and finance lease liabilities are $77 million and $29 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 third quarter of 2019 included:

- Revenues in the third quarter of 2019 were $4,264 million, a decrease of 6%, or 5% in local currency terms, compared to the third quarter of 2018, mainly due to generic competition to COPAXONE®, a decline in revenues from BENDEKA® / TREANDA® and certain other specialty products in the United States, as well as declines in revenues in Russia and Japan, partially offset by higher revenues from AUSTEDO®, AJOVY® and QVAR® in the United States.
- Our North America segment generated revenues of $2,051 million and profit of $565 million in the third quarter of 2019. Revenues decreased by 9% compared to the third quarter of 2018, mainly due to a decline in revenues from COPAXONE and certain other specialty products, partially offset by higher revenues from AUSTEDO, AJOVY and QVAR. Profit decreased by 13%, mainly due to the changes in revenues described above, partially offset by cost reductions and efficiency measures as part of the restructuring plan.
- Our Europe segment generated revenues of $1,163 million and profit of $341 million in the third quarter of 2019. Revenues decreased by 4%. In local currency terms, revenues were flat compared to the third quarter of 2018, mainly due to strong new generic product launches and higher sales of OTC products, mostly offset by a decline in COPAXONE revenues due to competing glatiramer acetate products. Profit increased by 15%, mainly due to strong new generic product launches, cost reductions and efficiency measures as part of the restructuring plan, partially offset by the impact of currency fluctuations.
- Our International Markets segment generated revenues of $736 million and profit of $130 million in the third quarter of 2019. Revenues increased by 1% in both U.S. dollars and local currency terms, compared to the third quarter of 2018. The increase in revenues was mainly due to higher distribution activities in Israel, partially offset by lower sales in Japan and Russia. Profit increased by 6%, mainly due to cost reductions and efficiency measures as part of the restructuring plan.
- Intangible asset impairments were $177 million in the third quarter of 2019, compared to $519 million in the third quarter of 2018. The impairment expenses in the third quarter of 2019 were related to identifiable product rights of $99 million and IPR&D assets of $78 million. These impairments were mainly related to products acquired from Actavis Generics in the United States and Hong Kong.
- Operating loss was $81 million in the third quarter of 2019, compared to income of $16 million in the third quarter of 2018. The decrease was mainly due to higher provisions in connection with legal settlements and loss contingencies, partially offset by lower intangible asset impairments, lower R&D expenses and higher profit in our Europe segment.
- In the third quarter of 2019, we recorded an expense of $468 million in legal settlements and loss contingencies, compared to $19 million in the third quarter of 2018. The expense in the third quarter of 2019 was mainly related to an increase in the estimated settlement provision recorded in connection with the remaining opioid cases.
- Exchange rate movements between the third quarter of 2019 and the third quarter of 2018 negatively impacted revenues by $55 million and operating income by $19 million.

- As of September 30, 2019, our debt was $26,942 million, compared to $28,726 million as of June 30, 2019. The decrease was mainly due to repayment at maturity of our $1,556 million 1.7% senior notes, as well as decreased exchange rate fluctuations.
- Cash flow generated from operating activities during the third quarter of 2019 was $325 million, compared to $421 million in the third quarter of 2018. The decrease in cash flow in the third quarter of 2019 was mainly due to lower revenues and a reduction in sales reserves associated with the revenue decline.
- Cash flow generated from operating activities in the third quarter of 2019, net of cash received for capital investments and beneficial interest collected in exchange for securitized trade receivables, was $551 million, compared to $704 million in the third quarter of 2018. The decrease in cash flow in the third quarter of 2019 was mainly due to the reasons mentioned above, as well as higher capital investments during the third quarter of 2019 compared to the third quarter of 2018.

Transactions

On October 10, 2019, we entered into an agreement to sell and lease back the land and building of our distribution center in Israel. Net proceeds from the asset sale amounted to $128 million. See also note 20 to our consolidated financial statements.

Changes in Senior Management

In August 2019, we announced the departure of Mr. Michael McClellan from his role as Executive Vice President and Chief Financial Officer. On November 7, 2019, we announced that Mr. Eli Kalif was appointed Executive Vice President and Chief Financial Officer and a member of Teva Executive Management, effective December 22, 2019. In the interim period between Mr. McClellan's departure on November 8, 2019 and the beginning of Mr. Kalif's service on December 22, 2019, our President and Chief Executive Officer, Mr. Kåre Schultz, will perform the chief financial officer's functions.

In October 2019, we announced the departure of Dr. Carlo de Notaristefani from his role as Executive Vice President, Global Operations. Effective October 2, 2019, Mr. Eric Drapé was appointed Executive Vice President, Global Operations and a member of Teva Executive Management. Prior to this appointment, Mr. Drapé served as Executive Vice President and Chief Quality Officer.

In October 2019, Iris Beck-Codner stepped down from her role as Executive Vice President, Global Brand and Communications. Mark Sabag, Executive Vice President, Global Human Resources, assumed the responsibilities of the Global Brand and Communications function.

Results of Operations

Comparison of Three Months Ended September 30, 2019 to Three Months Ended September 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 September 30,		Percentage Change
	2019	2018	2019 - 2018
	%	%	%
Net revenues	100	100	(6)
Gross profit	43	44	(7)
Research and development expenses	6	7	(23)
Selling and marketing expenses	14	15	(15)
General and administrative expenses	7	7	(8)
Intangible assets impairment	4	11	(66)
Other assets impairments, restructuring and other items	4	3	15
Legal settlements and loss contingencies	11	§	NA
Other income	§	(1)	—
Operating income (loss)	(2)	§	—
Financial expenses, net	5	5	(8)
Income (loss) before income taxes	(7)	(5)	37
Income taxes (benefit)	§	(1)	—
Share in losses (income) of associated companies, net	§	§	NA
Net income attributable to non-controlling interests	§	§	NA
Net income (loss) attributable to Teva	(7)	(5)	51
Dividends on preferred shares	—	1	NA
Net income (loss) attributable to ordinary shareholders	(7)	(6)	15

§ 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 September 30, 2019 and 2018:

	Three months ended September 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 2,051	100%	$ 2,265	100.0%
Gross profit	1,048	51.1%	1,196	52.8%
R&D expenses	156	7.6%	158	7.0%
S&M expenses	219	10.7%	265	11.7%
G&A expenses	112	5.5%	128	5.7%
Other (income) expense	(5)	§	(4)	§
Segment profit*	$ 565	27.5%	$ 649	28.7%

* 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 third quarter of 2019 were $2,051 million, a decrease of $214 million, or 9%, compared to the third quarter of 2018, mainly due to a decline in revenues of COPAXONE and certain other specialty products, partially offset by higher revenues from AUSTEDO, AJOVY and QVAR.

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 September 30, 2019 and 2018:

	Three months ended September 30,		Percentage Change 2019-2018
	2019	2018	
	(U.S. $ in millions)		
Generic products	$ 914	$ 922	(1%)
COPAXONE	271	463	(41%)
BENDEKA/TREANDA	124	161	(23%)
ProAir®*	71	107	(34%)
QVAR	60	36	68%
AJOVY	25	—	NA
AUSTEDO	105	62	71%
Anda	351	333	5%
Other	131	182	(28%)
Total	$ 2,051	$ 2,265	(9%)

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

Generic products revenues in our North America segment in the third quarter of 2019 were $914 million flat compared to the third 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 third quarter of 2019 were epinephrine injection (the generic equivalent of EpiPen®), albuterol sulfate inhalation aerosol (ProAir® HFA authorized generic of Teva's specialty product), lidocaine transdermal patch (the generic equivalent of Lidoderm Patch®), amphetamine salt tablets (the generic equivalent of Adderall IR®) and icatibant acetate injection (the generic equivalent of Firazyr®).

In the third quarter of 2019, we led the U.S. generics market in total prescriptions and new prescriptions, with approximately 391 million total prescriptions (based on trailing twelve months), representing 10.6% of total U.S. generic prescriptions according to IQVIA data.

COPAXONE revenues in our North America segment in the third quarter of 2019 decreased by 41% to $271 million, compared to the third quarter of 2018, mainly due to generic competition in the United States.

COPAXONE revenues in the United States were $257 million in the third quarter of 2019.

Revenues of COPAXONE in our North America segment were 68% of global COPAXONE revenues in the third quarter of 2019, compared to 77% in the third quarter of 2018.

COPAXONE global sales accounted for approximately 9% of our global revenues in the third 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. A hearing for an appeal in this case has been set for June 2020.

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 third quarter of 2019 decreased by 23% to $124 million, compared to the third quarter of 2018, mainly due to the June 2018 launch of Belrapzo® (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. In September 2019, a patent infringement action against four of the five ANDA filers for generic versions of BENDEKA was tried in the United States District Court for the District of Delaware. We await a decision from the court, which could come as early as the first half of 2020. The asserted patents expire in 2031.

ProAir revenues in our North America segment in the third quarter of 2019 decreased by 34% to $71 million, compared to the third quarter of 2018, mainly due to lower volumes and 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% (46.5% including our ProAir HFA authorized generic) in terms of total number of prescriptions for albuterol inhalers during the third quarter of 2019, compared to 45.2% in the third 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 third quarter of 2019 increased by 68% to $60 million, compared to the third 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 19.9% in terms of total number of prescriptions during the third quarter of 2019, compared to 21.7% in the third quarter of 2018.

AJOVY revenues in our North America segment in the third quarter of 2019 were $25 million. AJOVY was approved by the FDA and launched in the United States in September 2018 for the preventive treatment of migraine in adults.

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 the litigation in the district court has been stayed pending resolution of the IPRs. The patent office hearing on the first set of six IPRs is scheduled for November 22, 2019 and the hearing on the remaining three IPRs is scheduled for January 8, 2020. 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 third quarter of 2019 increased by 71%, to $105 million, compared to $62 million in the third 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 in the third quarter of 2019 increased by 5% to $351 million, compared to $333 million in the third 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 third 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))*
Oseltamivir phosphate for oral suspension, 6 mg / mL	Tamiflu®	July	$ 281
Icatibant injection, 30 mg / 3 mL	Firazyr®	July	$ 304
Pregabalin capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg & 300 mg	Lyrica®	July	$ 5,456
Ramelteon tablets, 8 mg	Rozerem®	July	$ 91
Bisoprolol fumarate and hydrochlorothiazide tablets, 2.5 mg/6.25 mg, 5 mg/6.25 mg & 10 mg/6.25 mg **	Ziac®	August	$ 42
Doxycycline hyclate delayed-release tablets, USP, 50 mg & 200 mg	Doryx®	August	$ 20
Mycophenolic acid delayed-release tablets, USP, 180 mg & 360 mg	Myfortic® DR	August	$ 180
Epinephrine injection, USP (auto-injector), 0.15 mg/0.3 mL	EpiPen® and EpiPen Jr®	August	$ 201
Minocycline hydrochloride extended-release tablets, USP, 55 mg	Solodyn® ER	August	$ 44
Fulvestrant injection, 250 mg / 5 mL (50 mg/mL)	***	August	—
Triamcinolone acetonide injectable suspension, USP, 40 mg/mL (40 mg), 40 mg/mL (200 mg) & 40 mg/mL (400 mg)	Kenalog®-40	August	$ 135
Acyclovir cream, 5% ****	Zovirax®	August	$ 97
Fosaprepitant for injection, 150 mg/Vial	***	September	—
Treprostinil Injection, 1 mg/mL (20 mg), 2.5 mg/mL (50 mg), 5 mg/mL (100 mg) & 10 mg/mL (200 mg)	Remodulin®	September	$ 3

* The figures presented are for the twelve months ended in the calendar quarter immediately prior to our launch or re-launch.
** Authorized generic – Teva brand.
*** Approved via 505(b)(2) regulatory pathway; not equivalent to a brand product.
**** Authorized generic.

Our generic products pipeline in the United States includes, as of September 30, 2019, 244 product applications awaiting FDA approval, including 81 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 June 30, 2019 exceeding $112 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 98 of these products, or 119 products including final approvals where launch is pending a settlement agreement or court decision. Collectively, these first to file opportunities represent over $73 billion in U.S. brand sales for the twelve months ended June 30, 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 third 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))*
Ivermectin lotion, 0.5%	Sklice®	$ 81
Sildenafil, 10mg/mL	Revatio®	$ 189

* 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 September 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 (September 2019)	
TV-46000 (risperidone LAI)	Schizophrenia	LAI	3 (April 2018)	
Migraine and Pain				
fremanezumab (anti CGRP)	Post traumatic headache	Subcutaneous	2	
	fibromyalgia	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)	Discontinued.
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)	Expected to launch in the U.S. in November 2019.
HERZUMA® (formerly CT-P06)	(biosimilar to Herceptin® US)		Approved by FDA (December 2018) Approved in Canada (September 2019)	

North America Gross Profit

Gross profit from our North America segment in the third quarter of 2019 was $1,048 million, a decrease of 12%, compared to $1,196 million in the third 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 third quarter of 2019 decreased to 51.1%, compared to 52.8% in the third 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 third quarter of 2019 were $156 million, a decrease of 1%, compared to $158 million in the third quarter of 2018.

For a description of our R&D expenses in the third 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 third quarter of 2019 were $219 million, a decrease of 17%, compared to $265 million in the third 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 third quarter of 2019 were $112 million, a decrease of 12%, compared to $128 million in the third quarter of 2018. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan, partially offset by legal expenses.

North America Other Income (Expense)

Other income from our North America segment in the third quarter of 2019 was $5 million, compared to other income of $4 million in the third quarter of 2018.

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 third quarter of 2019 was $565 million, a decrease of 13%, compared to $649 million in the third 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, as well as cost reductions and efficiency measures as part of the restructuring plan.

Europe Segment

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

	Three months ended September 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 1,163	100%	$ 1,212	100%
Gross profit	662	56.9%	676	55.8%
R&D expenses	63	5.4%	62	5.1%
S&M expenses	206	17.7%	242	20.0%
G&A expenses	56	4.9%	74	6.1%
Other (income) expense	(4)	§	1	§
Segment profit*	$ 341	29.3%	$ 297	24.5%

* 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 third quarter of 2019 were $1,163 million, a decrease of 4% or $49 million, compared to the third quarter of 2018. In local currency terms, revenues were flat, mainly due to strong new generic product launches and higher sales of OTC products, mostly offset by a decline in COPAXONE revenues due to competing glatiramer acetate products.

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 September 30, 2019 and 2018:

	Three months ended September 30,		Percentage Change 2018-2019
	2019	2018	
	(U.S. $ in millions)		
Generic products	$ 836	$ 845	(1%)
COPAXONE	106	124	(14%)
Respiratory products	87	93	(7%)
Other	134	150	(10%)
Total	$ 1,163	$ 1,212	(4%)

Generic products revenues in our Europe segment in the third quarter of 2019, including OTC products, decreased by 1% to $836 million, compared to the third quarter of 2018. In local currency terms, revenues increased by 4% compared to the third quarter of 2018, mainly due to strong new generic product launches and higher sales of OTC products.

COPAXONE revenues in our Europe segment in the third quarter of 2019 decreased by 14% to $106 million, compared to the third quarter of 2018. In local currency terms, revenues decreased by 10%, mainly due to price reductions and volume decline resulting from competing glatiramer acetate products.

Revenues of COPAXONE in our Europe segment were 27% of global COPAXONE revenues in the third quarter of 2019, compared to 21% in the third 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 third quarter of 2019 decreased by 7% to $87 million, compared to the third quarter of 2018. In local currency terms, revenues decreased by 2%, mainly due to lower sales in the United Kingdom.

AJOVY was granted a Marketing Authorization by the European Medicines Agency ("EMA") in the European Union in a centralized process in April 2019. AJOVY launched in Germany on May 15, 2019 and we continue to progress with launches in other European Union countries. For information about AJOVY patent protection, see "—North America Revenues—Revenues by Major Product" above.

Product Launches and Pipeline

As of September 30, 2019, our generic products pipeline in Europe included 509 generic approvals relating to 66 compounds in 135 formulations, and approximately 1,140 marketing authorization applications pending approval in 37 European countries, relating to 135 compounds in 276 formulations in 30 countries.

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

Europe Gross Profit

Gross profit from our Europe segment in the third quarter of 2019 was $662 million, a decrease of 2% compared to $676 million in the third 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 third quarter of 2019 increased to 56.9%, compared to 55.8% in the third quarter of 2018. The increase was mainly due to lower cost of goods sold related to network optimization.

Europe R&D Expenses

R&D expenses relating to our Europe segment in the third quarter of 2019 were $63 million, an increase of 2% compared to $62 million in the third quarter of 2018.

For a description of our R&D expenses in the third 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 third quarter of 2019 were $206 million, a decrease of 15% compared to $242 million in the third 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 third quarter of 2019 were $56 million, a decrease of 24% compared to $74 million in the third 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 third quarter of 2019 was $341 million, an increase of 15%, compared to $297 million in the third quarter of 2018. The increase was mainly due to strong new generic product launches and cost reductions and efficiency measures as part of the restructuring plan, partially offset by the impact of currency fluctuations.

International Markets Segment

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

	Three months ended September 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 736	100%	$ 726	100%
Gross profit	295	40.1%	301	41.4%
R&D expenses	21	2.8%	21	2.9%
S&M expenses	114	15.4%	120	16.5%
G&A expenses	32	4.3%	37	5.1%
Other (income) expense	(1)	§	—	§
Segment profit*	$ 130	17.7%	$ 123	16.9%

* 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 third quarter of 2019 were $736 million, an increase of $10 million, or 1%, compared to the third quarter of 2018. In local currency terms, revenues increased 1% compared to the third quarter of 2018, mainly due to higher distribution activities in Israel, partially offset by lower sales in Japan and 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 September 30, 2019 and 2018:

	Three months ended September 30,		Percentage Change
	2019	2018	2018-2019
	(U.S. $ in millions)		
Generic products	$ 474	$ 498	(5%)
COPAXONE	20	14	39%
Distribution	176	149	18%
Other	66	65	3%
Total	$ 736	$ 726	1%

Generic products revenues in our International Markets segment in the third quarter of 2019, which include OTC products, decreased by 5% to $474 million, compared to the third quarter of 2018. In local currency terms, revenues decreased by 5%, mainly due to lower sales in Japan resulting from generic competition to off-patented products, as well as lower sales in Russia.

COPAXONE revenues in our International Markets segment in the third quarter of 2019 increased by 39% to $20 million, compared to $14 million in the third quarter of 2018. In local currency terms, revenues increased by 46%.

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

Distribution revenues in our International Markets segment in the third quarter of 2019 increased by 18% to $176 million, compared to $149 million in the third quarter of 2018. In local currency terms, revenues increased by 15%, mainly due to agreements with new distribution partners.

International Markets Gross Profit

Gross profit from our International Markets segment in the third quarter of 2019 was $295 million, a decrease of 2% compared to $301 million in the third quarter of 2018.

Gross profit margin for our International Markets segment in the third quarter of 2019 decreased to 40.1%, compared to 41.4% in the third quarter of 2018. The decrease was mainly due to changes in product mix.

International Markets R&D Expenses

R&D expenses relating to our International Markets segment in the third quarter of 2019 were $21 million, flat compared to the third quarter of 2018.

For a description of our R&D expenses in the third 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 third quarter of 2019 were $114 million, a decrease of 5% compared to $120 million in the third 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 third quarter of 2019 were $32 million, a decrease of 15% compared to $37 million in the third 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 third quarter of 2019 was $130 million, an increase of 6%, compared to $123 million in the third quarter of 2018. The increase was mainly due to 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 third quarter of 2019 were $314 million, a decrease of 4% compared to the third quarter of 2018. In local currency terms, revenues decreased by 2%.

API sales to third parties in the third quarter of 2019 were $176 million, an increase of 3%, in both U.S. dollar and local currency terms, compared to the third quarter of 2018.

Teva Consolidated Results

Revenues

Revenues in the third quarter of 2019 were $4,264 million, a decrease of 6%, or 5% in local currency terms, compared to the third quarter of 2018, mainly due to generic competition to COPAXONE, a decline in revenues from BENDEKA/TREANDA and certain other specialty products in the United States, as well as a decline in revenues in Russia 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 third quarter of 2019 negatively impacted revenues by $55 million compared to the third quarter of 2018.

Gross Profit

Gross profit in the third quarter of 2019 was $1,830 million, a decrease of 7% compared to the third 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 42.9% in the third quarter of 2019, compared to 43.7% in the third quarter of 2018.

The decrease in gross profit as a percentage of revenues was mainly due to lower profitability in North America, resulting mainly from a decline in COPAXONE revenues due to generic competition, partially offset by lower amortization expenses and higher profitability in Europe, resulting mainly from lower cost of goods sold related to network optimization.

Research and Development (R&D) Expenses

Net R&D expenses in the third quarter of 2019 were $240 million, a decrease of 23% compared to the third 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 third 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 third quarter of 2019, compared to the third quarter of 2018, primarily resulted from cost of labor reductions, pipeline optimization and project terminations, partially offset by increased investment in early stage projects.

R&D expenses as a percentage of revenues were 5.6% in the third quarter of 2019, compared to 6.9% in the third quarter of 2018.

Selling and Marketing (S&M) Expenses

S&M expenses in the third quarter of 2019 were $595 million, a decrease of 15% compared to the third 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 13.9% in the third quarter of 2019, compared to 15.4% in the third quarter of 2018.

General and Administrative (G&A) Expenses

G&A expenses in the third quarter of 2019 were $285 million, a decrease of 8% compared to the third 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 6.7% in the third quarter of 2019, compared to 6.8% in the third quarter of 2018.

Intangible Asset Impairments

We recorded expenses of $177 million for identifiable intangible asset impairments in the third quarter of 2019, compared to expenses of $519 million in the third quarter of 2018. See note 6 to our consolidated financial statements.

Goodwill Impairment

No goodwill impairments were recorded in the third quarter of 2019 and 2018.

Other Assets Impairments, Restructuring and Other Items

We recorded expenses of $160 million for other assets impairments, restructuring and other items in the third quarter of 2019, compared to expenses of $139 million in the third 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 $63 million in revenues from this site in the remainder of 2019 and approximately $230 million in 2020, 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. As of September 30, 2019, the accumulated impact of this recall 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 third quarter of 2019, we recorded $61 million of restructuring expenses, compared to $88 million in the third quarter of 2018. The expenses in the third 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 11,554 full-time-equivalent employees.

Legal Settlements and Loss Contingencies

In the third quarter of 2019, we recorded an expense of $468 million in legal settlements and loss contingencies, compared to $19 million in the third quarter of 2018. The expense in the third quarter of 2019 was mainly related to an increase in the estimated settlement provision recorded in connection with the remaining opioid cases. See note 16 to our consolidated financial statements.

Other Income

Other income in the third quarter of 2019 was $14 million, compared to $35 million in the third quarter of 2018.

Operating Income (Loss)

Operating loss was $81 million in the third quarter of 2019, compared to operating income of $16 million in the third quarter of 2018.

Operating income (loss) as a percentage of revenues was 1.9% in the third quarter of 2019, compared to 0.4% in the third quarter of 2018. The decrease was mainly due to higher provisions in connection with legal settlements and loss contingencies, partially offset by lower intangible asset impairments, lower R&D expenses and higher profit in our Europe segment.

Financial Expenses, Net

Financial expenses were $211 million in the third quarter of 2019, compared to $229 million in the third quarter of 2018. Financial expenses in the third quarter of 2019 were mainly comprised of interest expenses of $219 million. Financial expenses in the third quarter of 2018 were mainly comprised of interest expenses of $240 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 September 30, 2019 and 2018:

	Three months ended September 30,	
	2019	2018
	(U.S. $ in millions)	
North America profit	$ 565	$ 649
Europe profit	341	297
International Markets profit	130	123
Total segments profit	1,036	1,069
Profit of other activities	16	35
	1,051	1,104
Amounts not allocated to segments:		
Amortization	255	297
Other assets impairments, restructuring and other items	160	139
Goodwill impairment	—	—
Intangible asset impairments	177	519
Gain on divestitures, net of divestitures related costs	(3)	(31)
Other R&D expenses (income)	(7)	60
Costs related to regulatory actions taken in facilities	11	1
Legal settlements and loss contingencies	468	19
Other unallocated amounts	72	84
Consolidated operating income (loss)	(81)	16
Financial expenses, net	211	229
Consolidated income (loss) before income taxes	$ (292)	$ (213)

Tax Rate

In the third quarter of 2019, we recognized a tax expense of $11 million, on pre-tax loss of $292 million. In the third quarter of 2018, we recognized a tax benefit of $26 million, or 12%, on pre-tax loss of $213 million. Our tax rate for the third quarter of 2019 was mainly affected by impairments, amortization, legal settlements with low corresponding tax effect 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

Share in losses of associated companies, net in the third quarter of 2019 was $4 million, compared to $10 million in the third quarter of 2018.

Net Income (Loss)

Net loss attributable to Teva was $314 million in the third quarter of 2019, compared to net loss of $208 million in the third quarter of 2018.

Net loss attributable to ordinary shareholders was $314 million in the third quarter of 2019, compared to net loss of $273 million in the third 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 September 30, 2019 and 2018 were 1,092 million and 1,018 million shares, respectively.

In computing loss per share for the three months ended September 30, 2019 and 2018, 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 66 million shares (including shares issued due to unpaid dividends up to that date) for the three months ended September 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 $0.29 in the third quarter of 2019, compared to diluted loss per share of $0.27 in the third 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 September 30, 2019 and 2018, the fully diluted share count for purposes of calculating our market capitalization was approximately 1,107 million and 1,111 million, respectively.

Impact of Currency Fluctuations on Results of Operations

In the third 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 and Russian ruble) impact our results.

During the third 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 37%, British pound by 5% and euro by 4%. The following main currencies relevant to our operations increased in value against the U.S. dollar: Japanese yen by 4% and new Israeli shekel by 3%.

As a result, exchange rate movements during the third quarter of 2019 negatively impacted overall revenues by $55 million and our operating income by $19 million, in comparison with the third 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 Nine Months Ended September 30, 2019 to Nine Months Ended September 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 nine months ended September 30, 2019 and 2018. Additional factors affecting the nine 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		Percentage Change
	Nine Months Ended September 30,		
	2019	2018	2019 - 2018
	%	%	%
Net revenues	100.0	100.0	(10)
Gross profit	43.3	44.2	(12)
Research and development expenses	6.0	6.4	(15)
Selling and marketing expenses	14.8	14.8	(10)
General and administrative expenses	6.8	6.7	(8)
Other asset impairments, restructuring and other items	2.0	5.8	(69)
Goodwill impairment	—	2.1	—
Legal settlements and loss contingencies	9.1	(8.7)	—
Other income	(0.2)	(2.3)	(91)
Operating income (loss)	(4.6)	10.8	—
Financial expenses, net	4.9	5.1	(14)
Income (loss) before income taxes	(9.5)	5.6	—
Income taxes (benefit)	(1.2)	(0.4)	184
Share in (profits) losses of associated companies, net	0.1	0.5	(89)
Net income (loss) attributable to non-controlling interests	(0.3)	0.2	—
Net income (loss) attributable to Teva	(8.6)	5.1	—
Dividends on preferred shares	—	1.4	—
Net income (loss) attributable to ordinary shareholders	(8.6)	3.8	—

Segment Information

North America Segment

The following table presents revenues, expenses and profit for our North America segment for the nine months ended September 30, 2019 and 2018:

	Nine months ended September 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$6,169	100%	$7,059	100.0%
Gross profit	3,155	51.1%	3,778	53.5%
R&D expenses	497	8.0%	528	7.5%
S&M expenses	756	12.3%	813	11.5%
G&A expenses	342	5.5%	357	5.1%
Other (income) expense	(6)	§	(206)	(2.9%)
Segment profit*	$1,566	25.4%	$2,286	32.4%

* 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 nine months of 2019 were $6,169 million, a decrease of $890 million, or 13%, compared to the first nine 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 nine months ended September 30, 2019 and 2018:

	Nine months ended September 30,		Percentage Change
	2019	2018	2018-2019
	(U.S. $ in millions)		
Generic products	$2,826	$2,957	(4%)
COPAXONE	753	1,403	(46%)
BENDEKA/TREANDA	353	502	(30%)
ProAir*	194	352	(45%)
QVAR	183	173	6%
AJOVY	68	—	N/A
AUSTEDO	276	136	103%
Anda	1,080	984	10%
Other	436	554	(21%)
Total	$6,169	$7,059	

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

North America Gross Profit

Gross profit from our North America segment in the first nine months of 2019 was $3,155 million, a decrease of 17%, compared to $3,778 million in the first nine months of 2018.

Gross profit margin for our North America segment in the first nine months of 2019 decreased to 51.1% from 53.5% in the first nine months of 2018.

North America R&D Expenses

R&D expenses relating to our North America segment in the first nine months of 2019 were $497 million, a decrease of 6%, compared to $528 million in the first nine months of 2018.

North America S&M Expenses

S&M expenses relating to our North America segment in the first nine months of 2019 were $756 million, a decrease of 7%, compared to $813 million in the first nine months of 2018.

North America G&A Expenses

G&A expenses relating to our North America segment in the first nine months of 2019 were $342 million, a decrease of 4%, compared to $357 million in the first nine months of 2018.

North America Other Income (Expense)

Other income from our North America segment in the first nine months of 2019 was $6 million, compared to $206 million in the first nine months of 2018.

North America Profit

Profit from our North America segment in the first nine months of 2019 was $1,566 million, a decrease of 31%, compared to $2,286 million in the first nine months of 2018.

Europe Segment

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

	Nine months ended September 30,			
	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 3,611	100%	$ 3,982	100%
Gross profit	2,066	57.2%	2,195	55.1%
R&D expenses	199	5.5%	208	5.2%
S&M expenses	637	17.6%	725	18.2%
G&A expenses	175	4.8%	243	6.1%
Other (income) expense	(5)	§	(1)	§
Segment profit*	$ 1,060	29.4%	$ 1,020	25.6%

* 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 nine months of 2019 were $3,611 million, a decrease of 9% or $371 million, compared to the first nine months of 2018. In local currency terms, revenues decreased by 4% compared to the first nine months of 2018, mainly due to a decline in COPAXONE revenues due to 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 nine months ended September 30, 2019 and 2018:

	Nine months ended September 30,		Percentage Change 2018-2019
	2019	2018	
	(U.S. $ in millions)		
Generic products	$2,599	$2,749	(5%)
COPAXONE	327	417	(22%)
Respiratory products	267	312	(14%)
Other	417	504	(17%)
Total	$3,611	$3,982	(9%)

Europe Gross Profit

Gross profit from our Europe segment in the first nine months of 2019 was $2,066 million, a decrease of 6% compared to $2,195 million in the first nine months of 2018.

Gross profit margin for our Europe segment in the first nine months of 2019 increased to 57.2% from 55.1% in the first nine months of 2018.

Europe R&D Expenses

R&D expenses relating to our Europe segment in the first nine months of 2019 were $199 million, a decrease of 4%, compared to $208 million in the first nine months of 2018.

Europe S&M Expenses

S&M expenses relating to our Europe segment in the first nine months of 2019 were $637 million, a decrease of 12%, compared to $725 million in the first nine months of 2018.

Europe G&A Expenses

G&A expenses relating to our Europe segment in the first nine months of 2019 were $175 million, a decrease of 28%, compared to $243 million in the first nine months of 2018.

Europe Profit

Profit from our Europe segment in the first nine months of 2019 was $1,060 million, an increase of 4%, compared to $1,020 million in the first nine months of 2018.

International Markets Segment

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

	2019		2018	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 2,145	100%	$ 2,265	100%
Gross profit	877	40.9%	942	41.6%
R&D expenses	66	3.1%	70	3.1%
S&M expenses	348	16.2%	384	16.9%
G&A expenses	102	4.7%	115	5.1%
Other (income) expense	(2)	§	(11)	§
Segment profit*	$ 363	16.9%	$ 384	16.9%

* 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 nine months of 2019 were $2,145 million, a decrease of $120 million, or 5%, compared to the first nine months of 2018. In local currency terms, revenues decreased by 1% compared to the first nine 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 nine months ended September 30, 2019 and 2018:

	Nine months ended September 30,		Percentage Change
	2019	2018	2018-2019
	(U.S. $ in millions)		
Generic products	$1,404	$1,523	(8%)
COPAXONE	46	52	(12%)
Distribution	491	456	8%
Other	204	233	(13%)
Total	$2,145	$2,265	(5%)

International Markets Gross Profit

Gross profit from our International Markets segment in the first nine months of 2019 was $877 million, a decrease of 7%, compared to $942 million in the first nine months of 2018.

Gross profit margin for our International Markets segment in the first nine months of 2019 decreased to 40.9%, from 41.6% in the first nine months of 2018. The decrease was mainly due to lower sales in Japan.

International Markets R&D Expenses

R&D expenses relating to our International Markets segment in the first nine months of 2019 were $66 million, a decrease of 5%, compared to $70 million in the first nine months of 2018.

International Markets S&M Expenses

S&M expenses relating to our International Markets segment in the first nine months of 2019 were $348 million, a decrease of 9%, compared to $384 million in the first nine months of 2018.

International Markets G&A Expenses

G&A expenses relating to our International Markets segment in the first nine months of 2019 were $102 million, a decrease of 12%, compared to $115 million in the first nine months of 2018.

International Markets Profit

Profit from our International Markets segment in the first nine months of 2019 was $363 million, a decrease of 6%, compared to $384 million in the first nine months of 2018.

Other Activities

Our revenues from other activities in the first nine months of 2019 decreased by 2% to $972 million, compared to the first nine months of 2018. In local currency terms, revenues were flat.

API sales to third parties in the first nine months of 2019 increased by 6%, in both U.S. dollar and local currency terms, to $566 million, compared to the first nine months of 2018.

Teva Consolidated Results

Revenues

Revenues in the first nine months of 2019 were $12,896 million, a decrease of 10% or 7% in local currency terms, compared to the first nine months of 2018.

Exchange rate movements during the first nine months of 2019, compared to the first nine months of 2018, negatively impacted revenues by $357 million.

Gross Profit

Gross profit in the first nine months of 2019 was $5,579 million, a decrease of $746 million compared to the first nine months of 2018.

Gross profit as a percentage of revenues was 43.3% in the first nine months of 2019, compared to 44.2% in the first nine months of 2018.

Research and Development (R&D) Expenses

Net R&D expenses in the first nine months of 2019 were $778 million, a decrease of 15% compared to the first nine months of 2018.

R&D expenses as a percentage of revenues were 6.0% in the first nine months of 2019, compared to 6.4% in the first nine months of 2018.

Selling and Marketing (S&M) Expenses

S&M expenses in the first nine months of 2019 were $1,908 million, a decrease of 10% compared to the first nine months of 2018.

S&M expenses as a percentage of revenues were 14.8% in the first nine months of 2019, flat compared to the first nine months of 2018.

General and Administrative (G&A) Expenses

G&A expenses in the first nine months of 2019 were $873 million, a decrease of 8% compared to the first nine months of 2018.

G&A expenses as a percentage of revenues were 6.8% in the first nine months of 2019, compared to 6.7% in the first nine months of 2018.

Intangible Asset Impairments

We recorded expenses of $1,206 million for identifiable intangible asset impairments, in the first nine months of 2019, compared to expenses of $1,246 million in the first nine months of 2018. See note 6 to our consolidated financial statements.

Goodwill Impairment

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

Other Asset Impairments, Restructuring and Other Items

We recorded expenses of $263 million for other asset impairments, restructuring and other items in the first nine months of 2019, compared to expenses of $834 million in the first nine months of 2018. See note 14 to our consolidated financial statements.

Legal Settlements and Loss Contingencies

In the first nine months of 2019, we recorded an expense of $1,171 million in legal settlements and loss contingencies, compared to an income of $1,239 million in the first nine months of 2018. The expense in the first nine months of 2019 was mainly related to an estimated settlement provision recorded in connection with the remaining opioid cases. See note 16 to our consolidated financial statements.

Other Income

Other income in the first nine months of 2019 was $29 million, compared to $334 million in the first nine months of 2018.

Other income as a percentage of revenues was 0.2% in the first nine months of 2019, compared to 2.3% in the first nine months of 2018.

Operating Income (Loss)

Operating loss was $591 million in the first nine months of 2019, compared to an operating income of $1,527 million in the first nine months of 2018.

Financial Expenses, Net

Financial expenses were $635 million in the first nine months of 2019, compared to $736 million in the first nine months of 2018.

Financial expenses in the first nine months of 2019 were mainly comprised of interest expenses of $672 million, partially offset by $36 million of interest income. Financial expenses in the first nine months of 2018 were mainly comprised of interest expenses of $689 million, $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, as well as a $22 million loss resulting from our hedging and derivatives activities, partially offset by $33 million of interest income.

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 nine months ended September 30, 2019 and 2018:

	Nine months ended September 30,	
	2019	2018
	(U.S. $ in millions)	
North America profit	$ 1,566	$ 2,286
Europe profit	1,060	1,020
International Markets profit	363	384
Total segments profit	2,989	3,690
Profit (loss) of other activities	92	87
	3,081	3,777
Amounts not allocated to segments:		
Amortization	823	909
Other asset impairments, restructuring and other items	263	834
Goodwill impairment	—	300
Intangible asset impairments	1,206	1,246
Gain on divestitures, net of divestitures related costs	(12)	(114)
Other R&D expenses	(7)	82
Costs related to regulatory actions taken in facilities	28	6
Legal settlements and loss contingencies	1,171	(1,239)
Other unallocated amounts	201	226
Consolidated operating income (loss)	(591)	1,527
Financial expenses, net	635	736
Consolidated income (loss) before income taxes	$(1,226)	$ 791

Tax Rate

In the first nine months of 2019, we recognized a tax benefit of $159 million, or 13%, on pre-tax loss of $1,226 million. In the first nine months of 2018, we recognized a tax benefit of $56 million, on pre-tax income of $791 million. Our tax rate for the first nine months of 2019 was mainly affected by impairments, amortization, legal settlements with low corresponding tax effect 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 nine months of 2019 was $8 million, compared to share in losses of $76 million in the first nine months of 2018.

Net Income (Loss)

Net loss attributable to Teva was $1,108 million in the first nine months of 2019, compared to net income attributable to Teva of $736 million in the first nine months of 2018.

Net loss attributable to ordinary shareholders was $1,108 million in the first nine months of 2019, compared to net income of $541 million in the first nine 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 nine months ended September 30, 2019 and 2018 were 1,091 million and 1,020 million shares, respectively.

In computing diluted loss per share for the nine months ended September 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 nine months ended September 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 68 million shares (including shares issued due to unpaid dividends up to that date) for the nine months ended September 30, 2018, as well as for the convertible senior debentures, since both had an anti-dilutive effect on earnings per share.

Diluted loss per share was $1.02 in the first nine months of 2019, compared to diluted earnings per share of $0.53 in the first nine months of 2018.

Impact of Currency Fluctuations on Results of Operations

In the first nine months 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 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, Israeli shekel, Canadian dollar and Russian ruble) impact our results. During the first nine months of 2019, the following main currencies relevant to our operations decreased in value against the U.S. dollar: Argentinean peso by 44%, Polish zloty by 7%, Russian ruble by 6%, euro by 6% and British pound by 6% (all compared on a nine-month average basis).

As a result, exchange rate movements during the first nine months of 2019 negatively impacted overall revenues by $357 million and our operating income by $110 million, in comparison to the first nine months of 2018.

Liquidity and Capital Resources

Total balance sheet assets were $57,246 million as of September 30, 2019, compared to $59,424 million as of June 30, 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 $306 million as of September 30, 2019, compared to negative $65 million as of June 30, 2019.

Accrued expenses as of September 30, 2019, were $1,748 million, compared to $2,335 million as of June 30, 2019. The lower accrued expenses in the third quarter of 2019 resulted mainly from a reclassification of provisions made under legal settlements and loss contingencies in the second quarter of 2019 to long-term liabilities.

Investment in property, plant and equipment in the third quarter of 2019 was approximately $169 million, compared to $112 million in the second quarter of 2019. Depreciation in the third quarter of 2019 was $151 million, compared to $153 million in the second quarter of 2019.

Cash and cash equivalents and short-term and long-term investments as of September 30, 2019 were $1,301 million, compared to $2,232 million as of June 30, 2019. The decrease in the third quarter of 2019 was mainly due to repayment at maturity of our $1,556 million 1.7% senior note in July 2019, partially offset by 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 September 30, 2019, $100 million were outstanding under the RCF. As of the date of this quarterly report on Form 10-Q, no amounts are 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 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 September 30, 2019, our debt was $26,942 million, compared to $28,726 million as of June 30, 2019. The decrease was mainly due to repayment at maturity of our $1,556 million 1.7% senior notes, as well as exchange rate 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.

During the third quarter of 2019, we borrowed $500 million under the RCF and repaid $400 million of such borrowings. As of September 30, 2019, $100 million was outstanding under the RCF. As of the date of this Quarterly Report on Form 10-Q, no amounts were outstanding under the RCF.

Our debt as of September 30, 2019 was effectively denominated in the following currencies: 65% in U.S. dollars, 32% in euros and 3% in Swiss francs.

The portion of total debt classified as short-term as of September 30, 2019 was 12%, compared to 10% as of June 30, 2019.

Our financial leverage was 64% as of September 30, 2019, a slight decrease compared to 65% as of June 30, 2019.

Our average debt maturity was approximately 6.4 years as of September 30, 2019, compared to 6.3 years as of June 30, 2019.

Total Equity

Total equity was $14,925 million as of September 30, 2019, compared to $15,251 million as of June 30, 2019. The decrease was mainly due to $307 million of net loss and the negative impact of $138 million from exchange rate fluctuations, partially offset by $87 million of unrealized gain from derivative financial instruments in the third quarter of 2019.

Exchange rate fluctuations affected our balance sheet, as approximately 36% of our net assets in the third quarter of 2019 (including both non-monetary and monetary assets) were in currencies other than the U.S. dollar. When compared to June 30, 2019, changes in currency rates had a negative impact of $138 million on our equity as of September 30, 2019, mainly due to the changes in value against the U.S. dollar of: the Polish zloty by 7%, the Chilean peso by 7%, the euro by 4%, the Bulgarian lev by 4% and the British pound by 3%. All comparisons are on a quarter-end to quarter-end basis.

Cash Flow

Cash flow generated from operating activities during the third quarter of 2019 was $325 million, compared to $421 million in the third quarter of 2018. The decrease in the third quarter of 2019 was mainly due to lower revenues and a reduction in sales reserves associated with the revenue decline.

Cash flow generated from operating activities in the third quarter of 2019, net of cash received for capital investments and beneficial interest collected in exchange for securitized trade receivables, was $551 million, compared to $704 million in the third quarter of 2018. The decrease in cash flow was mainly due to the reasons mentioned above, as well as higher capital investments during the third quarter of 2019 compared to the third quarter of 2018.

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. TRUXIMA is expected to launch in the U.S. in November 2019.

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:

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

	Three Months Ended September 30, 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	2,435	220				11	7			35			2,162
R&D expenses	240						5			(7)			242
S&M expenses	595	35					9						551
G&A expenses	285						14			1			270
Other (income) expense	(14)								(3)				(11)
Legal settlements and loss contingencies	468		468										—
Other assets impairments, restructuring and other items	160			28	61			51		21			—
Intangible assets impairment	177			177									0
Financial expenses, net	211										3		208
Income taxes	11											(172)	183
Share in losses of associated companies – net	4												4
Net income (loss) attributable to non-controlling interests	7										(12)		19
Total reconciled items		255	468	204	61	11	35	51	(3)	51	(9)	(172)	
EPS—Basic	(0.29)											0.87	0.58
EPS—Diluted	(0.29)											0.87	0.58

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

	Three Months Ended September 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	2,552	246						1	7		30			2,268
R&D expenses	311				60				7		1			243
S&M expenses	699	51							14					634
G&A expenses	309								17		8			284
Other (income) expense	(35)										(31)			(4)
Legal settlements and loss contingencies	19		19											—
Other assets impairments, restructuring and other items	139			2		4	88			29	16			—
Intangible assets impairment	519			519										—
Financial expenses, net	229											(7)		236
Income taxes	(26)												(111)	85
Share in losses of associated companies – net	10											9		1
Net income (loss) attributable to non-controlling interests	11											(12)		23
Total reconciled items		297	19	521	60	4	88	1	45	29	24	(10)	(111)	
EPS—Basic	(0.27)												0.95	0.68
EPS—Diluted	(0.27)												0.95	0.68

The non-GAAP diluted weighted average number of shares was 1,022 million for the three months ended September 30, 2018.

	Nine Months Ended September 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	7,318	717					28	21			96				6,456
R&D expenses	778							17			(7)				768
S&M expenses	1,908	105						29							1,774
G&A expenses	873							37							836
Other (income) expense	(29)									(12)					(17)
Legal settlements and loss contingencies	1,171		1,171												—
Other assets impairments, restructuring and other items	263			96	2	140			4		22				—
Intangible assets impairment	1,206			1,206											—
Financial expenses, net	635											9			626
Income taxes	(159)												(662)	61	442
Share in losses of associated companies – net	8														8
Net income (loss) attributable to non-controlling interests	33											(28)			61
Total reconciled items		823	1,171	1,302	2	140	28	104	4	(12)	111	(19)	(662)	61	
EPS—Basic	(1.02)													2.80	1.78
EPS—Diluted	(1.02)													2.80	1.78

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

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

	Nine months ended September 30, 2018															
	U.S. $ and shares in millions (except per share amounts)															
	Excluded for non-GAAP measurement															
	GAAP	Amortization of purchased intangible assets	Goodwill impairment	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	Gain on sale of business	Other non GAAP items	Other items	Corresponding tax effect	Non GAAP
Cost of sales	7,970	771							6	22			94			7,077
R&D expenses	918					82				21			2			813
S&M expenses	2,119	138								35			(4)			1,950
G&A expenses	954									44			12			898
Other (income) expense	(334)											(114)				(220)
Legal settlements and loss contingencies	(1,239)			(1,239)												—
Other assets impairments, restructuring and other items	834				255		9	442			84		44			—
Intangible assets impairment	1,246				1,246											—
Goodwill impairment	300		300													—
Financial expenses, net	736													59		677
Income taxes	(56)														(479)	423
Share in losses of associated companies – net	76													103		(27)
Net income (loss) attributable to non-controlling interests	35													(32)		67
Total reconciled items																
Total reconciled items		909	300	(1,239)	1,501	82	9	442	6	122	84	(114)	148	130	(479)	
EPS—Basic	0.53														1.87	2.40
EPS—Diluted	0.53														1.86	2.39

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

Non-GAAP Tax Rate

Non-GAAP income taxes for the third quarter of 2019 were $183 million, or 22%, on pre-tax non-GAAP income of $843 million. Non-GAAP income taxes in the third quarter of 2018 were $85 million, or 10%, on pre-tax non-GAAP income of $868 million. Our non-GAAP tax rate for the third quarter of 2019 was mainly affected by legal settlements with low corresponding tax effect, interest expense disallowance and other changes to tax positions and deductions.

Non-GAAP income taxes for the first nine months of 2019 were $442 million, or 18%, on pre-tax non-GAAP income of $2,454 million. Non-GAAP income taxes in the first nine months of 2018 were $423 million, or 14% on pre-tax non-GAAP income of $3,100 million.

We expect our annual non-GAAP tax rate for 2019 to be 18%, which is higher than our previous projections and our non-GAAP tax rate for 2018. This is due to legal settlements with low corresponding tax effect, interest expense disallowance and other changes to tax positions and deductions. 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 September 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

In the third quarter of 2019 Teva completed the implementation of a company-wide enterprise resource planning (ERP) system in the U.S. to upgrade certain operational and financial processes. In connection with this ERP implementation, there have been changes in internal control over financial reporting during the quarter ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, the Company'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

Except as set forth below, 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.

Public concern over the abuse of opioid medications in the United States, including increased legal and regulatory action, could negatively affect our business.

Certain governmental and regulatory agencies are focused on the abuse of opioid medications in the United States. Federal, state and local governmental and regulatory agencies are conducting investigations of us, other pharmaceutical manufacturers and other supply chain participants with regard to the manufacture, sale, marketing and distribution of opioid medications. A number of state attorneys general, including a coordinated multistate effort, are investigating our sales and marketing of opioids and we have received subpoena requests from the U.S. Department of Justice seeking documents relating to the manufacture, marketing and sale of opioid medications. In addition, we are currently litigating civil claims brought by various states and political subdivisions as well as private claimants, against various manufacturers, distributors and retail pharmacies throughout the United States in connection with our manufacture, sale and distribution of opioids. On October 21, 2019, Teva and certain other defendants reached an agreement in principle with a group of Attorneys General from North Carolina, Pennsylvania, Tennessee and Texas for a nationwide settlement framework. The framework is designed to provide a mechanism by which Teva attempts to seek resolution of remaining potential and pending opioid claims by both the U.S. states and political subdivisions (i.e., counties, tribes and other plaintiffs) thereof. Under this agreement, Teva would provide buprenorphine naloxone (sublingual tablets), in quantities with an estimated value up to approximately $23 billion at wholesale acquisition cost over a ten year period. In addition, Teva would also provide cash payments of up to $250 million over a ten year period. This global settlement framework is predicated on settlement with all U.S. states and related subdivisions. Teva cannot predict if the nationwide settlement framework will be finalized. Responding to governmental investigations and managing legal proceedings is costly and involves a significant diversion of management attention. Such proceedings are unpredictable and may develop over lengthy periods of time. An adverse resolution of any of these lawsuits or investigations may involve substantial monetary penalties and could have a material and adverse effect on our reputation, business, results of operations and cash flows. See "Government Investigations and Litigation Relating to Pricing and Marketing" in note 16 to the consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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

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	Inline XBRL Instance Document (The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

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: November 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: November 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: November 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 September 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: November 7, 2019

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

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