TEVA PHARMACEUTICAL INDUSTRIES LTD Form 10-Q November 01, 2018 Table of Contents

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, 2018

OR

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

Commission file number 001-16174

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Exact name of registrant as specified in its charter)

Israel (State or other jurisdiction of incorporation or organization)

Not Applicable (IRS Employer Identification Number)

5 Basel Street, Petach Tikva, ISRAEL (Address of principal executive offices)

4951033 (Zip code)

+972 (3) 914-8171

(Registrant s telephone number, including area code)

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 October 30, 2018, the registrant had 1,018,711,443 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 Industric Limited and its subsidiaries, and references to revenues refer to net revenues. References to U.S. dollars, dollars, U.S. and are to the lawful currency of the United States of America, and references to NIS are to new Israeli shekels. References to MS are to multiple sclerosis. Market data, including both sales and share data, is based on information provided by IQVIA (formerly IMS Health Inc.), a provider of market research to the pharmaceutical industry (IQVIA), unless otherwise stated. References to Actavis Generics are to the generic pharmaceuticals business we purchased from Allergan plc (Allergan) on August 2, 2016. References to R&D are to Research and Development, references to IPR&D are to in-process R&D, references to S&M are to Selling and Marketing and references to G&A are to General and Administrative. Some amounts in this report may not add up due to rounding. All percentages have been calculated using unrounded amounts.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical information, this Quarterly Report on Form 10-Q, and the reports and documents incorporated by reference in this Quarterly Report on Form 10-Q, may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management s current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly

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

compliance, regulatory and litigation matters, including: costs and delays resulting from the extensive governmental regulation to which we are subject; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; 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 our Annual Report on Form 10-K for the year ended December 31, 2017, including the sections thereof captioned Risk Factors and Forward Looking Statements, and in our subsequent quarterly reports on Form 10-Q and other filings with the Securities and Exchange Commission, which are available at www.sec.gov and <a href="https://www.

PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS TEVA PHARMACEUTICAL INDUSTRIES LIMITED

CONSOLIDATED BALANCE SHEETS

(U.S. dollars in millions)

(Unaudited)

	Sept	ember 30, 2018	Dec	ember 31, 2017
ASSETS				
Current assets:				
Cash and cash equivalents	\$	1,875	\$	963
Trade receivables		5,665		7,128
Inventories		4,866		4,924
Prepaid expenses		911		1,100
Other current assets		483		701
Assets held for sale		81		566
Total current assets		13,881		15,382
Deferred income taxes		427		574
Other non-current assets		722		932
Property, plant and equipment, net		7,101		7,673
Identifiable intangible assets, net		15,345		17,640
Goodwill		27,585		28,414
Total assets	\$	65,061	\$	70,615
LIABILITIES AND EQUITY				
Current liabilities:				
Short-term debt	\$	2,673	\$	3,646
Sales reserves and allowances		6,701		7,881
Trade payables		1,626		2,069
Employee-related obligations		712		549
Accrued expenses		2,232		3,014
Other current liabilities		886		724
Liabilities held for sale				38
Total current liabilities		14,830		17,921
Long-term liabilities:				
Deferred income taxes		2,478		3,277

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Other taxes and long-term liabilities		1,803		1,843
Senior notes and loans		26,816		28,829
Total long-term liabilities		31,097		33,949
Commitments and contingencies, see note 16		45.005		51.050
Total liabilities		45,927		51,870
Equity:				
Teva shareholders equity:				
Preferred shares of NIS 0.10 par value per mandatory convertible preferred				
share; September 30, 2018 and December 31, 2017: authorized 5.0 million				
shares; issued 3.7 million shares		3,825		3,631
Ordinary shares of NIS 0.10 par value per share; September 30, 2018 and				
December 31, 2017: authorized 2,495 million shares; issued 1,125 million				
shares and 1,124 million shares, respectively		54		54
Additional paid-in capital		23,404		23,479
Accumulated deficit		(3,072)		(3,808)
Accumulated other comprehensive loss		(2,335)		(1,848)
Treasury shares as of September 30, 2018 and December 31, 2017 106 million				
ordinary shares and 107 million ordinary shares, respectively		(4,146)		(4,149)
		17,730		17,359
Non-controlling interests		1,404		1,386
Total conity		19,134		18,745
Total equity		19,134		10,743
Total liabilities and equity	\$	65,061	\$	70,615
1 over monitore with equity	Ψ	55,001	Ψ	70,013

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, 2018 2017					ended 30, 2017		
Net revenues	\$	4,529	\$	5,617	\$	14,295	\$	16,987
Cost of sales		2,508		2,967		7,865		8,643
Gross profit		2,021		2,650		6,430		8,344
Research and development expenses		311		531		918		1,432
Selling and marketing expenses		743		843		2,224		2,745
General and administrative expenses		309		372		954		1,101
Other asset impairments, restructuring and other items		658		550		2,080		1,209
Goodwill impairment						300		6,100
Legal settlements and loss contingencies		19		(20)		(1,239)		324
Other income		(35)		(4)		(334)		(100)
Operating income (loss)		16		378		1,527		(4,467)
Financial expenses, net		229		259		736		704
Income (loss) before income taxes		(213)		119		791		(5,171)
Tax benefits		(26)		(494)		(56)		(462)
Share in losses of associated companies, net		10		3		76		10
Net income (loss)		(197)		610		771		(4,719)
Net income attributable to non-controlling interests		11		15		35		11
Net income (loss) attributable to Teva		(208)		595		736		(4,730)
Dividends on preferred shares		65		65		195		195
Net income (loss) attributable to ordinary shareholders	\$	(273)	\$	530	\$	541	\$	(4,925)
Earnings (loss) per share attributable to ordinary shareholders:								
Basic	\$	(0.27)	\$	0.52	\$	0.53	\$	(4.85)
Diluted	\$	(0.27)	\$	0.52	\$	0.53	\$	(4.85)

Weighted average number of shares (in millions):

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Basic	1,018	1,017	1,018	1,016
Diluted	1,018	1,017	1,020	1,016

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,				N	s ended er 30,		
		2018	2	017	2018			2017
Net income (loss)	\$	(197)	\$	610	\$	771	\$	(4,719)
Other comprehensive income (loss), net of tax:								
Currency translation adjustment		(105)		264		(577)		1,136
Unrealized gain (loss) from derivative financial instruments		19		(49)		75		(118)
Unrealized gain (loss) from available-for-sale securities		1		(17)				20
Unrealized gain (loss) on defined benefit plans		1		1				(12)
Total other comprehensive income (loss)		(84)		199		(502)		1,026
Total comprehensive income (loss)		(281)		809		269		(3,693)
Comprehensive income (loss) attributable to non-controlling								
interests		(26)		11		20		75
Comprehensive income (loss) attributable to Teva	\$	(255)	\$	798	\$	249	\$	(3,768)

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 montl Septemb 2018	
Operating activities:		
Net income (loss)	\$ 771	\$ (4,719)
Adjustments to reconcile net income (loss) to net cash provided by operations:		
Net change in operating assets and liabilities	(1,521)	(1,717)
Depreciation and amortization	1,460	1,584
Impairment of long-lived assets	1,501	564
Deferred income taxes, net and uncertain tax positions	(650)	(733)
Goodwill impairment	300	6,100
Stock-based compensation	122	106
Impairment of equity investment	103	
Research and development in process	54	175
Net gain from sale of long-lived assets and investments	(53)	(48)
Other items	(8)	9
Venezuela impairment of net monetary assets		45
Net cash provided by operating activities	2,079	1,366
Investing activities:		
Beneficial interest collected in exchange for securitized trade receivables	1,372	962
Proceeds from sales of business, investments and long-lived assets	880	1,607
Purchases of property, plant and equipment	(438)	(607)
Purchases of investments and other assets	(56)	(194)
Other investing activities	34	(277)
Acquisitions of subsidiaries, net of cash acquired		43
Net cash provided by investing activities	1,792	1,534
Financing activities:		
Repayment of senior notes and loans and other long-term liabilities	(6,989)	(1,005)
Proceeds from senior notes and loans, net of issuance costs	4,434	507
Net change in short-term debt	(262)	(1,630)
Other financing activities	(13)	(69)
Dividends paid on ordinary shares	(12)	(814)
Dividends paid on preferred shares	(10)	(195)

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Dividends paid to non-controlling interests				(38)			
Net cash used in financing activities		(2,852)		(3,244)			
Translation adjustment on cash and cash equivalents		(107)		36			
Net change in cash and cash equivalents Balance of cash and cash equivalents at beginning of period		912 963		(308) 988			
Balance of cash and cash equivalents at end of period	\$	1,875	\$	680			
Non-cash financing and investing activities:							
Beneficial interest obtained in exchange for securitized trade receivables	\$	1,345	\$	911			
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, 2017, as filed with the Securities and Exchange Commission (SEC). Amounts as of December 31, 2017 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, 2018 are not necessarily indicative of results that could be expected for the entire fiscal year.

Note 2 Significant accounting policies:

Recently adopted accounting pronouncements

On January 1, 2018, Teva adopted the new accounting standard ASC 606, Revenue from Contracts with Customers, and all the related amendments (new revenue standard) to all contracts using the modified retrospective method. The cumulative effect of initially applying the new revenue standard was immaterial. See note 9 for further discussion.

In May 2017, the FASB issued guidance on changes to terms and conditions of share-based payment awards. The amendment provides guidance about which changes to terms or conditions of a share-based payment award require an entity to apply modification accounting. The guidance is effective for the fiscal year beginning on January 1, 2018, including interim periods within that year. Teva adopted the provisions of this update in the first quarter of 2018. The impact that this new standard has on Teva s financial statements after adoption will depend on any future modification of share-based compensation.

In February 2017, the FASB issued guidance on de-recognition of nonfinancial assets. The amendments address the recognition of gains and losses on the transfer (i.e., sale) of nonfinancial assets to counterparties other than customers. The guidance conforms de-recognition on nonfinancial assets with the model for transactions in the new revenue standard. Teva adopted the provisions of this update in the first quarter of 2018 with no material impact on its consolidated financial statements.

In August 2016, the FASB issued guidance on statements of cash flows. The guidance addresses eight specific issues: debt prepayment or debt extinguishment costs; settlement of certain debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interest in securitization transactions; and separately identifiable cash flows and application of predominance principle. The amendments should be applied retrospectively. Teva adopted the provisions of this update in the first quarter of 2018. This resulted in the reclassification of \$962 million of beneficial interest in securitization transactions from operating activities to investing activities for the nine month period ended September 30, 2017.

In January 2016, the FASB issued guidance which updates certain aspects of recognition, measurement, presentation and disclosure of equity investments. The guidance requires entities to recognize changes in fair value in net income rather than in accumulated other comprehensive income. Teva adopted the provisions of this update in the first quarter of 2018. Following the adoption, the Company recorded a \$5 million opening balance reclassification from accumulated other comprehensive loss to retained earnings. See note 10.

Recently issued accounting pronouncements, not yet adopted

In August 2018, the FASB issued guidance that 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 guidance that 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

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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 will need to 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 July 2018, the FASB issued a codification improvement, which does not prescribe any new accounting guidance, but instead provides minor improvements and clarifications to various FASB accounting guidance. Certain updates are applicable immediately while others provide for a transition period until the next fiscal year beginning after December 15, 2018. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In June 2018, the FASB issued guidance which 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. The guidance will be effective for fiscal years beginning after December 31, 2018, although early adoption is permitted. The Company does not expect that the adoption of this guidance will have a significant impact on its consolidated financial statements.

In February 2018, the FASB issued guidance on the reclassification of certain tax effects from accumulated other comprehensive income. The guidance allows reclassification of stranded tax effects resulting from the Tax Cuts and Jobs Act from accumulated other comprehensive income to retained earnings. This guidance is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company does not expect that the adoption of this guidance will have a significant impact on its consolidated financial statements.

In August 2017, the FASB issued guidance on derivatives and hedging, which 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. The guidance will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years (early adoption is permitted for any interim and annual financial statements that have not yet been issued). Teva is currently evaluating the potential effect of the guidance on its consolidated financial statements.

In June 2016, the FASB issued guidance on financial instruments. The 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.

In February 2016, the FASB issued guidance on leases. The guidance requires entities to record lease assets and lease liabilities on the balance sheet and disclose key information about leasing arrangements. In September 2017, the FASB issued additional amendments providing clarification and implementation guidance. The guidance will become effective for interim and annual periods beginning on January 1, 2019 (early adoption is permitted). In January 2018, the FASB issued an update that permits an entity to elect an optional transition practical expedient to not evaluate land easements that existed or expired before the entity s adoption of the new standard and that were not previously accounted for as leases. In July 2018, the FASB issued both codification improvements, which clarify how to apply certain aspects of the new lease standard and an update. The update provided to either adopt at the earliest period presented using a modified retrospective approach, or to continue applying the guidance under the current lease

standard in the comparative periods presented in the consolidated financial statements. Companies that elect this option would record a cumulative-effect adjustment to the opening balance of retained earnings on the date of adoption. The Company expects to apply the guidance using the cumulative-effect approach, thereby applying the new guidance at the effective date, without adjusting the comparative periods and, if necessary, recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

The Company is performing a comprehensive evaluation of the impact of the adoption of this guidance, which includes assessing the Company s lease portfolio, implementation of a new enterprise-wide lease management system to meet reporting requirements, assessing the impact to business processes and implementation of internal controls over financial reporting and related disclosure requirements. The Company is working closely with the software system developer, as the timely readiness of the lease software system is critical to ensure an efficient and effective adoption of the standard. Although the Company has not finalized its process of evaluating the impact of adoption of the ASU on its consolidated financial statements, the Company expects there will be a material increase to assets and liabilities related to the recognition of new right-of-use assets and lease liabilities on the Company s consolidated balance sheet for leases currently classified as operating leases. The Company does not, however, expect a material impact to its consolidated statements of income.

NOTE 3 Certain transactions:

Business acquisitions:

Actavis Generics and Anda acquisitions

On August 2, 2016, Teva consummated its 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 consummated the acquisition of Anda Inc. (Anda), the fourth largest distributor of generic pharmaceuticals in the United States, from Allergan, for cash consideration of \$500 million. The purchase is a transaction 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. Following the terms of the agreement, Teva submitted an adjustment for \$1.4 billion with regards to a working capital true up as well as potential recoveries of purchase price related to certain tax items. 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. The Agreement also provides that Teva and Allergan will jointly dismiss the working capital dispute arbitration, as well as actual or potential claims under the Master Purchase Agreement, dated July 26, 2015, by and between Teva and Allergan, for breach of any representation, warranty or covenant (other than any breach of a post-closing covenant not known as of the date of the settlement agreement). 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 on the breach of contract claim for which the sellers made a one-time payment to Teva. As the measurement period has ended, this was recorded as a gain under legal settlements and loss contingencies in the first quarter of 2018. This settlement was approved by the court and Teva s breach of contract claim was subsequently dismissed.

Assets and Liabilities Held For Sale:

Certain Women s Health and Other Specialty Products

On September 17, 2017, Teva entered into a definitive agreement under which CVC Capital Partners Fund VI would acquire a portfolio of products for \$703 million in cash. The portfolio of products, which is marketed and sold outside of the United States, includes the women shealth products OVALEAP, ZOELY®, SEASONIQUE®, COLPOTROPHINE® and other specialty products such as ACTONEL®.

As of December 31, 2017, the Company accounted for this transaction as assets and liabilities held for sale and determined that the fair value less cost to sell exceeded the carrying value of the business. The Company disposed \$329 million of goodwill associated with the divested business.

On January 31, 2018, Teva completed the sale of the portfolio of products to CVC Capital Partners Fund VI. As a result of these transactions, the Company recognized a net gain on sale of approximately \$93 million in the first quarter of 2018 within other income in the consolidated statement of income. The transaction expenses for these divestitures of approximately \$2 million were recognized concurrently and included as a reduction to the net gain on sale.

The Company determined that the sale of its global women s health businesses did not constitute a strategic shift and that it did not, and will not, have a major effect on its operations and financial results. Accordingly, the operations associated with the transactions are not reported as discontinued operations.

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The table below summarizes the major classes of assets and liabilities included as held for sale as of September 30, 2018 and December 31, 2017:

	September 30, 201 (U.S	18 Decemb 5. \$ in millio	· ·
Inventories			39
Property, plant and equipment, net (*)	41		16
Identifiable intangible assets, net			236
Goodwill (*)	40		275
Total assets of the disposal group classified as held for sale in the consolidated balance			
sheets	\$81	\$	566
Other taxes and long-term liabilities			38
Total liabilities of the disposal group classified as held for sale in the consolidated			
balance sheets	\$	\$	38

(*) Mainly comprised of certain facilities in Israel.

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.

PGT Healthcare Partnership

In April 2018, Teva signed a separation agreement with the Procter & Gamble Company (P&G) to terminate Teva s joint venture with 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.

The separation became effective on July 1, 2018. 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 will continue to provide 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 asset 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 to settle the dissolution.

Alder BioPharmaceuticals

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

AUSTEDO®

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

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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 fremanezumab 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 fremanezumab sales in Japan.

AttenukineTM

In December 2016, Teva entered into a license agreement for research, development, manufacture and commercializing of AttenukineTM 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.

Ninlaro®

In November 2016, Teva entered into an agreement to sell its royalties and other rights in Ninlaro® (ixazomib) to a subsidiary of Takeda, for a \$150 million upfront payment to Teva and an additional \$150 million payment based on sales during 2017. Teva was entitled to these royalties pursuant to an agreement from 2014 assigning the Ninlaro® patents to an affiliate of Takeda in consideration of milestone payments and sales royalties. In the first six months of 2017, Teva received payments in the amount of \$150 million, which were recognized as revenue for the period.

Celltrion

In October 2016, Teva and Celltrion, Inc. (Celltrion) entered into a collaborative agreement to commercialize two of Celltrion s 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 spain 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 and \$35 million were paid in the second quarter of 2017 and the first quarter of 2018, respectively, and a provision of \$60 million was recorded in the third quarter of 2018.

NOTE 4 Inventories:

Inventories, net of reserves, consisted of the following:

September 30, December 31, 2018 2017

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(U.S. \$ in millions) Finished products \$2,679 \$ 2,689 Raw and packaging materials 1,395 1,454 Products in process 609 597 Materials in transit and payments on account 183 184 \$4,866 \$ 4,924

NOTE 5 Property, plant and equipment:

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

	September 30, 2018	Dece	ember 31, 2017
	(U.S. \$ i	n milli	ions)
Machinery and equipment	\$ 5,783	\$	5,809
Buildings	3,179		3,329
Computer equipment and other assets	2,115		2,016
Payments on account	538		634
Land (1)	361		390
	11,976		12,178
Less accumulated depreciation	4,875		4,505
·			
	\$ 7,101	\$	7,673

(1) Land includes long-term leasehold rights in various locations, with useful lives between 30 and 99 years. **NOTE 6** Identifiable intangible assets:

Identifiable intangible assets consisted of the following:

	Gross carrying amount net of impairment September 30 December 31 Sep			amo	ımula rtizat Dece	ion	Net carrying amount September 30 December 31,			
	2018	2018 2017		2018 (U.S. \$	2018 2017 (U.S. \$ in millions)				2017	
Product rights	\$ 21,094	\$	21,011	\$9,132	\$	8,276	\$11,962	\$	12,735	
Trade names	610		617	82		55	528		562	
Research and development in										
process	2,855		4,343				2,855		4,343	
Total	\$ 24,559	\$	25,971	\$ 9,214	\$	8,331	\$ 15,345	\$	17,640	

Product rights and trade names are assets presented at amortized cost. These assets represent a portfolio of pharmaceutical products from various categories with a weighted average amortization life of approximately 11 years. Amortization of intangible assets was \$297 million and \$357 million for the three months ended September 30, 2018 and 2017, respectively and \$909 million and \$1,088 million for the nine months ended September 30, 2018 and 2017, respectively. Amortization is recorded under cost of sales or S&M expenses, depending on the nature of the asset.

The fair value of acquired identifiable intangible assets is generally determined using an income approach. This method starts with a forecast of all expected future net cash flows associated with the asset and then adjusts the forecast to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams.

Whenever impairment indicators are identified for definite life intangible assets, Teva reconsiders the asset s estimated life, calculates the undiscounted value of the asset s or asset group s cash flows and then calculates, if required, the discounted value of cash flow by applying an appropriate discount rate to the undiscounted cash flow streams. Teva then compares such value against the asset s or asset group s carrying amount. If the carrying amount is greater, Teva records an impairment loss for the excess of carrying value over fair value based on the discounted cash flows.

The more significant estimates and assumptions inherent in the estimate of the fair value of identifiable intangible assets include all assumptions associated with forecasting product profitability, including sales and cost to sell projections, R&D expenditure for ongoing support of product rights or continued development of IPR&D, estimated useful lives and IPR&D expected launch dates. Additionally, for IPR&D assets the risk of failure has been factored into the fair value measure.

Impairment of identifiable intangible assets of \$519 million and \$355 million for the three months ended September 30, 2018 and 2017, respectively and \$1,246 million and \$409 million for the nine months ended September 30, 2018 and 2017, respectively. Impairments of identifiable intangible assets are recorded in earnings under other asset impairments, restructuring and other items. See note 14.

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Additional reductions to IPR&D intangibles relate to reclassification to product rights following regulatory approvals of generic products and impairments of assets due to development status, changes in projected launch date or changes in commercial projections related to products under development.

In the first nine months of 2018, Teva reclassified approximately \$553 million relating to certain products from IPR&D to product rights following regulatory approval, mainly \$444 million in connection with AJOVY (fremanezumab) and \$103 million in connection with mesalamine.

NOTE 7 Goodwill:

The changes in the carrying amount of goodwill for the period ended September 30, 2018 were as follows:

					North	North International			
	Generics	Specialty (U.S. \$ in		Total	America	Europe (U.S. \$ in a		Other	Total
Balance as of December 31, 2017 (1)	\$ 18,864	\$ 8,464	\$ 1,086	\$ 28,414	\$	\$	\$	\$	\$
Relative fair value allocation	(18,864)	(8,464)	(1,086)	(28,414)	11,144	9,001	5,404	2,865	28,414
Balance as of January 1, 2018 Goodwill impairment ⁽³⁾					11,144	9,001	5,404 (300)	2,865	28,414 (300)
Goodwill disposal ⁽²⁾ Goodwill reclassified as assets to held for sale						(65)	(14)	(40)	(79)
Translation differences					(21)	(338)	(50)	(1)	(410)
Balance as of September 30, 2018 (1)	\$	\$	\$	\$	\$ 11,123	\$ 8,598	\$ 5,040	\$ 2,824	\$ 27,585

- (1) Accumulated goodwill impairment as of September 30, 2018 and December 31, 2017 was approximately \$18.3 billion and \$18.0 billion, respectively.
- (2) Due to the divestment of the women s health business, the sale of Actavis Brazil and other activity.
- (3) Due to the goodwill impairment related to the Rimsa and/or Mexico reporting unit.

In November 2017, Teva announced a new organizational structure and leadership changes to enable strategic alignment across its portfolios, regions and functions. Teva now operates its business through three segments: North America, Europe and International Markets. The purpose of the new structure is to enable stronger alignment and integration between operations, commercial regions, R&D and Teva s global marketing and portfolio function, in order to optimize its product lifecycle across the therapeutic areas. Teva began reporting its financial results under this structure in the first quarter of 2018.

In addition to these three segments, Teva has other activities, primarily the sale of active pharmaceutical ingredients (API) to third parties and certain contract manufacturing services. See note 17.

Following the announcement of its new organizational structure and leadership changes in November 2017, Teva conducted an analysis of its business segments, which led to changes in Teva s identified reporting units, operating and reporting segments. As a result, on January 1, 2018, Teva reallocated its goodwill to the adjusted reporting units using a relative fair value allocation. In conjunction with the goodwill reallocation, Teva performed a goodwill impairment test for the balances in its adjusted reporting units, utilizing the same annual operating plan (AOP) and long range plan model that were used in its 2017 annual impairment test; the Company concluded that the fair value of each reporting unit was in excess of its carrying value.

During the first quarter of 2018, Teva identified an increase in certain components of the weighted average cost of capital (WACC), such as an increase in the risk free interest and the unlevered beta. The Company addressed these changes in rates as an indication for impairment and performed an additional impairment test as of March 31, 2018.

Based on its revised analysis, Teva recorded a goodwill impairment of \$180 million related to its Rimsa reporting unit in the first quarter of 2018. The remaining goodwill allocated to this reporting unit was \$706 million as of March 31, 2018. This impairment was driven by the change in fair value, including the discount rate updated for the WACC change noted above, and the change in allocated net assets to the reporting unit. See note 3.

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In the second quarter of 2018, 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 exceeded their fair value:

Historically, Rimsa had been carved out as a separate reporting unit due to the significant operational challenges. Teva wanted to ensure that any impairment related to Rimsa would be recorded, by separating it from the International Markets reporting unit. During the second quarter of 2018, Rimsa and Teva Mexico substantially completed the integration process and as a result Teva decided to utilize the combined Mexico reporting unit for goodwill impairment testing, as opposed to Rimsa only in prior periods.

Following the integration, and although the remediation plan is progressing in connection with Rimsa legacy products, Teva estimates that the recovery time will be longer than initially planned, specifically in connection with the time to regain lost market share. As a result, the Company recorded an additional goodwill impairment charge of \$120 million related to its Mexico reporting unit in the second quarter of 2018.

Additionally, the Company identified further developments with respect to legislation proposed by the Russian Ministry of Health. The draft legislation includes, among other items, amendments in the mechanism of regulating prices for vital and essential medicines. The suggested amendments triggered a public discussion between authorities and pharmaceutical companies, which ended in the second quarter of 2018, followed by an internal discussion by the relevant authorities. The estimated impact of developments and uncertainties with respect to the final legislation in Russia were reflected in the LRP and triggered an impairment test for the International Markets reporting unit and related intangible assets, significantly decreasing the difference between the estimated fair value and estimated carrying value of the reporting unit, from 6% to 2%; however no impairment was recorded.

After assessing the totality of relevant events and circumstances, Teva determined that, as of the second quarter of 2018, it is not more likely than not that the fair value of its remaining reporting units is less than their carrying amount.

In light of the integration and the progress toward operational remediation in Rimsa as discussed above, Teva concluded that commencing July 1, 2018, it would no longer view Mexico separately from the International Markets reporting unit and accordingly will no longer perform impairment testing on Mexico as a separate reporting unit.

During the third quarter of 2018, Teva identified an increase in the risk free interest rate, which caused an increase in WACC. In addition, certain currencies in countries included in Teva's International Markets reporting unit experienced significant devaluations. Teva addressed these events as an indication for impairment and performed an additional impairment test for the International Markets and Europe reporting units as of September 30, 2018. Teva assumed that the currency devaluations would cause price increases of its imported goods to those countries which would not be completely offset by corresponding price adjustments to the selling price of Teva's goods. These changes decreased the difference between the estimated fair value and estimated carrying value of the International Markets reporting unit from 2% to 1% and of the Europe reporting unit from 6% to 4%, however, no impairment charge was recorded for either reporting unit.

In the third quarter of 2018, the fair value exceeded the estimated carrying value by 36% and 43% for North America and Other reporting units, respectively.

Based on current macro-economic developments and capital markets assumptions and holding all other assumptions constant, an increase in the risk free interest rate of 0.5% would result in an increase to Teva s WACC by approximately the same amount and consequently in a change in fair value of the International Markets reporting unit of \$653 million, resulting in an impairment of \$605 million. In addition, the same change in the Europe reporting unit would result in a change in fair value of \$871 million, resulting in an impairment of \$243 million.

Teva determines the fair value of its reporting units using a weighting of fair values derived from the income approach. The income approach is a forward-looking approach for estimating fair value and utilizes the 2018 remaining year forecast, projections for growth off that base with an associated price erosion, as well as terminal growth rate. Within the income approach, the method that was used is the discounted cash flow method. Teva started 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 applied 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 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.

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NOTE 8 Earnings (Loss) per share:

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

In computing the diluted loss per share for the three months ended September 30, 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. Diluted earnings per share for the three months ended September 30, 2017 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 66 million (including shares that may be issued due to unpaid dividends to date) for the three months ended September 30, 2018 and 59 million for the three months ended September 30, 2017, as well as for the convertible senior debentures for the respective periods, since both had an anti-dilutive effect on earnings (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. In computing loss per share for the nine months ended September 30, 2017, 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 68 million (including shares that may be issued due to unpaid dividends to date) for the nine months ended September 30, 2018 and 59 million for the nine months ended September 30, 2017, as well as for the convertible senior debentures for the respective periods, since both had an anti-dilutive effect on earnings (loss) per share.

NOTE 9 Revenue from contracts with customers:

On January 1, 2018, Teva adopted the new revenue standard to all contracts using the modified retrospective method. The cumulative effect of initially applying the new revenue standard was immaterial.

Revenue recognition prior to the adoption of the new revenue standard

Please refer to note 1 to the consolidated financial statements and critical accounting policies included in Teva s Annual Report on Form 10-K for the year ended December 31, 2017 for a summary of the significant accounting policies.

Revenue recognition following the adoption of the new revenue standard

A contract with a customer exists only when: the parties to the contract have approved it and are committed to perform their respective obligations, the Company can identify each party s rights regarding the distinct goods or services to be transferred (performance obligations), the Company can determine the transaction price for the goods or services to be transferred, the contract has commercial substance and it is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

Revenues are recorded in the amount of consideration to which the Company expects to be entitled in exchange for performance obligations upon transfer of control to the customer, excluding amounts collected on behalf of other third parties and sales taxes.

The amount of consideration to which Teva expects to be entitled varies as a result of rebates, chargebacks, returns and other sales reserve and allowances (SR&A) the Company offers its customers and their customers, as well as the occurrence or nonoccurrence of future events, including milestone events. A minimum amount of variable consideration is recorded concurrently with the satisfaction of performance obligations to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimates of variable consideration are based on historical experience and the specific terms in the individual agreements (which the Company believes approximates expected value). Rebates and chargebacks are the largest components of SR&A. For further description of SR&A components and how they are estimated, see Variable Consideration below.

Shipping and handling costs after control over a product has transferred to a customer are accounted for as a fulfillment cost and are recorded under S&M expenses.

Teva does not adjust the promised amount of consideration for the effects of a significant financing component since the Company expects, at contract inception, that the period between the time of transfer of the promised goods or services to the customer and the time the customer pays for these goods or services to be generally one year or less, based on the practical expedient. The Company s credit terms to customers are in average between thirty and ninety days.

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The Company generally recognizes the incremental costs of obtaining contracts as an expense since the amortization period of the assets that the Company otherwise would have recognized is one year or less. The costs are recorded under S&M expenses. Similarly, Teva does not disclose the value of unsatisfied performance obligations for contracts with original expected duration of one year or less.

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, 2018 International						
	North AmericaEurope		Market	s Othe	r activities	Total	
		(U.S. \$ in millions)					
Sale of goods	1,902	1,210	5:	25	166	3,803	
Licensing arrangements	29	1			2	32	
Distribution	333	1	14	49		483	
Other	1		:	52	158	211	
	\$ 2,265	\$ 1,212	\$ 72	26 \$	326	\$ 4,529	

Three months ended September 30, 2017						
International						
North AmericaEurope		Markets	Othe	r activities	Total	
(U.S. \$ in millions)						
2,724	1,321	67	72	168	4,885	
25			1	1	27	
294	59	14	16		499	
		(53	143	206	
\$ 3,043	\$ 1,380	\$ 88	32 \$	312	\$ 5,617	
	2,724 25 294	North AmericaEurope 2,724 1,321 25 294 59	North AmericaEurope North AmericaEurope 2,724 1,321 67 25 294 59 14	International North AmericaEurope Markets Other (U.S. \$ in millions) 2,724 1,321 672 25 1 294 59 146 63 63	International Markets Other activities (U.S. \$ in millions) 2,724 1,321 672 168 25 1 1 294 59 146 63 143	

		Nine months ended September 30, 2018					
		International					
	North Amer	North AmericaEurope		Other activiti	ies Total		
		(U.S. \$ in millions)					
Sale of goods	5,983	3,956	1,617	520	5 12,082		
Licensing arrangements	91	19	21	(5 137		
Distribution	984	7	456		1,447		
Other	1		171	457	7 629		
	\$7,059	\$ 3,982	\$ 2,265	\$ 989	\$ 14,295		

Nine months ended September 30, 2017

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	International				
	North AmericaEurope		Markets	Other activities	Total
	(U.S. \$ in millions)				
Sale of goods	8,338	3,848	1,862	567	14,615
Licensing arrangements	249	2	36	4	291
Distribution	864	166	406		1,436
Other	1		181	463	645
	\$ 9,452	\$ 4,016	\$ 2,485	\$ 1,034	\$ 16,987

Nature of revenue streams

Revenue from sales of goods, including sales to distributors is recognized when the customer obtains control of the product. This generally occurs when products are shipped once the Company has a present right to payment and legal title, and risk and rewards of ownership are obtained by the customer.

Licensing arrangements performance obligations generally include intellectual property (IP) rights, certain R&D and contract manufacturing services. The Company accounts for IP rights and services separately if they are distinct i.e. if they are separately

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identifiable from other items in the arrangement and if the customer can benefit from them on their own or with other resources that are readily available to the customer. The consideration is allocated between IP rights and services based on their relative stand-alone selling prices.

Revenue for distinct IP rights is accounted for based on the nature of the promise to grant the license. In determining whether the Company s promise is to provide a right to access its IP or a right to use its IP, the Company considers the nature of the IP to which the customer will have rights. IP is either functional IP which has significant standalone functionality or symbolic IP which does not have significant standalone functionality. Revenue from functional IP is recognized at the point in time when control of the distinct license is transferred to the customer, when the Company has a present right to payment and risks and rewards of ownership are transferred to the customer. Revenue from symbolic IP is recognized over the access period to the Company s IP.

Revenue from sales based milestones and royalties promised in exchange for a license of IP is recognized only when, or as, the later of subsequent sale or the performance obligation to which some or all of the sales-based royalty has been allocated, is satisfied. Revenues from licensing arrangements included royalty income of \$31 million and \$27 million for the three months ended September 30, 2018 and 2017, respectively. Revenues from licensing arrangements included royalty income of \$82 million and \$239 million for the nine months ended September 30, 2018 and 2017, respectively. The amounts recognized in 2017 include royalty income resulting from the Ninlaro® transaction.

Distribution revenues are derived from sales of third-party products for which the Company acts as distributor, mostly in the United States via Anda and in Israel. The Company is the principal in these arrangements and therefore records revenue on a gross basis as it controls the promised goods before transferring these goods to the customer. Revenue is recognized when the customer obtains control of the products. This generally occurs when products are shipped once the Company has a present right to payment and legal title, and risk and rewards of ownership are obtained by the customer.

Other revenues are primarily comprised of contract manufacturing services, sales of medical devices, and other miscellaneous items. Revenue is recognized when the customer obtains control of the products. This generally occurs when products are shipped once the Company has a present right to payment and legal title and risk and rewards of ownership are obtained by the customer.

Contract assets and liabilities

Contract assets are mainly comprised of trade receivables net of allowance for doubtful debts, which includes amounts billed and currently due from customers.

Contract liabilities are mainly comprised of deferred revenues which were immaterial as of September 30, 2018 and December 31, 2017, respectively.

Variable consideration

Variable consideration mainly includes 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. The following describes the nature of each deduction and how provisions are estimated:

Rebates

Rebates are primarily related to volume incentives and are offered to key customers to promote loyalty. These rebate programs provide that, upon the attainment of pre-established volumes or the attainment of revenue milestones for a specified period, the customer receives a rebate. Since rebates are contractually agreed upon, they are estimated based on the specific terms in each agreement based on historical trends and expected sales. Externally obtained inventory levels are evaluated in relation to estimates made for rebates payable to indirect customers.

Medicaid and Other Governmental Rebates

Pharmaceutical manufacturers whose products are covered by the Medicaid program are required to provide a rebate to each state as a percentage of their average manufacturer s price for the products dispensed. Many states have also implemented supplemental rebate programs that obligate manufacturers to pay rebates in excess of those required under federal law. The Company estimates these rebates based on historical trends of rebates paid, as well as on changes in wholesaler inventory levels and increases or decreases in sales.

Chargebacks

The Company has arrangements with various third parties, such as managed care organizations and drug store chains, establishing prices for certain of Teva s products. While these arrangements are made between the Company and the customers, the customers independently select a wholesaler from which they purchase the products. Alternatively, certain wholesalers may enter into

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agreements with the customers, with Teva s concurrence, which establish the pricing for certain products which the wholesalers provide. Under either arrangement, Teva will issue a credit (referred to as a chargeback) to the wholesaler for the difference between the invoice price to the wholesaler and the customer s contract price. Provisions for chargebacks involve estimates of contract prices of over 2,000 products and multiple contracts with multiple wholesalers. The provision for chargebacks varies in relation to changes in product mix, pricing and the level of inventory at the wholesalers and therefore will not necessarily fluctuate in proportion to an increase or decrease in sales. Provisions for estimating chargebacks are calculated using historical chargeback experience and/or expected chargeback levels for new products and anticipated pricing changes. Teva considers current and expected price competition when evaluating the provision for chargebacks. Chargeback provisions are compared to externally obtained distribution channel reports for reasonableness. The Company regularly monitors the provision for chargebacks and makes adjustments when the Company believes that actual chargebacks may differ from estimated provisions.

Other Promotional Arrangements

Other promotional or incentive arrangements are periodically offered to customers, specifically related to the launch of products or other targeted promotions. Provisions are made in the period for which the Company can estimate the incentive earned by the customer, in accordance with the contractual terms. The Company regularly monitors the provision for other promotional arrangements and makes adjustments when Teva believes that the actual provision may differ from the estimated provisions.

Shelf Stock Adjustments

The custom in the pharmaceutical industry is generally to grant customers a shelf stock adjustment based on the customers existing inventory contemporaneously with decreases in the market price of the related product. The most significant of these relate to products for which an exclusive or semi-exclusive period exists. Provisions for price reductions depend on future events, including price competition, new competitive launches and the level of customer inventories at the time of the price decline. Teva regularly monitors the competitive factors that influence the pricing of its products and customer inventory levels and adjust these estimates where appropriate.

Returns

Returns primarily relate to customer returns of expired products which, the customer has the right to return up to one year following the expiration date. Such returned products are destroyed and credits and/or refunds are issued to the customer for the value of the returns. Accordingly, no returned assets are recoded in connection with those products. The returns provision is estimated by applying a historical return rate to the amounts of revenue estimated to be subject to returns. Revenue subject to returns is estimated based on the lag time from time of sale to date of return. The estimated lag time is developed by analyzing historical experience. Additionally, The Company considers specific factors, such as levels of inventory in the distribution channel, product dating and expiration, size and maturity of launch, entrance of new competitors, changes in formularies or packaging and any changes to customer terms, for determining the overall expected levels of returns.

Prompt Pay Discounts

Prompt pay discounts are offered to most customers to encourage timely payment. Discounts are estimated at the time of invoice based on historical discounts in relation to sales. Prompt pay discounts are almost always utilized by customers. As a result, the actual discounts do not vary significantly from the estimated amount.

SR&A to U.S. customers comprised approximately 84% of the Company s total SR&A as of September 30, 2018, with the remaining balance primarily in Canada and Germany. The changes in SR&A for third-party sales for the period ended September 30, 2018 were as follows:

			S	ales Res	erv	es and A	llov	vances					
	Reserves included in Accounts Receivable net		gove	edicaid and other rnmenta owances(Cha	rgebacks U.S.\$ in							Γotal
Balance at December 31, 2017	\$ 196	\$ 3,077	\$	1,908	\$	1,849	\$	780	\$ 267	\$	7,881	\$	8,077
Provisions related to sale made in current year	S		Ψ	·	Ψ	ŕ	Ψ			Ψ	,		ŕ
period	380	4,956		931		7,738		232	309		14,166		14,546
Provisions related to sale made in prior periods	s 7	(39)		17		3		21	(19)		(17)		(10)
Credits and payments	(412)	(5,082)		(1,288)		(8,203)		(364)	(354)		(15,291)	(15,703)
Translation differences		(20)		(4)		(3)		(4)	(7)		(38)		(38)
Balance at September 30, 2018	, \$ 171	2,892	\$	1,564	\$	1,384	\$	665	\$ 196	\$	6,701	\$	6,872

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 Universe Foreign currency translation adjustments	Avail	ecurities	Der fin instr	ivative ancial	Act gains and sei (costs	fit Plans uarial /(losses) prior rvice)/credits	Total
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
	(562)				75		2	(485)

Net other comprehensive income (loss)

before tax

before tax					
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)

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^{*} 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)					Act	fit Plans uarial	
	Foreign currency translation adjustments		ecurities	fin inst	rivative ancial ruments in million	and se: (costs	/(losses) prior rvice /credits	Total
Balance, December 31, 2016	\$ (2,769)	\$	(7)	\$	(302)	\$	(81)	\$ (3,159)
Other comprehensive income (loss) before reclassifications Amounts reclassified to the statements of	1,124		56		(138)		(9)	1,033
income	(52)		(41)		20		2	(71)
Net other comprehensive income (loss) before tax Corresponding income tax	1,072		15 5		(118)		(7) (5)	962
Net other comprehensive income (loss) after tax *	1,072		20		(118)		(12)	962
Balance, September 30, 2017	\$ (1,697)	\$	13	\$	(420)	\$	(93)	\$ (2,197)

NOTE 11 Debt obligations:

Short-term debt:

	Weighted average interest rate as September 30, 2018	s of Maturity	September 3 2018 (U.S. \$	2017
Term loan JPY 28.3 billion (5)	JPY LIBOR+0.25%	2018	\$	\$ 251
Convertible debentures	0.25%	2026*	514	514
Other	9.37%	2018	1	1
Current maturities of long-term liabilities			2,158	2,880
Total short term debt			\$ 2,673	\$ 3,646

^{*} Amounts do not include a \$64 million gain from foreign currency translation adjustments attributable to non-controlling interests.

^{*} Net-share settlement feature exercisable at any time.

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Senior notes and loans:

	Weighted average interest		September 30,De	ecember 31,
	rate as of September 30, 2018	Maturity	2018	2017
	* %	·	(U.S. \$ in n	nillions)
Senior notes EUR 1,660 million (8)	0.38%	2020	\$ 1,924 \$	and the second second
Senior notes EUR 1,500 million	1.13%	2024	1,731	1,788
Senior notes EUR 1,300 million	1.25%	2023	1,501	1,550
Senior notes EUR 1,000 million (3)	2.88%	2019	,	1,199
Senior notes EUR 900 million (1)	4.50%	2025	1,045	ĺ
Senior notes EUR 750 million	1.63%	2028	863	891
Senior notes EUR 700 million (1)	3.25%	2022	812	
Senior notes EUR 700 million	1.88%	2027	810	837
Senior notes USD 3,500 million	3.15%	2026	3,493	3,492
Senior notes USD 3,000 million	2.20%	2021	2,997	2,996
Senior notes USD 3,000 million	2.80%	2023	2,993	2,992
Senior notes USD 1,700 million (8)	1.70%	2019	1,700	2,000
Senior notes USD 2,000 million	4.10%	2046	1,984	1,984
Senior notes USD 1,500 million (3)	1.40%	2018		1,500
Senior notes USD 1,250 million (2)	6.00%	2024	1,250	
Senior notes USD 1,250 million (2)	6.75%	2028	1,250	
Senior notes USD 844 million	2.95%	2022	862	864
Senior notes USD 789 million	6.15%	2036	782	781
Senior notes USD 700 million	2.25%	2020	700	700
Senior notes USD 613 million	3.65%	2021	622	624
Senior notes USD 588 million	3.65%	2021	587	587
Senior notes CHF 450 million	1.50%	2018	458	461
Senior notes CHF 350 million	0.50%	2022	357	360
Senior notes CHF 350 million	1.00%	2025	357	360
Senior notes CHF 300 million (9)	0.13%	2018		308
Fair value hedge accounting adjustments			(24)	(2)
Total senior notes			29,054	28,367
Term loan USD 2.5 billion (4)	LIBOR +1.1375%	2018	_,,,,,	285
Term loan USD 2.5 billion (4)	LIBOR +1.50%	2017-2020		2,000
Term loan JPY 58.5 billion (5)	JPY LIBOR +0.55%	2022		519
Term loan JPY 35 billion (6)	1.42%	2019		311
Term loan JPY 35 billion (6)	JPY LIBOR +0.3%	2018		311
Total loans				3,426
Debentures USD 15 million (7)	7.20%	2018		15
Other	7.78%	2026	6	5
Total debentures and others			6	20
Less current maturities			(2,158)	(2,880)

Derivative instruments	24	2
Less debt issuance costs	(110)	(106)
Total senior notes and loans	\$ 26,816	\$ 28,829

- (1) In March 2018, Teva Pharmaceutical Finance Netherlands II B.V., a Teva finance subsidiary, issued senior notes in an aggregate principal amount of 1.6 billion.
- (2) In March 2018, Teva Pharmaceutical Finance Netherlands III B.V., a Teva finance subsidiary, issued senior notes in an aggregate principal amount of \$2.5 billion.
- (3) In March 2018, Teva redeemed in full its \$1.5 billion 1.4% senior notes due in July 2018 and its 1.0 billion 2.88% senior notes due in April 2019.
- (4) During the first quarter of 2018, Teva prepaid approximately \$2.3 billion principal amount of the remaining term loan facilities.

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- (5) During the first quarter of 2018, Teva prepaid in full JPY 86.8 billion principal amount of the outstanding term loan facilities of which JPY 28.3 billion were in short-term debt as of December 31, 2017.
- (6) During the first quarter of 2018, Teva prepaid in full JPY 70 billion of its 1.42% and JPY LIBOR+0.3% outstanding term loans.
- (7) During the first quarter of 2018, Teva prepaid in full \$15 million of its outstanding debentures.
- (8) In September 2018, Teva consummated a cash tender offer for certain of its outstanding senior notes. As a result of the offer, Teva redeemed \$300 million aggregate principal amount of its 1.7% senior notes and 90 million principal amount of its 0.38% senior notes.
- (9) In July 2018, Teva repaid at maturity CHF 300 million of its 0.13% 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 (as defined), if any.

Long term debt as of September 30, 2018 is effectively denominated (taking into consideration cross currency swap agreements) in the following currencies: U.S. dollar 63%, euro 34% and Swiss franc 3%.

Teva s principal sources of short-term liquidity are its existing cash investments, liquid securities and available credit facilities, primarily its \$3 billion syndicated revolving credit facility (RCF), which was not utilized as of September 30, 2018, as well as internally generated funds. In connection with the requirements of the RCF, the Company entered into negative pledge agreements with certain banks and institutional investors. Under the agreements, the Company and its subsidiaries have undertaken not to register floating charges on assets in favor of any third parties without the prior consent of the banks, to maintain certain financial ratios, including the requirement to maintain compliance with a net debt to EBITDA ratio, which becomes more restrictive over time, and to fulfill other restrictions, as stipulated by the agreements. As of September 30, 2018, the Company did not have any outstanding debt under the RCF, which is its only debt subject to the net debt to EBITDA covenant. Assuming utilization of the RCF, and under specified circumstances, including non-compliance with such covenants and the unavailability of any waiver, amendment or other modification thereto and the expiration of any applicable grace period thereto, substantially all of the Company s debt could be negatively impacted by non-compliance with such covenants. The Company has sufficient resources to meet its financial obligations in the ordinary course of business for at least twelve months from the date of the release of this quarterly report.

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 term loans and bank facilities mostly approximates their carrying value, since they bear interest at rates close to the prevailing market rates.

Financial instruments measured at fair value

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

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

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

Level 2: Observable inputs that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available.

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In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs, to the extent possible, and considers counterparty credit risk in its assessment of fair value.

There were no transfers between Level 1, Level 2 and Level 3 during the first nine months of 2018.

Financial items carried at fair value as of September 30, 2018 and December 31, 2017 are classified in the tables below in one of the three categories described above:

	Level 1	Level 2	er 30, 2018 Level 3 n millions)	Total
Cash and cash equivalents:				
Money markets	\$ 302	\$	\$	\$ 302
Cash, deposits and other	1,573			1,573
Investment in securities:				
Equity securities	53			53
Other, mainly debt securities	2		18	20
Derivatives:				
Asset derivatives options and forward contracts		23		23
Asset derivatives cross currency swaps		42		42
Liabilities derivatives options and forward contracts		(14)		(14)
Liabilities derivatives interest rate and cross-currency swaps		(82)		(82)
Contingent consideration*		,	(717)	(717)
			,	,
Total	\$1,930	\$ (31)	\$ (699)	\$1,200
		, ,	, ,	
		Decembe	er 31, 2017	
	Level 1		Level 3 n millions)	Total

			December 31, 2017					
	Lev	vel 1	_	vel 2 .S. \$ in	Lev mill		T	otal
Cash and cash equivalents:								
Money markets	\$	5	\$		\$		\$	5
Cash, deposits and other		958						958
Investment in securities:								
Equity securities		65						65
Other, mainly debt securities		14				18		32
Derivatives:								
Asset derivatives options and forward contracts				17				17
Asset derivatives cross-currency swaps				25				25
Liability derivatives options and forward contracts				(15)				(15)
Liabilities derivatives interest rate and cross-currency swaps				(98)				(98)
Contingent consideration*					((735)		(735)
Total	\$ 1,	,042	\$	(71)	\$ ((717)	\$	254

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

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

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

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

	Septemb	onths ended per 30, 2018 in millions)
Fair value at the beginning of the period	\$	(717)
Adjustments to provisions for contingent		
consideration:		
Actavis Generics transaction		(21)
Labrys transaction		(17)
Eagle transaction		(46)
Settlement of contingent consideration:		
Eagle transaction		102
Fair value at the end of the period	\$	(699)

Financial instruments not measured at fair value

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

	Estimated fair value*				
	September 30, 2018 (ILS. \$ i	December 31 2017 in millions)			
Senior notes included under senior notes and loans	\$ 24,775	\$	23,459		
Senior notes and convertible senior debentures included under short-term debt	2,614		2,713		
Total	\$ 27,389	\$	26,172		

NOTE 13 Derivative instruments and hedging activities:

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

September 30, December 31, 2018 2017

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

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(U.S. \$ in millions)

	(C.S. 4 III IIIIIIIIII)		
Cross-currency swap cash flow hedge	\$ 588	\$	588
Cross-currency swap net investment hedge	1,000		1,000
Interest rate swap fair value hedge	500		500

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

	Fair value							
	Desig	gnated as	Not designated as					
	hedging instruments		he	dging				
			inst	rumen	ts			
	September 30	December 31 S e	eptember 30	Decen	iber 31,			
	2018	2017	2018	20	017			
Reported under		(U.S. \$ in	millions)					
Asset derivatives:								
Other current assets:								
Option and forward contracts	\$	\$	\$ 23	\$	17			
Other non-current assets:								
Cross-currency swaps cash flow hedge	42	25						
Liability derivatives:								
Other current liabilities:								
Option and forward contracts			(14)		(15)			
Other taxes and long-term liabilities:								
Cross-currency swaps net investment hedge	(58)	(96)						
Senior notes and loans:								
Interest rate swaps fair value hedge	(24)	(2)						

Derivatives on foreign exchange contracts mainly hedge Teva s balance sheet items from currency exposure but are not designated as hedging instruments for accounting purposes. With respect to such derivatives, gains of \$11 million and losses of \$72 million were recognized under financial expenses, net for the nine months ended September 30, 2018 and 2017, respectively, and gains of \$6 million and losses of \$14 million were recognized under financial expenses, net for the three months ended September 30, 2018 and 2017, respectively. Such losses and gains offset the revaluation of the balance sheet items which is also recorded under financial expenses, net.

During the second quarter of 2018, the Company entered into option contracts and designed these transactions to limit the exposure of foreign exchange fluctuations on the euro 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. During the third quarter of 2018, the impact of such derivative instruments was immaterial.

With respect to the interest rate and cross-currency swap agreements, gains of \$1 million and \$4 million were recognized under financial expenses, net for the nine months ended September 30, 2018 and 2017, respectively, and gains of \$0.5 million and \$1 million were recognized under financial expenses, net for the three months ended September 30, 2018 and 2017, respectively. Such gains mainly reflect the differences between the fixed interest rate and the floating interest rate.

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, 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 as part of other comprehensive income is 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 \$21 million and \$20 million were recognized under financial expenses, net for the nine months ended September 30, 2018 and 2017, respectively, and losses of \$7 million were recognized under financial expenses, net for each of the three months ended September 30, 2018 and 2017.

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In the third quarter of 2016, Teva terminated interest rate swap agreements designated as fair value hedge relating to certain senior notes. Settlement of these transactions resulted in a gain position of \$41 million. The fair value hedge accounting adjustments of these instruments recorded under senior notes and loans will be amortized under financial expenses, net over the life of the debt. With respect to these terminated interest rate swap agreements, gains of \$5 million were recognized under financial expenses, net for both the nine months ended September 30, 2018 and 2017, and gains of \$2 million were recognized under financial expenses, net for both the three months ended September 30, 2018 and 2017.

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.

In each of the first and second quarters of 2017, Teva entered into a cross currency swap agreement maturing in 2020 with a notional amount of \$500 million. These cross currency swaps were designated as a net investment hedge of Teva s euro denominated net assets, in order to reduce the risk of adverse exchange rate fluctuations. The effective portion of the hedge will be determined by looking into changes in spot exchange rate. The change in fair value of the cross currency swap attributable to changes other than those due to fluctuations in the spot exchange rates are excluded from the assessment of hedge effectiveness and are reported directly in the statement of income.

With respect to these cross currency swap agreements, gains of \$22 million and \$8 million were recognized under financial expenses, net for the nine months ended September 30, 2018 and 2017, respectively, and gains of \$6 million and \$4 million were recognized under financial expenses, net for the three months ended September 30, 2018 and 2017, respectively.

NOTE 14 Other asset impairments, restructuring and other items:

Other impairments, restructuring and other items consisted of the following:

	Three months ended Nine months ended						
	Septem	ber 30,	Septem	ber 30,			
	2018	2017	2018	2017			
		(U.S. \$ in millions)					
Restructuring expenses	\$ 88	\$ 72	\$ 442	\$ 300			
Integration and acquisition expenses	4	31	9	87			
Contingent consideration	29	18	84	179			
Impairments of long-lived assets	521	408	1,501	564			
Other	16	21	44	79			
Total	\$ 658	\$ 550	\$ 2,080	\$ 1,209			

In determining the estimated fair value of long-lived assets, Teva utilized a discounted cash flow model. The key assumptions within the model related to forecasting future revenue and operating income, an appropriate WACC and an appropriate terminal value based on the nature of the long-lived asset. The Company s updated forecasts of net cash flows for the impaired assets reflect, among others, the following: (i) for IPR&D assets, the impact of changes to the development programs, the projected development and regulatory timeframes and the risks associated with these assets; and (ii) for product rights, pricing and volume projections, as well as patent life and any significant changes to the competitive environment.

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

Impairments

Impairments of long-lived intangible assets in the third quarter of 2018 were \$519 million, mainly consisting of:

- a) IPR&D assets of \$306 million, mainly related to revaluation of generic products acquired from Actavis Generics due to development progress and changes in other key valuation indications (e.g., market size, legal landscape, launch date or discount rate).
- b) Identifiable product rights of \$185 million, mainly due to updated market assumptions regarding price and volume of products acquired from Actavis Generics currently marketed in the United States and supply constraints.

Impairments of property, plant and equipment of \$2 million.

Impairments of long-lived intangible assets in the first nine months of 2018 were \$1,246 million, mainly consisting of:

- a) IPR&D assets of \$867 million, mainly related to revaluation of generic products acquired from Actavis Generics due to development progress and changes in other key valuation indications (e.g., market size, legal landscape, launch date or discount rate).
- b) Identifiable product rights of \$328 million due to updated market assumptions regarding price and volume of products acquired from Actavis Generics currently marketed in the United States and supply constraints.

Impairments of property, plant and equipment in the first nine months of 2018 were \$255 million, mainly consisting of:

- a) \$155 million related to the restructuring plan, including:
 - \$113 million related to site closures in Israel; and
 - \$42 million related to the consolidation of headquarters and distribution sites in the United States.
- b) Other impairment costs, mainly \$64 million related to a plant located in India in connection with the P&G separation agreement. See note 3.

Restructuring

In the three months ended September 30, 2018, Teva recorded \$88 million of restructuring expenses, compared to \$72 million in the three months ended September 30, 2017.

In the first nine months of 2018, Teva recorded \$442 million of restructuring expenses, compared to \$300 million in the first nine months of 2017. The expenses in the first nine months of 2018 were primarily related to headcount reductions across all functions.

Since the announcement of its restructuring plan, Teva reduced its global headcount by approximately 9,100 full-time-equivalent employees.

During the three months ended September 30, 2018, Teva recorded a \$2 million impairment of property, plant and equipment related to restructuring costs.

During the first nine months of 2018 Teva recorded a \$155 million impairment of property, plant and equipment related to restructuring costs as detailed in Impairments above.

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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 mon		ed Septen 2017		
			millions)		
Restructuring	(-				
Employee termination	\$	62	\$	54	
Other		26		18	
Total	\$	88	\$	72	
	201	Septemb 18	ths ended per 30, 2017 millions)		
Other	`		ĺ		
Cost of sales	\$	8	\$	3	
Selling and marketing expenses				3	
Other items	Nine months en September 30 2018 2				
D ()	(U	.S. \$ in r	millions)		
Restructuring	ф	380	¢	220	
Employee termination Other	\$	62	\$	228 72	
Other		02		12	
Total	\$	442	\$	300	
	Nine mont		d Septem 2017		
		-	2017 (millions		
Other	(0	ф 111 1	111110113)		
Cost of sales	\$	23	\$	5	
Selling and marketing expenses	Ψ	23	Ŷ	3	
Other items		54		J	
	41 C	J-T			

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

Employee	
termination costs Other	Total

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Provision	(U.S	(U.S. \$ in millio							
Balance as of January 1, 2018	\$ (294)	\$ (17)	\$ (311)						
Provision	(380)	(62)	(442)						
Utilization and other*	418	51	469						
Balance as of September 30, 2018	\$ (256)	\$ (28)	\$ (284)						

* Includes adjustments for foreign currency translation.

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). Teva is working diligently to investigate the FDA s observations in a manner consistent with Current Good Manufacturing Practices (CGMPs) and to address those observations as quickly and as thoroughly as possible. The impact of such investigation and remediation on the financial statements in the third quarter of 2018 was immaterial. However, if Teva is unable to remediate the findings in a timely manner, Teva may face additional consequences, including potential delays in FDA approval for future products from the site, other financial implications due to loss of revenues, impairments, inventory write offs, customer penalties, idle capacity charges and other costs of remediation.

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 an unexpected impurity in the API provided by a third party supplier, Zhejiang Huahai

Pharmaceutical (Zhejiang), used in the production of such medicines. On September 28, 2018, the FDA issued an import ban on all APIs and other drug products made by Zhejiang in its Chuannan site into the United States. On the same date, the EU authorities issued to Zhejiang a statement of non-compliance for the manufacture of valsartan (and its intermediates) for EU medicines produced in the Chuannan site, thus prohibiting marketing authorization holders in the EU from using such valsartan materials in the production of finished products. On October 15, 2018, the EU authorities announced that Zhejiang was under increased supervision with respect to other APIs produced by Zhejiang. Many regulatory agencies around the world continue to review information relating to valsartan medicines and the sartan products as a group. The impact of this recall on the Company's financial statements in the first nine months of 2018 was \$46 million, primarily related to recall and inventory reserves. Depending on the scope of regulatory actions, duration of the API outage and severity of the impurity, Teva may face additional loss of revenues and profits, customer penalties, impairments and/or other litigation costs.

NOTE 15 Legal settlements and loss contingencies:

In the third quarter of 2018, the Company recorded expenses of \$19 million for legal settlements and loss contingencies, compared to income of \$20 million in the third quarter of 2017.

In the first nine months of 2018, Teva recorded income of \$1,239 million in connection with legal settlements, compared to an expense of \$324 million in the first nine months of 2017. The income in the first nine months of 2018 consisted primarily of the working capital adjustment with Allergan, the Rimsa settlement and reversal of the reserve recorded in the second quarter of 2017 with respect to the carvedilol patent litigation.

As of September 30, 2018 and December 31, 2017 Teva s provision for legal settlements and loss contingencies recorded under accrued expenses was \$663 million and \$1,232 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.

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,

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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, where Teva has in recent years increased the number of launches of its generic versions of branded pharmaceuticals prior to the expiration of the innovator s patents. The laws concerning generic pharmaceuticals and patents differ from country to country. Damages for patent infringement in Europe may include lost profits or a reasonable royalty, but enhanced damages for willful infringement are generally not available.

In 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 Core[®]) in September 2007. Teva vigorously disputed GSK s claims on the merits and also disputed the amount and nature of GSK s alleged damages. 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. Teva filed post-trial motions for judgment as a matter of law asking the court to overturn the jury verdict on inducement, invalidity, and the award of lost profits damages, and GSK filed post-trial motions asking the court to increase the damages amount in light of the willful infringement finding and to set the interest rate(s) to be applied to the total damages amount. 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 denied Teva s motion seeking to overturn the jury verdict with respect to invalidity and denied GSK s motion seeking to increase the damages award. On May 25, 2018, GSK appealed the decision, and Teva filed an appeal of certain adverse rulings. If the appeal of the district court s decision is decided against Teva, the case would be remanded to the district court for it to consider Teva s other legal and equitable defenses that have not yet been considered by the district court. The provision that was included in the financial statements for this matter has been reversed as the exposure is no longer considered probable.

In 2014, Teva Canada succeeded in its challenge of the bortezomib (the generic equivalent of Velcade®) product and mannitol ester patents under the Patented Medicines (Notice Of Compliance) Regulations (PM(NOC)). Teva commenced sales in the first quarter of 2015. At the time of Teva s launch, annual sales of Velcade were approximately 94 million Canadian dollars. 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. On December 20, 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 (approximately \$159 million) plus post-judgment interest. The trial, which is limited to the issue of patent validity and infringement, began on January 29, 2018 and concluded on March 8, 2018. On June 27, 2018, the court issued its opinion in Teva s favor and ruled that Janssen and Millennium are to pay Teva 5 million Canadian dollars in Section 8 damages. On September 28, 2018, Janssen and Millennium filed an appeal of this decision with respect to two of the patents subject to the original proceedings. If the decision is overturned on appeal, Teva could owe the capped damages set forth above. In addition to the potential damages that could be awarded, if Janssen and Millennium are ultimately successful in this claim, Teva could be ordered to cease sales of its bortezomib product.

On July 8, 2011, Helsinn sued Teva over its filing of an ANDA to market a generic version of palonosetron IV solution (the generic equivalent of Aloxi[®]), and in November 2015, the District Court of New Jersey ruled against Teva. Teva appealed this decision, and in May 2017, the Federal Circuit Court of Appeals reversed the district court s ruling and found the asserted patents invalid. In January 2018, full appellate review of that decision was denied. Helsinn filed an appeal with the US Supreme Court, which was granted on June 25, 2018. Oral argument has been scheduled for December 4, 2018. If the Supreme Court reverses the appellate decision, the case may be remanded to the district court. Separately, in October 2014, Helsinn filed an additional claim on later-acquired patents, but that litigation was stayed pending the outcome of the original case. Following the appellate court s decision in

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Teva s favor in the original case, Helsinn reopened the stayed case on the later-acquired patent and filed a motion for a preliminary injunction based on that later-acquired patent. On January 30, 2018, the District Court of New Jersey denied Helsinn s request for a preliminary injunction. Teva launched its generic palonosetron IV solution after obtaining final regulatory approval on March 23, 2018. If Teva ultimately loses either one of the cases discussed above, Teva may be ordered, by the court, to cease sales of its generic product and/or pay damages to Helsinn. Aloxi® annual sales as of November 2017 were \$459 million in the U.S.

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 commercial insurance it desires, or any commercial 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 trebled under the relevant statutes, plus attorneys fees and costs. The alleged damages generally depend on the size of the branded market and the length of the alleged delay, and can be substantial potentially measured in multiples of the annual brand sales particularly where the alleged delays are lengthy or branded drugs with annual sales in the billions of dollars are involved.

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

In June 2013, the United States Supreme Court held, in Federal Trade Commission v. Actavis, Inc. (the AndroGel case), that a rule of reason test should be applied in analyzing whether such settlements potentially violate the federal antitrust laws. The Supreme Court held that a trial court must analyze each agreement in its entirety in order to determine whether it violates the antitrust laws.

This new test has resulted in increased scrutiny of Teva s patent settlements, additional action by the FTC and state and local authorities, and an increased risk of liability in Teva s currently pending antitrust litigations.

In April 2006, certain subsidiaries of Teva were named in a class action lawsuit filed in the U.S. District Court for the Eastern District of Pennsylvania. The case alleges that the settlement agreements entered into between Cephalon, Inc., now a Teva subsidiary (Cephalon), and various generic pharmaceutical companies in late 2005 and early 2006 to resolve patent litigation involving certain finished modafinil products (marketed as PROVIGIL®) were unlawful because they had the effect of excluding generic competition. The case also alleges that Cephalon improperly asserted its PROVIGIL patent against the generic pharmaceutical companies. The first lawsuit was brought by King Drug Company of Florence, Inc. on behalf of itself and as a proposed class action on behalf of any other person or entity that purchased PROVIGIL directly from Cephalon. Similar allegations were made in other complaints, including those filed on behalf of a proposed class of end payers of PROVIGIL, by certain individual end payers, by certain retail chain pharmacies and by Apotex, Inc. (collectively, these cases are referred to as the Philadelphia Modafinil Action). Separately, Apotex challenged Cephalon s PROVIGIL patent, and in October 2011, the court found the patent to be invalid and unenforceable based on inequitable conduct. This decision was affirmed on appeal in April 2013. Teva has either settled or reached agreements in principle to settle with all of the plaintiffs in the Philadelphia Modafinil Action, However, one of the end payers, United Healthcare Services, took the position that it is not bound by the settlement that was agreed to on its behalf and brought a separate action in Minnesota federal court, which was transferred to the U.S. District Court for the Eastern District of Pennsylvania, where Teva had filed suit to enforce the settlement. A bench trial was held in April 2018, and the court issued its opinion on September 19, 2018, ruling in Teva s favor

and holding that United Healthcare is bound by the settlement. On October 16, 2018, United Healthcare moved the court to amend its final judgment and to clarify that the final judgment does not address how settlement proceeds should be allocated among United Healthcare and the other end payers. That motion was denied on October 30, 2018. Additionally, Cephalon and Teva have reached a settlement with 48 state attorneys general, which was approved by the court on November 7, 2016. Certain other claimants, including the State of California, have given notices of potential claims related to these settlement agreements. Teva has produced documents and information in response to discovery requests issued by the California Attorney General s office as part of its ongoing investigation of generic competition to PROVIGIL.

In May 2015, Cephalon entered into a consent decree with the FTC under which the FTC dismissed its claims against Cephalon in the FTC Modafinil Action in exchange for payment of \$1.2 billion (less set-offs for prior settlements) by Cephalon and Teva into a settlement fund. Under the consent decree, Teva also agreed to certain injunctive relief with respect to the types of settlement agreements Teva may enter into to resolve patent litigation in the United States for a period of ten years. The settlement fund does not cover any judgments or settlements outside the United States.

Following an investigation initiated by the European Commission in April 2011 regarding a modafinil patent settlement in Europe, the 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. Teva submitted its defense in writing and an oral hearing was held. No final decision regarding infringement has yet been taken by the Commission. The sales of modafinil in the European Economic Area during the last full year of the alleged infringement amounted to EUR 46.5 million.

In January 2009, the FTC and the State of California filed a complaint for injunctive relief in California federal court alleging that a September 2006 patent lawsuit settlement between Watson Pharmaceuticals, Inc. (Watson), now a Teva subsidiary, and Solvay Pharmaceuticals, Inc. (Solvay) relating to Andro@el% (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 direct purchaser plaintiffs filing separately) and the various actions were consolidated in a multidistrict litigation in Georgia federal court. The defendants filed various summary judgment motions on September 29, 2017, which the district court granted in part, and denied in part, on June 13, 2018. The direct-purchaser plaintiffs moved for class certification on February 9, 2018 and that motion was denied on July 16, 2018. The direct-purchaser plaintiffs have not sought to immediately appeal the denial of such class certification. As a result, the three direct purchasers that had sought class certification can proceed as individual plaintiffs, but any other member of the proposed direct purchaser class will need to file a separate, individual lawsuit if it wishes to participate in the litigation. The court has ordered a bench trial on the FTC s claims to start on February 25, 2019, with a jury trial on the private plaintiffs claims to be scheduled thereafter. Annual sales of AndroGel® 1% at the time of the settlement were approximately \$350 million, and annual sales of the AndroGel franchise (AndroGel® 1% and AndroGel® 1.62%) were approximately \$140 million and \$1.05 billion, respectively, at the time Actavis launched its generic version of AndroGel® 1% in November 2015.

In December 2011, three groups of plaintiffs sued Wyeth and Teva for alleged violations of the antitrust laws in connection with their settlement of patent litigation involving extended release venlafaxine (generic Effexor® XR) entered into in November 2005. The cases were filed by a purported class of direct purchasers, by a purported class of indirect purchasers and by certain chain pharmacies in the United States District Court for the District of New Jersey. The plaintiffs claim that the settlement agreement between Wyeth and Teva unlawfully delayed generic entry. In October 2014, the court granted Teva s motion to dismiss in the direct purchaser cases, after which the parties agreed that the court s reasoning applied equally to the indirect purchaser cases. Plaintiffs appealed, and on August 21, 2017, the Third Circuit reversed the district court s decision and remanded for further proceedings. On November 20, 2017, Teva and Wyeth filed a petition for a writ of certiorari in the United States Supreme Court. That petition was denied

on February 20, 2018, and litigation has resumed before the district court. Annual sales of Effexor® XR were approximately \$2.6 billion at the time of settlement and at the time generic versions were launched in July 2010.

In February 2012, two purported classes of direct-purchaser plaintiffs sued GSK and Teva in New Jersey federal court for alleged violations of the antitrust laws in connection with their settlement of patent litigation involving lamotrigine (generic Lamictal®) entered into in February 2005. The plaintiffs claim that the settlement agreement unlawfully delayed generic entry and seek unspecified damages. In December 2012, the court dismissed the case, but in June 2015, the Third Circuit reversed and remanded for further proceedings. On February 19, 2016, Teva and GSK filed a petition for a writ of certiorari in the United States Supreme Court, which was denied on November 7, 2016. In the meantime, litigation has resumed before the district court, and direct-purchaser plaintiffs moved for class certification in June 2018. That motion has been fully briefed and remains pending. Annual sales of Lamictal® were approximately \$950 million at the time of the settlement, and approximately \$2.3 billion at the time generic competition commenced in July 2008.

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

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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. 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, but defendants appealed, and on May 31, 2018, the Court of Appeal, Fourth Appellate District, reversed and instructed the Superior Court to grant defendants motion. The District Attorney petitioned the California Supreme Court to review the Court of Appeal s decision. The petition was granted on August 22, 2018, and the District Attorney filed its opening brief before the California Supreme Court on September 21, 2018. Annual sales of Niaspan® were approximately \$416 million at the time of the settlement and approximately \$1.1 billion at the time generic competition commenced in September 2013.

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 reached an agreement to settle the multidistrict litigation with the various plaintiff groups in the first quarter of 2018. A provision for these settlements has been included in the financial statements, and in September 2018, the district court gave final approval for the settlements with the direct purchaser and end-payer plaintiffs. The FTC has 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. After the FTC dismissed its claims in Pennsylvania, but before it re-filed them in California, Watson and Allergan filed suit against the FTC in the same Pennsylvania federal court where the agency had initially brought its lawsuit, seeking a declaratory judgment that the FTC s claims are not authorized by statute, or, in the alternative, that the FTC does not have statutory authority to pursue disgorgement. The federal court in California stayed both the FTC s claims and the State of California s claims against Allergan and Watson, pending the outcome of the declaratory judgment action in Pennsylvania. On October 29, 2018, the Pennsylvania court dismissed that declaratory judgment action for lack of jurisdiction. Annual sales of Lidoderm® at the time of the settlement were approximately \$1.2 billion, and were approximately \$1.4 billion at the time Actavis launched its generic version in September 2013.

Since November 2013, numerous lawsuits have been filed in various federal courts by purported classes of end payers for, and direct purchasers of, Aggrenox® (dipyridamole/aspirin tablets) against Boehringer Ingelheim (BI), the innovator, and several Teva subsidiaries. The lawsuits allege, among other things, that the settlement agreement between BI and Barr entered into in August 2008 violated the antitrust laws. A multidistrict litigation has been established in the U.S. District Court for the District of Connecticut. Teva and BI s motion to dismiss was denied in March 2015. 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, Humana and Blue Cross/Blue Shield of Louisiana. A provision has been included in the financial statements for this matter. The district court overruled certain objections to the end payer settlement, including objections made by the Orange County District Attorney, and approved such settlement. The District Attorney subsequently appealed the court s approval to the Second Circuit. Opt-outs from the end payer class have also

appealed certain aspects of the court s approval order to the Second Circuit. Those appeals remain pending. Annual sales of Aggrenox® were approximately \$340 million at the time of the settlement and approximately \$455 million at the time generic competition began 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 Acto plus 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 (including Takeda s December 2010 settlement agreement with Teva) violated the antitrust laws. The Court dismissed the end payer lawsuits against all defendants in September 2015. In October 2015, the end payers appealed that ruling, and on March 22, 2016, a stipulation was filed dismissing Teva and the other generic defendants from the appeal. 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 after the Court of Appeals for the Second Circuit s decision. Defendants had moved to dismiss the direct purchasers original complaint. Supplemental briefing on that motion based on the new allegations in the amended complaint was completed on June 29, 2017 and oral argument was held on October 23, 2018. At the time of the settlement, annual sales of Actos® were approximately \$3.7 billion and annual sales of ACTO plus Met® were approximately \$500 million. At the time generic

competition commenced in August 2012, annual sales of Actos® were approximately \$2.8 billion and annual sales of ACTO plus Met® were approximately \$430 million.

In June 2014, two groups of end payers sued AstraZeneca and Teva, as well as Ranbaxy and Dr. Reddy s, in the Philadelphia Court of Common Pleas for violating the antitrust laws by entering into settlement agreements to resolve the esomeprazole (generic Nexium®) patent litigation (the Philadelphia Esomeprazole Actions). These end payers had opted out of a class action that was filed in the Massachusetts federal court in September 2012 and resulted in a jury verdict in December 2014 in favor of AstraZeneca and Ranbaxy (the Massachusetts Action). Prior to the jury verdict, Teva settled with all plaintiffs in the Massachusetts Action for \$24 million. The allegations in the Philadelphia Esomeprazole Actions are nearly identical to those in the Massachusetts Action. The Philadelphia Esomeprazole Actions were stayed pending resolution of the Massachusetts Action, which was on appeal to the Court of Appeals for the First Circuit with respect to the claims against the non-settling defendants, AstraZeneca and Ranbaxy. On November 21, 2016, the First Circuit affirmed the district court s judgment in favor of AstraZeneca and Ranbaxy, and the plaintiffs petitions for rehearing and rehearing en banc were denied on January 10, 2017.

In September 2014, the FTC sued AbbVie Inc. and certain of its affiliates (AbbVie) as well as Teva in the U.S. District Court for the Eastern District of Pennsylvania alleging that they violated the antitrust laws when they entered into a settlement agreement to resolve the AndroGel® patent litigation and a supply agreement under which AbbVie agreed to supply Teva with an authorized generic version of TriCor®. The FTC alleges that Teva agreed to delay the entry of its generic testosterone gel product in exchange for entering into the TriCor supply agreement. In May 2015, the court dismissed the FTC s claim concerning the settlement and supply agreements, and thus dismissed Teva from the case entirely. The FTC proceeded with a separate claim against AbbVie alone and in June 2018, following a bench trial, the court held that AbbVie had violated the antitrust laws by filing sham patent infringement lawsuits against both Teva and Perrigo in the underlying AndroGel patent litigation. The court ordered AbbVie to pay \$448 million in disgorgement but declined to award injunctive relief. The FTC has since filed a notice of appeal as to, among other things, the district court s May 2015 dismissal of the FTC s claim against Teva, referenced above.

Since May 2015, two lawsuits have been filed in the U.S. District Court for the Southern District of New York by a purported class of direct purchasers of, and a purported class of end payers for, Namenda IR® (memantine hydrochloride) against Forest Laboratories, LLC (Forest), the innovator, and several generic manufacturers, including Teva. Teva is only a defendant in the end payer case, in which defendants moved to dismiss the claims made by the end payers. The lawsuits allege, among other things, that the settlement agreements between Forest and the generic manufacturers (including Forest s November 2009 settlement agreement with Teva) violated the antitrust laws. On September 13, 2016, the court denied defendants motions to dismiss, but stayed the cases with respect to the claims brought under state law, which are the only claims asserted against Teva. The court lifted the stay on September 10, 2018 and has referred the parties to mediation. Annual sales of Namenda IR® at the time of the settlement were approximately \$1.1 billion, and are currently approximately \$1.4 billion.

On March 8, 2016 and April 11, 2016, certain Actavis subsidiaries in the United Kingdom, including Auden Mckenzie Holdings Limited, received notices from the U.K. Competition and Markets Authority (CMA) that it had launched formal investigations under Section 25 of the Competition Act of 1998 (Competition Act) into suspected breaches of competition law in connection with the supply of 10mg and 20mg hydrocortisone tablets. On December 16, 2016, the CMA issued a statement of objections (a provisional finding of infringement of the Competition Act) in respect of certain allegations against Actavis UK and Allergan, which was later reissued to include certain Auden Mckenzie entities. A response was submitted and an oral hearing was held. On December 18, 2017, the CMA issued a Statement of Draft Penalty Calculation. A response was submitted and an oral hearing was held. No final decision regarding infringement of competition law has yet been issued by the CMA. On March 3, 2017, the CMA issued a second statement of objection in respect of certain additional allegations (relating to the same products and covering part of

the same time period as for the first statement of objections) against Actavis UK, Allergan, and a number of other companies, which was later reissued to include certain Auden Mckenzie entities. A response was submitted and an oral hearing was held. 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 as a result of the investigations in respect of conduct prior to the closing date of the sale. 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. Further to the Master Purchase Agreement with Allergan whereby Teva agreed to indemnify Allergan for liabilities related to acquired assets, Teva agreed with Allergan to settle and release Teva s indemnity claim and Allergan s potential losses arising from the CMA in connection with this matter, pursuant to the agreement the parties entered into on January 31, 2018. See note 3.

In November 2016, three putative indirect purchaser class actions were filed in federal courts in Wisconsin, Massachusetts and Florida against Shire U.S., Inc. and Shire LLC (collectively, Shire) and Actavis, alleging that Shire s 2013 patent litigation settlement with Actavis related to the ADHD drug Intuni® (guanfacine) violated various state consumer protection and antitrust laws. On December 30, 2016 and January 11, 2017, two additional similar actions were filed, also in Massachusetts federal court, against Shire and Actavis or Teva (as successor to Actavis) by putative classes of direct purchaser plaintiffs. All five cases are now in Massachusetts federal court and on March 10, 2017, both the indirect purchaser plaintiffs and the direct purchaser plaintiffs filed

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consolidated amended complaints. Annual sales of Intuniv® were approximately \$335 million at the time of the settlement, and approximately \$327 million at the time generic competition began in 2014.

Government Investigations and Litigation Relating to Pricing and Marketing

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

A number of state attorneys general have filed various actions against Teva and/or certain of its subsidiaries, including certain Actavis 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, to be paid over time through January 2020. 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 of 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 of 2018 and has since been satisfied in full. The Actavis subsidiaries remain parties to active litigation in Utah where previously dismissed claims against Watson are now on appeal. A provision for these cases has been 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, which revealed that the U.S. Attorney had notified the court in November 2014 that it had declined to intervene in and proceed with the lawsuit. The *qui tam* relators, however, are moving forward with the lawsuit. In June 2015, Teva filed motions to dismiss the complaint. In February 2016, the court stayed its decision on the relators—claims based on state and local laws, denied Teva—s motions to dismiss the False Claims Act claims, and instructed the relators to amend their complaint with additional information. In March 2016, the relators filed an amended complaint, which Teva answered in April 2016. The parties completed discovery. In August 2018, Teva filed a motion for summary judgment on all claims, which is now pending before the court. No trial date has been set.

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 expects to move to dismiss the complaint in November 2018.

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 will move to dismiss in November 2018.

Beginning in May 2014, various complaints were 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 and agencies across the country. There are actions currently pending against Teva and its affiliates that have been brought by various states, subdivisions and state agencies 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 Proceeding). In addition to the complaints filed by states, state agencies and political subdivisions, over 1,500 total lawsuits have been filed in various states, both in state and federal courts. Most of the federal class action cases, as well as

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state cases that have been removed, have been consolidated into the MDL Proceeding. Complaints asserting claims under similar provisions of different state law, generally contend that the defendants allegedly engaged in improper marketing and distribution of opioids, including ACTIQ® and FENTORA. The complaints also assert claims related to Teva s generic opioid products. In addition, several dozen complaints filed by cities, counties and the State of Delaware have named Anda, Inc. (and other distributors and manufacturers) alleging that Anda failed to develop and implement systems sufficient to identify suspicious orders of opioid products and prevent the abuse and diversion of such products to individuals who used them for other than legitimate medical purposes. Plaintiffs seek a variety of remedies, including restitution, civil penalties, disgorgement of profits, treble damages, attorneys fees and injunctive relief. None of the complaints specify the exact amount of damages at issue. Teva and its affiliates that are defendants in the various lawsuits deny all allegations asserted in these complaints and have filed or will file motions to dismiss where possible. On August 13, 2018, the judge in the MDL Proceeding issued a revised case management order setting the first trial for September 2019. The court has also commenced motion to dismiss briefing on certain issues in bellwether cases and the first set of briefing was completed in July 2018. On October 5, 2018, the court issued a Report & Recommendation on the first motion to dismiss filed in the bellwether cases, in which it denied defendants motions to dismiss except for the common law public nuisance claim, which was dismissed. Motions to dismiss in eight additional similar cases remain pending. In addition, discovery has commenced in the MDL Proceeding for three cases based in Ohio and fact discovery is ongoing. Other cases remain pending in various state courts, including Oklahoma, where a trial is scheduled to begin in May 2019. In some jurisdictions, such as Connecticut, Illinois, New York, Pennsylvania and Texas, certain state court cases have been transferred to a single court within their respective state court systems for coordinated pretrial proceedings. Several state courts have allowed discovery to begin. On April 27, 2018, Teva received subpoena requests from the DOJ seeking documents relating to the manufacture, marketing and sale of opioids. Teva is complying with this subpoena. In addition, a number of state attorneys general, including a coordinated multistate effort, have initiated investigations into sales and marketing practices of Teva and its affiliates with respect to opioids. Other states are conducting their own investigations outside of the multistate group. Teva is cooperating with these ongoing investigations and cannot predict the outcome at this time.

On June 21, 2016, Teva USA received a subpoena from the Antitrust Division of the DOJ 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 fully 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 (specifically, section 1 of the Sherman Act) alleging price fixing of generic products in the United States. An amended complaint was filed on March 1, 2017 adding twenty additional states to the named plaintiffs and adding supplemental state law claims. The states seek a finding that the defendants—actions violated federal antitrust law, and state antitrust and consumer protection laws, as well as injunctive relief, disgorgement, damages on behalf of various state and governmental entities and consumers, civil penalties and costs. On August 3, 2017, the Judicial Panel on Multidistrict Litigation (JPML) transferred this action to the generic drug multidistrict litigation pending in federal court in Pennsylvania, which is discussed in greater detail below. On July 17, 2017, a new complaint was filed in the District Court of Connecticut on behalf of four additional states—Arkansas, Missouri, New Mexico and West Virginia, as well as the District of Columbia. These plaintiffs were not previously party to the State Attorney General action that commenced in December 2016. This complaint, which the JPML has also transferred to the generic drug multidistrict litigation discussed below, makes the same factual allegations and claims that are at issue in the earlier State Attorneys General complaint. On October 31, 2017 the attorneys general of 45 states plus Puerto Rico and the District of Columbia filed a motion for leave to file an amended complaint in this action. The proposed amended complaint names Actavis and Teva as defendants, and adds

new allegations and claims to those appearing in the prior complaints. Defendants have opposed the motion. On June 5, 2018, the District Court for the Eastern District of Pennsylvania granted the attorneys general s motion to amend.

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, increase, maintain and/or stabilize the prices of certain generic products, 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, the JPML entered an order transferring such cases brought by classes of direct or indirect purchasers for coordination or consolidation with the multidistrict litigation currently pending in the Eastern District of Pennsylvania. The panel subsequently transferred further cases to that court and the plaintiffs filed consolidated amended complaints on August 15, 2017. Defendants moved to dismiss certain of those consolidated amended complaints on October 6, 2017. On October 16, 2018, the pending motions to dismiss were denied. Pursuant to orders dated February and April 2018, the court overseeing the multidistrict litigation lifted the stay of discovery on a limited basis to allow for document discovery and non-merits based depositions. Teva and Actavis deny having engaged in any conduct that would give rise to liability with respect to the above-mentioned subpoenas and civil suits.

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 fully 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 fully in responding to the subpoena.

In December 2016, Teva resolved certain claims under the U.S. Foreign Corrupt Practices Act (FCPA) with the SEC and the DOJ, as more fully described in Teva s 2017 Annual Report. The settlement included a fine, disgorgement and prejudgment interest; a three-year deferred prosecution agreement (DPA) for Teva; a guilty plea by Teva s Russian subsidiary to criminal charges of violations of the anti-bribery provisions of the FCPA; consent to entry of a final judgment against Teva resolving civil claims of violations of the anti-bribery, internal controls and books and records provisions of the FCPA; 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 December 1, 2017, Teva and the current and former officer and director defendants subsequently filed motions to dismiss the consolidated amended complaint, with prejudice. On April 3, 2018, the court granted the motions to dismiss without prejudice. Lead plaintiff filed a second amended complaint on June 22, 2018, purportedly on behalf of purchasers of Teva s securities between February 6, 2014 and August 3, 2017. The second complaint asserts that Teva and certain of its current and former officers and directors violated federal securities laws in connection with Teva s alleged failure to disclose pricing strategies for various drugs in its generic drug portfolio and by making allegedly false or misleading statements in certain offering materials issued during the class period. The second complaint seeks unspecified damages, legal fees, interest, and costs. Teva and the current and former officer and director defendants filed motions to dismiss the second complaint on September 14, 2018. Lead plaintiff s opposition to the motions to dismiss is due on November 9, 2018.

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 Tevas 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 consolidated putative securities class action described above.

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

On August 21 and 30, 2017, each of Elliot Grodko and Barry Baker 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 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.

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Between August and October 2018, four 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 are Fir Tree Value Master Fund, L.P. and FT SOF V Holdings, LLC; The Phoenix Insurance Company Ltd., The Phoenix Pension Ltd., Excellence Gemel & Hishtalmut Ltd., Excellence Kesem ETNS and Excellence Mutual Fund; Nordea Investment Management AB; and the State of Alaska Department of Revenue, Treasury Division and the Alaska Permanent Fund Corporation, and they filed their complaints in the Court of Common Pleas of Montgomery County, Pennsylvania on August 3, 2018, the U.S. District Court for the Eastern District of Pennsylvania on August 3, 2018 and the U.S. District Court for the District of Connecticut on October 10 and October 16, 2018, respectively. In the two cases filed in August 2018, Teva and the current and former officer and director defendants filed motions to transfer the cases to the U.S. District Court for the District of Connecticut, where the Ontario Teachers Securities Litigation is pending. In the two cases filed in October 2018, the parties jointly moved to stay the case pending resolution of the motions to dismiss filed in the consolidated putative securities class action described above.

Motions to approve derivative actions against certain past and present directors and officers have been filed in Israel with respect to alleged negligence and recklessness with respect to the acquisition of the Rimsa business and the acquisition of Actavis Generics. Motions for document disclosure prior to initiating derivative actions were filed with respect to dividend distribution, executive compensation and several patent settlement agreements. 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 is 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). All defendants have moved to dismiss the complaint and those motions remain pending.

NOTE 17 Segments:

In November 2017, Teva announced a new organizational structure and leadership changes to enable strategic alignment across its portfolios, regions and functions. Teva now operates its business through three segments: North America, Europe and International Markets. The purpose of the new structure is to enable stronger alignment and integration between operations, commercial regions,

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R&D and Teva s global marketing and portfolio function, in order to optimize its product lifecycle across the therapeutic areas. The Company began reporting its financial results under this structure in the first quarter of 2018.

In addition to these three segments, Teva has other activities, primarily the sale of API to third parties and certain contract manufacturing services.

All the above changes were reflected through retroactive revision of prior period segment information.

Since 2013 and until December 31, 2017, Teva had two reportable segments: generic and specialty medicines. The generic medicines segment included Teva s OTC and API businesses. Teva s other activities included distribution activities, sales of medical devices and certain contract manufacturing operation (CMO) services.

Teva now 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.

Teva s Chief Executive Officer (CEO), who is the chief operating decision maker (CODM), reviews financial information prepared on a consolidated basis, accompanied by disaggregated information about revenues and contributed profit by the three identified reportable segments, namely North America, Europe and International Markets, to make decisions about resources to be allocated to the segments and assess their performance.

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

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

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

a. Segment information:

	North America Three		Eur months ei	ope ided Sept		ional Markets
	2018	2017	2018	2017	2018	2017
			(U.S. \$ i	n millions	s)	
Revenues	\$ 2,265	\$3,043	\$1,212	\$1,380	\$ 720	5 \$ 882
Gross profit	1,232	1,833	683	721	30	1 351
R&D expenses	158	230	62	101	2	1 35
S&M expenses	301	325	249	289	120	158
G&A expenses	128	149	74	90	3′	7 51
Other income (loss)	(4)	(1)	1			(3)
Segment profit	\$ 649	\$1,130	\$ 297	\$ 241	\$ 123	3 \$ 110

	North A	North America Nine		Europe months ended Septer		al Markets
	2018	2017	2018 (U.S. \$ i	2017 n millions	2018	2017
Revenues	\$7,059	\$9,452	\$3,982	\$4,016	\$ 2,265	\$ 2,485
Gross profit	3,867	5,971	2,211	2,147	942	1,043
R&D expenses	528	777	208	312	70	129
S&M expenses	902	1,158	741	864	384	503
G&A expenses	357	432	243	258	115	144
Other income	(206)	(82)	(1)	(15)	(11)	(4)
Segment profit	\$ 2.286	\$ 3.686	\$ 1.020	\$ 728	\$ 384	\$ 271

	Three months ended September 30, 2018 2017 (U.S. \$ in millions)			Nine months ender September 30, 2018 2017 (U.S. \$ in millions			
North America profit	\$	649	\$ 1,			2,286	\$ 3,686
Europe profit		297		241		1,020	728
International Markets profit		123		110		384	271
Total segment profit Profit (loss) of other activities	-	1,069 35	1,	481 (11)		3,690 87	4,685
		1,104	1,	,470	3	3,777	4,688
Amounts not allocated to segments:							
Amortization		297		357		909	1,088
Other asset impairments, restructuring and other items		658		550	1	2,080	1,209
Goodwill impairment						300	6,100
Gain on divestitures, net of divestitures related costs		(31)				(114)	
Inventory step-up							67
Other R&D expenses		60		150		82	176
Costs related to regulatory actions taken in facilities		1		(1)		6	48
Legal settlements and loss contingencies		19		(20)	(1,239)	324
Other unallocated amounts		84		56		226	143
Consolidated operating income (loss)		16		378		1,527	(4,467)
Financial expenses, net		229		259		736	704
Consolidated income (loss) before income taxes	\$	(213)	\$	119	\$	791	\$ (5,171)

b. Segment revenues by major products and activities:

The following tables present revenues by major products and activities for the nine and three months ended September 30, 2018 and 2017:

	Th	Three months ended September 30,		Nine mon Septem	ths ended ber 30,	
	2	018	2	2017	2018 (U.S	2017 . \$ in
	J)	(U.S. \$ in millions)				ions)
North America segment						
Generic products	\$	922	\$	1,233	\$ 2,957	\$ 3,979
COPAXONE		463		819	1,403	2,475
BENDEKA / TREANDA		161		179	502	498
ProAir		107		155	352	399
QVAR		36		83	173	265
AUSTEDO		62		6	136	8

Distribution		333		294	984	864	
	Three months ended September 30, 2018 2017				2018	ths ended ber 30, 2017	
	(U	.S. \$ ir	n millio	ns)	millions)		
Europe segment							
Generic products	\$	845	\$	871	\$ 2,749	\$ 2,543	
COPAXONE		124		150	417	440	
Respiratory products		93		90	312	258	

		Three months ended September 30,				iths ended aber 30,
	_	2018 2017 (U.S. \$ in millions)			2018 (U.S. \$ in	2017 millions)
International Markets segment					(0.12.7 7	
Generic products	\$	498	\$	629	\$ 1,523	\$ 1,720
COPAXONE		14		18	52	65
Distribution		149		146	456	406

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 commencement of generic competition, even in the form of non-equivalent products, can result in a substantial decrease in revenues for a particular specialty medicine in a very short time. Any such expiration or loss of IP rights could therefore significantly adversely affect Teva s results of operations and financial condition.

NOTE 18 Other income:

	Three months ended September Mine months ended September 30									
	2	2018	2017	2	2018	2017				
	((U.S. \$ in millions)		(U.S. \$ in millions)						
Gain on divestitures, net of divestitures										
related costs (1)	\$	31		\$	114					