

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
 WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2021

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) 914-8213

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
Emerging growth company ☐	

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

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

As of June 30, 2021, the registrant had 1,102,885,659 ordinary shares outstanding.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

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TEVA PHARMACEUTICAL INDUSTRIES LIMITED

INTRODUCTION AND USE OF CERTAIN TERMS

Unless otherwise indicated, all references to the “Company,” “we,” “our” and “Teva” refer to Teva Pharmaceutical Industries Limited and its subsidiaries, and references to “revenues” refer to net revenues. References to “U.S. dollars,” “dollars,” “U.S. \$” and “\$” are to the lawful currency of the United States of America, and references to “NIS” are to new Israeli shekels. References to “ADS(s)” are to Teva’s American Depositary Share(s). References to “MS” are to multiple sclerosis. Market data, including both sales and share data, is based on information provided by IQVIA, a provider of market research to the pharmaceutical industry (“IQVIA”), unless otherwise stated. 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. This report on Form 10-Q contains many of the trademarks and trade names used by Teva in the United States and internationally to distinguish its products and services. Any third-party trademarks mentioned in this report are the property of their respective owners.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our ability to successfully compete in the marketplace, including: that we are substantially dependent on our generic products; consolidation of our customer base and commercial alliances among our customers; delays in launches of new generic products; the increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products; our ability to develop and commercialize biopharmaceutical products; competition for our specialty products, including AUSTEDO[®], AJOVY[®] and COPAXONE[®]; our ability to achieve expected results from investments in our product pipeline; our ability to develop and commercialize additional pharmaceutical products; 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: uncertainty regarding the COVID-19 pandemic and its impact on our business, financial condition, operations, cash flows, and liquidity and on the economy in general; our ability to successfully execute and maintain the activities and efforts related to the measures we have taken or may take in response to the COVID-19 pandemic and associated costs therewith; effectiveness of our optimization efforts; our ability to attract, hire and retain highly skilled personnel; manufacturing or quality control problems; interruptions in our supply chain; disruptions of information technology systems; breaches of our data security; variations in intellectual property laws; challenges associated with conducting business globally, including political or economic instability, major hostilities or terrorism; costs and delays resulting from the extensive pharmaceutical regulation to which we are subject or delays in governmental processing time due to travel and work restrictions caused by the COVID-19 pandemic; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; significant sales to a limited number of customers; 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: failure to comply with complex legal and regulatory environments; increased legal and regulatory action in connection with public concern over the abuse of opioid medications and our ability to reach a final resolution of the remaining opioid-related litigation; scrutiny from competition and pricing authorities around the world, including our ability to successfully defend against the U.S. Department of Justice (“DOJ”) criminal charges of Sherman Act violations; potential liability for patent infringement; product liability claims; failure to comply with complex Medicare and Medicaid reporting and payment obligations; compliance with anti-corruption sanctions and trade control laws; 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 (including as a result of potential tax reform in the United States); 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;

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

and other factors discussed in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2020, including in the sections captioned “Risk Factors.” Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TEVA PHARMACEUTICAL INDUSTRIES LIMITED CONSOLIDATED BALANCE SHEETS (U.S. dollars in millions, except for share data) (Unaudited)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,436	\$ 2,177
Accounts receivables, net of allowance for credit losses of \$120 million and \$126 million as of June 30, 2021 and December 31, 2020	4,488	4,581
Inventories	4,362	4,403
Prepaid expenses	1,022	945
Other current assets	484	710
Assets held for sale	29	189
Total current assets	12,822	13,005
Deferred income taxes	645	695
Other non-current assets	530	538
Property, plant and equipment, net	6,127	6,296
Operating lease right-of-use assets	531	559
Identifiable intangible assets, net	8,120	8,923
Goodwill	20,421	20,624
Total assets	\$49,195	\$ 50,640
LIABILITIES AND EQUITY		
Current liabilities:		
Short-term debt	\$ 3,530	\$ 3,188
Sales reserves and allowances	4,453	4,824
Accounts payables	1,551	1,756
Employee-related obligations	511	685
Accrued expenses	1,807	1,780
Other current liabilities	838	933
Total current liabilities	12,691	13,164
Long-term liabilities:		
Deferred income taxes	932	964
Other taxes and long-term liabilities	2,215	2,240
Senior notes and loans	21,602	22,731
Operating lease liabilities	444	479
Total long-term liabilities	25,193	26,414
Commitments and contingencies , see note 10		
Total liabilities	37,884	39,579
Equity:		
Teva shareholders' equity:		
Ordinary shares of NIS 0.10 par value per share; June 30, 2021 and December 31, 2020: authorized 2,495 million shares; issued 1,209 million shares and 1,202 million shares, respectively	57	57
Additional paid-in capital	27,503	27,443
Accumulated deficit	(10,662)	(10,946)
Accumulated other comprehensive loss	(2,446)	(2,399)
Treasury shares as of June 30, 2021 and December 31, 2020 — 106 million ordinary shares	(4,128)	(4,128)
	10,324	10,026
Non-controlling interests	987	1,035
Total equity	11,311	11,061
Total liabilities and equity	\$49,195	\$ 50,640

Amounts may not add up due to rounding.

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

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Net revenues	\$ 3,910	\$ 3,870	\$7,892	\$8,227
Cost of sales	2,037	2,107	4,141	4,402
Gross profit	1,873	1,763	3,750	3,826
Research and development expenses	248	225	501	446
Selling and marketing expenses	615	597	1,200	1,210
General and administrative expenses	242	264	532	567
Intangible assets impairments	195	120	274	768
Other assets impairments, restructuring and other items	28	381	165	502
Legal settlements and loss contingencies	6	13	110	(12)
Other income	(43)	(9)	(48)	(22)
Operating income (loss)	582	173	1,015	364
Financial expenses, net	274	223	564	448
Income (loss) before income taxes	308	(51)	451	(84)
Income taxes (benefit)	98	(104)	159	(163)
Share in (profits) losses of associated companies, net	(11)	—	(14)	0
Net income (loss)	221	53	306	78
Net income (loss) attributable to non-controlling interests	14	(87)	21	(131)
Net income (loss) attributable to Teva	207	140	284	209
Earnings (loss) per share attributable to ordinary shareholders:				
Basic	\$ 0.19	\$ 0.13	\$ 0.26	\$ 0.19
Diluted	\$ 0.19	\$ 0.13	\$ 0.26	\$ 0.19
Weighted average number of shares (in millions):				
Basic	1,103	1,096	1,101	1,095
Diluted	1,109	1,100	1,108	1,098

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

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Net income (loss)	\$ 221	\$ 53	\$ 306	\$ 78
Other comprehensive income (loss), net of tax:				
Currency translation adjustment	79	144	(130)	(416)
Unrealized gain (loss) from derivative financial instruments, net	7	7	14	37
Unrealized loss on defined benefit plans	1	—	1	—
Total other comprehensive income (loss)	87	151	(115)	(379)
Total comprehensive income (loss)	308	204	191	(301)
Comprehensive income (loss) attributable to non-controlling interests	13	(85)	(47)	(119)
Comprehensive income (loss) attributable to Teva	<u>\$ 295</u>	<u>\$ 289</u>	<u>\$ 238</u>	<u>\$ (182)</u>

Amounts may not add up due to rounding.

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

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Teva shareholders' equity								
	Ordinary shares		Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	Number of shares (in millions)	Stated value							
	(U.S. dollars in millions)								
Balance at March 31, 2021	1,208	57	27,474	(10,869)	(2,534)	(4,128)	10,000	975	10,975
Net Income (loss)				207			207	14	221
Other comprehensive income (loss)					88		88	(1)	87
Issuance of Shares	1	*					*		*
Stock-based compensation expense			29				29		29
Balance at June 30, 2021	1,209	\$ 57	\$ 27,503	\$ (10,662)	\$ (2,446)	\$ (4,128)	\$ 10,324	\$ 987	\$11,311

* Represents an amount less than \$0.5 million.

	Teva shareholders' equity								
	Ordinary shares		Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	Number of shares (in millions)	Stated value							
	(U.S. dollars in millions)								
Balance at March 31, 2020	1,201	56	27,342	(6,887)	(2,852)	(4,128)	13,531	1,057	14,588
Net Income (loss)				140			140	(87)	53
Other comprehensive income (loss)					149		149	2	151
Issuance of Shares	1	*							*
Stock-based compensation expense			32				32		32
Balance at June 30, 2020	1,202	\$ 57	\$ 27,374	\$ (6,747)	\$ (2,703)	\$ (4,128)	\$ 13,852	\$ 972	\$14,824

* Represents an amount less than \$0.5 million.

	Teva shareholders' equity								
	Ordinary shares			Retained earnings (accumulated deficit)	Accumulated other comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	Number of shares (in millions)	Stated value	Additional paid-in capital						
	(U.S. dollars in millions)								
Balance at December 31, 2020	1,202	57	27,443	(10,946)	(2,399)	(4,128)	10,026	1,035	11,061
Net Income (loss)				284			284	21	306
Other comprehensive income (loss)					(47)		(47)	(68)	(115)
Issuance of Shares	6	*					*		*
Stock-based compensation expense			60				60		60
Balance at June 30, 2021	1,209	\$ 57	\$ 27,503	\$ (10,662)	\$ (2,446)	\$ (4,128)	\$ 10,324	\$ 987	\$11,311

* Represents an amount less than \$0.5 million.

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

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	Teva shareholders' equity								
	Ordinary shares			Retained earnings (accumulated deficit)	Accumulated other comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	Number of shares (in millions)	Stated value	Additional paid-in capital						
	(U.S. dollars in millions)								
Balance at December 31, 2019	1,198	56	27,312	(6,956)	(2,312)	(4,128)	13,972	1,091	15,063
Net Income (loss)				209			209	(131)	78
Other comprehensive income (loss)					(391)		(391)	12	(379)
Issuance of shares	4	*					*		*
Stock-based compensation expense			62				62		62
Balance at June 30, 2020	1,202	\$ 57	\$ 27,374	\$ (6,747)	\$ (2,703)	\$ (4,128)	\$ 13,852	\$ 972	\$14,824

* Represents an amount less than \$0.5 million.

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

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

	Six months ended June 30,	
	2021	2020
Operating activities:		
Net income (loss)	\$ 306	\$ 78
Adjustments to reconcile net income (loss) to net cash provided by operations:		
Depreciation and amortization	681	781
Impairment of long-lived assets and assets held for sale	354	1,120
Net change in operating assets and liabilities	(1,679)	(1,002)
Deferred income taxes – net and uncertain tax positions	5	(502)
Stock-based compensation	60	62
Net loss (gain) from investments and from sale of long lived assets	93	24
Other items	(7)	17
Net cash provided by (used in) operating activities	<u>(187)</u>	<u>578</u>
Investing activities:		
Beneficial interest collected in exchange for securitized accounts receivables	881	769
Purchases of property, plant and equipment	(263)	(259)
Proceeds from sale of business and long lived assets	254	45
Proceeds from sale of investments	153	9
Other investing activities	(36)	1
Net cash provided by investing activities	<u>989</u>	<u>565</u>
Financing activities:		
Repayment of senior notes and loans and other long-term liabilities	—	(700)
Redemption of convertible senior notes	(491)	—
Other financing activities	(3)	(3)
Net cash used in financing activities	<u>(494)</u>	<u>(703)</u>
Translation adjustment on cash and cash equivalents	<u>(49)</u>	<u>(13)</u>
Net change in cash and cash equivalents	259	427
Balance of cash and cash equivalents at beginning of period	2,177	1,975
Balance of cash and cash equivalents at end of period	<u>\$ 2,436</u>	<u>\$ 2,402</u>
Non-cash financing and investing activities:		
Beneficial interest obtained in exchange for securitized accounts receivables	\$ 878	\$ 728

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

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

Note 1 – Basis of presentation:

a. 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 normal and 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 Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission ("SEC"). The year-end balance sheet data was derived from the audited consolidated financial statements as of December 31, 2020, but not all disclosures required by generally accepted accounting principles in the United States ("U.S. GAAP") are included.

In the process of preparing the consolidated financial statements, management makes estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. The inputs into Teva's judgments and estimates also consider the economic implications of the COVID-19 pandemic on its critical and significant accounting estimates, most significantly in relation to sales, reserves and allowances, IPR&D assets, marketed product rights and goodwill, all of which will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning the COVID-19 pandemic and the actions taken to contain or treat it, as well as the economic impact on Teva's employees, third-party manufacturers and suppliers, customers and markets. All estimates made by Teva related to the impact of the COVID-19 pandemic within its financial statements may change in future periods. Actual results could differ from those estimates.

The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of results that could be expected for the entire fiscal year. Certain amounts in the consolidated financial statements and associated notes may not add up due to rounding. All percentages have been calculated using unrounded amounts.

b. Significant accounting policies

Recently adopted accounting pronouncements

In March 2020, the FASB issued ASU 2020-04 "Reference Rate Reform (Topic 848)—Facilitation of the Effects of Reference Rate Reform on Financial Reporting." This guidance provides optional expedients and exceptions for applying generally accepted accounting principles to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The guidance applies only to contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. This guidance is effective for all entities as of March 12, 2020 through December 31, 2022. There was no impact to the Company's consolidated financial statements for the period ended June 30, 2021 as a result of adopting this standard update. The Company is continuing to evaluate the potential impact of the replacement of the LIBOR benchmark on its interest rate risk management activities and has started initial negotiations to transform the facility base rate of its securitization program. However, it is not expected to have a material impact on the consolidated financial results of operations, financial position or cash flows.

In December 2019, the FASB issued ASU 2019-12 "Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes" (the "update"). The amendments in this update simplify the accounting for income taxes by removing the following exceptions in ASC 740: (1) exception to the incremental approach for intra-period tax allocation when there is a loss from continuing operations and income or a gain from other items; (2) exception to accounting for basis differences for equity method investments when a foreign subsidiary becomes an equity method investment; and (3) exception to accounting for basis differences for a foreign subsidiary when a foreign equity method investment becomes a subsidiary; and (4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year.

In addition, the update also simplifies the accounting for income taxes in certain topics as follows: (1) requiring that an entity recognize a franchise tax (or similar tax) that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax; (2) requiring that an entity evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction; (3) specifying that an entity can elect (rather than be required to) allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements; and (4) requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. Teva adopted the provisions of this update as of January 1, 2021.

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

Based on the Company's evaluation of the above provisions, the Company notes that items (1) and (4) of this paragraph are not material. The adoption of this guidance did not have a material impact on the Company's consolidated financial results of operations, financial position or cash flows.

Recently issued accounting pronouncements, not yet adopted

In August 2020, the FASB issued ASU 2020-06 "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)." This guidance simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The amendments to this guidance are effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The adoption of this guidance will not have a significant impact on the Company's consolidated financial statements.

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

NOTE 2 – Certain transactions:

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.

Alvotech Partnership

In August 2020, Teva entered into a partnership agreement with biopharmaceutical company Alvotech for the exclusive commercialization in the U.S. of five biosimilar product candidates. The initial pipeline for this partnership contains biosimilar candidates addressing multiple therapeutic areas, including a proposed biosimilar to Humira[®]. Under this agreement, Alvotech is responsible for the development, registration and supply of the biosimilar product candidates and Teva will exclusively commercialize the products in the United States. Teva paid an upfront payment in the third quarter of 2020 and additional upfront and milestone payments in the second quarter of 2021 that were recorded as R&D expenses. Additional development and commercial milestone payments of up to \$450 million, as well as royalty payments, may be payable by Teva over the next few years. Teva and Alvotech will share profit from the commercialization of these biosimilars. In March 2021, Abbvie sued Alvotech for allegedly misappropriating confidential information relating to Humira[®]. Alvotech has disputed these claims. In addition, there is pending patent litigation between Abbvie and Alvotech.

Eli Lilly and Alder BioPharmaceuticals

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

On January 8, 2018, Teva signed a global license agreement with Alder BioPharmaceuticals ("Alder"). The agreement validates Teva's intellectual property 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 received a non-exclusive license to Teva's anti-CGRP antibodies patent portfolio to develop, manufacture and commercialize eptinezumab in the United States and worldwide, excluding Japan and Korea. Teva received a \$25 million upfront payment that was recognized as revenue during the first quarter of 2018, and a \$25 million milestone payment in March 2020 that was recognized as revenue in the first quarter of 2020. The agreement stipulates additional development and commercial milestone payments to Teva of up to \$150 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. There are no further plans in this indication following clinical trial results received in February 2020, which failed to meet their primary endpoints. The partnership agreement was terminated on February 5, 2021.

Otsuka

On May 12, 2017, Teva entered into a license and collaboration agreement with Otsuka Pharmaceutical Co. Ltd. ("Otsuka"), providing Otsuka with an exclusive license to conduct phase 2 and 3 clinical trials for AJOVY in Japan and, if approved, to commercialize the product in Japan. Otsuka paid Teva an upfront payment of \$50 million in consideration for the transaction. Results for these trials were received in January 2020 indicating that primary and secondary endpoints were achieved and that no clinically significant adverse events were observed in subjects. In the third quarter of 2020, Otsuka submitted an application to obtain manufacturing and marketing approval for AJOVY in Japan and, as a result, paid Teva a milestone payment of \$15 million, which was recognized as revenue in the third quarter of 2020. On June 23, 2021, AJOVY was approved in Japan. Teva may receive additional milestone payments upon achievement of certain development and revenue targets. Otsuka will also pay Teva royalties on AJOVY sales in Japan.

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

Celltrion

In October 2016, Teva and Celltrion, Inc. (“Celltrion”) entered into a collaborative agreement to commercialize Truxima[®] and Herzuma[®], two biosimilar products for the U.S. and Canadian markets. Teva paid Celltrion \$160 million, of which Teva received an aggregate credit of \$60 million as of March 31, 2021. Teva and Celltrion share the profit from the commercialization of these products. These two products, Truxima and Herzuma, were approved by the FDA in November and December 2018, respectively and were launched in the United States in November 2019 and March 2020, respectively. No additional milestone payments are expected.

Regeneron

In September 2016, Teva and Regeneron Pharmaceuticals, Inc. (“Regeneron”) entered into a collaborative agreement to develop and commercialize Regeneron’s pain medication product, fasinumab. Teva and Regeneron share in the global commercial rights to this product (excluding Japan, Korea and nine other Asian countries), 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 and additional payments for achievement of development milestones in an aggregate amount of \$120 million were paid during 2017 and 2018. The agreement stipulates additional development and commercial milestone payments of up to \$2,230 million, as well as future royalties. Currently, all non-essential activities and related expenditures for fasinumab have been put on hold. Next steps will be assessed together with Regeneron, with the intention of discussing data with the FDA.

Assets and Liabilities Held For Sale:

Certain assets of Teva’s business venture in Japan

Teva operated its business in Japan, which was part of Teva’s International Market segment, through a business venture with The Takeda Pharmaceutical Company Limited (“Takeda”), in which Teva owned a 51% stake and Takeda owned the remaining 49%.

In July 2020, Teva and Takeda entered into a purchase agreement to sell the majority of the business venture’s generic and operational assets. This transaction was completed on February 1, 2021.

Until the closing date Teva accounted for the business venture assets and liabilities that were sold, as held for sale and determined that the fair value less cost of sale did not exceed the carrying value, resulting in an impairment charge of \$247 million in other assets impairments, restructuring and other items recognized in 2020 and in the first quarter of 2021.

General

Assets held for sale as of June 30, 2021 include certain manufacturing assets that are expected to be sold within the next year. Assets held for sale as of December 31, 2020 included the Teva-Takeda business venture assets sold during the first quarter of 2021, certain OTC assets sold during the second quarter of 2021 and other manufacturing assets.

The table below summarizes all Teva assets included as held for sale as of June 30, 2021 and December 31, 2020:

	June 30, 2021	December 31, 2020
	(U.S. \$ in millions)	
Inventories	7	146
Property, plant and equipment, net and others	55	312
Goodwill	9	27
Adjustments of assets held for sale to fair value	(42)	(296)
Total assets of the disposal group classified as held for sale in the consolidated balance sheets	<u>\$ 29</u>	<u>\$ 189</u>

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NOTE 3 – Revenue from contracts with customers:

Disaggregation of revenue

The following table disaggregates Teva's revenues by major revenue streams. For additional information on disaggregation of revenues, see note 15.

	Three months ended June 30, 2021				Total
	North America	Europe	International Markets	Other activities	
	(U.S. \$ in millions)				
Sale of goods	1,621	1,185	462	198	3,465
Licensing arrangements	9	7	2	1	19
Distribution	316	\$	15	—	330
Other	(2)	(8)	7	99	96
	<u>\$ 1,943</u>	<u>\$ 1,184</u>	<u>\$ 485</u>	<u>\$ 298</u>	<u>\$3,910</u>

§ Represents an amount less than \$1 million.

	Three months ended June 30, 2020				Total
	North America	Europe	International Markets	Other activities	
	(U.S. \$ in millions)				
Sale of goods	1,658	1,000	457	211	3,326
Licensing arrangements	17	3	1	1	22
Distribution	374	—	7	—	381
Other	(2)	(2)	23	123	141
	<u>\$ 2,047</u>	<u>\$ 1,001</u>	<u>\$ 488</u>	<u>\$ 335</u>	<u>\$3,870</u>

	Six months ended June 30, 2021				Total
	North America	Europe	International Markets	Other activities	
	(U.S. \$ in millions)				
Sale of goods	3,289	2,363	902	374	6,928
Licensing arrangements	40	21	5	2	68
Distribution	605	\$	34	—	639
Other	(2)	14	35	210	257
	<u>\$ 3,932</u>	<u>\$ 2,398</u>	<u>\$ 975</u>	<u>\$ 587</u>	<u>\$7,892</u>

§ Represents an amount less than \$1 million.

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	Six months ended June 30, 2020				
	North America	Europe	International Markets	Other activities	Total
	(U.S. \$ in millions)				
Sale of goods	3,283	2,370	939	388	6,981
Licensing arrangements	42	15	4	2	63
Distribution	800	2	13	—	815
Other	4	17	97	252	369
	<u>\$ 4,129</u>	<u>\$2,404</u>	<u>\$ 1,053</u>	<u>\$ 642</u>	<u>\$8,227</u>

Variable consideration

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

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

SR&A to U.S. customers comprised approximately 78% of the Company’s total SR&A as of June 30, 2021 , with the remaining balance primarily in Canada and Germany. The changes in SR&A for third-party sales for the six months ended June 30, 2021 and 2020 were as follows:

	Sales Reserves and Allowances							Total
	Reserves included in Accounts Receivable, net	Rebates	Medicaid and other governmental allowances	Chargebacks	Returns	Other	Total reserves included in SR&A	
	(U.S. \$ in millions)							
Balance at December 31, 2020	\$ 80	\$ 2,054	\$ 828	\$ 1,108	\$ 686	\$ 148	\$ 4,824	\$ 4,904
Provisions related to sales made in current year	192	2,139	391	3,995	143	177	6,845	7,037
Provisions related to sales made in prior periods	(5)	(82)	(35)	(11)	(40)	(23)	(191)	(196)
Credits and payments	(196)	(2,355)	(362)	(3,934)	(186)	(176)	(7,013)	(7,209)
Translation differences	—	(8)	(3)	(1)	(1)	1	(12)	(12)
Balance at June 30, 2021	<u>\$ 71</u>	<u>1,748</u>	<u>\$ 819</u>	<u>\$ 1,157</u>	<u>\$ 602</u>	<u>\$ 127</u>	<u>\$ 4,453</u>	<u>\$ 4,524</u>

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	Reserves included in Accounts Receivable, net	Rebates	Medicaid and other governmental allowances	Chargebacks	Returns	Other	Total reserves included in SR&A	Total
	(U.S.\$ in millions)							
Balance at December 31, 2019	\$ 87	\$ 2,895	\$ 1,109	\$ 1,342	\$ 637	\$ 176	\$ 6,159	\$ 6,246
Provisions related to sales made in current year	193	2,588	434	4,325	216	50	7,613	7,806
Provisions related to sales made in prior periods	—	(191)	(105)	(15)	18	—	(293)	(293)
Credits and payments	(206)	(3,064)	(505)	(4,416)	(211)	(64)	(8,260)	(8,466)
Translation differences	—	(9)	—	(2)	(2)	(5)	(18)	(18)
Balance at June 30, 2020	<u>\$ 74</u>	<u>2,219</u>	<u>\$ 933</u>	<u>\$ 1,234</u>	<u>\$ 658</u>	<u>\$ 157</u>	<u>\$ 5,201</u>	<u>\$ 5,275</u>

NOTE 4 – Inventories:

Inventories, net of reserves, consisted of the following:

	June 30, 2021	December 31, 2020
	(U.S. \$ in millions)	
Finished products	\$ 2,223	\$ 2,378
Raw and packaging materials	1,333	1,231
Products in process	642	605
Materials in transit and payments on account	164	189
Total	<u>\$ 4,362</u>	<u>\$ 4,403</u>

NOTE 5 – Identifiable intangible assets:

Identifiable intangible assets consisted of the following:

	Gross carrying amount net of impairment		Accumulated amortization		Net carrying amount	
	June 30, 2021	December 31, 2020	June 30, 2021	December 31, 2020	June 30, 2021	December 31, 2020
	(U.S. \$ in millions)					
Product rights	\$ 19,226	\$ 19,650	\$ 12,171	\$ 12,094	\$ 7,055	\$ 7,556
Trade names	648	621	219	165	429	456
In process research and development	636	911	—	—	636	911
Total	<u>\$ 20,510</u>	<u>\$ 21,182</u>	<u>\$ 12,390</u>	<u>\$ 12,259</u>	<u>\$ 8,120</u>	<u>\$ 8,923</u>

Product rights and trade names

Product rights and trade names are assets presented at amortized cost. Product rights and trade names represent a portfolio of pharmaceutical products from various therapeutic categories from various acquisitions with a weighted average life of approximately 10 years.

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Amortization of intangible assets was \$173 million and \$249 million in the three months ended June 30, 2021 and 2020, respectively.

Amortization of intangible assets was \$414 million and \$507 million in the six months ended June 30, 2021 and 2020, respectively.

IPR&D

Teva's IPR&D are assets that have not yet been approved in major markets. Teva's IPR&D is comprised mainly of various generic products from the Actavis Generics acquisition of \$601 million. IPR&D carries intrinsic risks that the asset might not succeed in advanced phases and may be impaired in future periods.

In the first six months of 2021, Teva reclassified \$162 million of products from IPR&D to product rights, of which \$123 million were reclassified in connection with lenalidomide (generic equivalent of Revlimid®).

Intangible assets impairments

Impairments of long-lived intangible assets for the three months ended June 30, 2021 and 2020, were \$195 million and \$120 million, respectively.

Impairments in the second quarter of 2021 consisted of:

- (a) Identifiable product rights of \$168 million due to: (i) \$30 million related to lenalidomide (generic equivalent of Revlimid®), resulting from modified competition assumptions as a result of settlements between the innovator and other generic filers, and (ii) \$138 million, mainly related to updated market assumptions regarding price and volume of products acquired from Actavis Generics that are primarily marketed in the United States; and
- (b) IPR&D assets of \$27 million due to generic pipeline products acquired from Actavis Generics resulting from development progress and changes in other key valuation indications (e.g., market size, competition assumptions, legal landscape, launch date) in the United States.

Impairments in the second quarter of 2020 consisted of:

- (a) Identifiable product rights of \$103 million, mainly due to updated market assumptions regarding price and volume of products acquired from Actavis Generics; and
- (b) IPR&D assets of \$17 million, mainly due to generic pipeline products acquired from Actavis Generics resulting from development progress and changes in other key valuation indications (e.g., market size, competition assumptions, legal landscape, launch date or discount rate).

Impairments of long-lived intangible assets for the six months ended June 30, 2021 and 2020, were \$274 million and \$768 million, respectively.

Impairments in the first six months of 2021 consisted of:

- (a) Identifiable product rights of \$196 million due to: (i) \$30 million related to lenalidomide (generic equivalent of Revlimid®), resulting from modified competition assumptions as a result of settlements between the innovator and other generic filers, and (ii) \$166 million, mainly related to updated market assumptions regarding price and volume of products acquired from Actavis Generics that are primarily marketed in the United States; and
- (b) IPR&D assets of \$78 million, due to generic pipeline products acquired from Actavis Generics resulting from development progress and changes in other key valuation indications (e.g., market size, competition assumptions, legal landscape, launch date) in the United States.

Impairments in the first six months of 2020 consisted of:

- (a) Identifiable product rights of \$420 million, mainly due to: (i) \$232 million due to updated market assumptions regarding price and volume of products acquired from Actavis Generics; and (ii) \$165 million in Japan in connection with ongoing regulatory pricing reductions and generic competition; and

- (b) IPR&D assets of \$348 million, primarily due to: (i) \$211 million related to AUSTEDO for the treatment of Tourette syndrome in pediatric patients in the United States following clinical trial results received in February 2020, which failed to meet their primary endpoints; and (ii) \$117 million related to generic pipeline products acquired from Actavis Generics resulting from development progress and changes in other key valuation indications (e.g., market size, competition assumptions, legal landscape, launch date) in the United States.

The fair value measurement of the impaired intangible assets in the first six months of 2021 is based on significant unobservable inputs in the market and thus represents a Level 3 measurement within the fair value hierarchy. The discount rate applied ranged from 7.25% to 10%. A probability of success factor ranging from 20% to 90% was used in the fair value calculation to reflect inherent regulatory and commercial risk of IPR&D.

NOTE 6 – Goodwill:

The changes in the carrying amount of goodwill for the period ended June 30, 2021 were as follows:

	North America	Europe	International Markets	Other	Total
		(U.S. \$ in millions)			
Balance as of December 31, 2020 (1)	\$ 6,473	\$ 9,102	\$ 2,362	\$ 2,687	\$ 20,624
Changes during the period:					
Goodwill reclassified as assets held for sale		(7)			(7)
Translation differences	12	(198)	(10)		(196)
Balance as of June 30, 2021 (1)	\$ 6,485	\$ 8,897	\$ 2,352	\$ 2,687	\$ 20,421

(1) Accumulated goodwill impairment as of June 30, 2021 and December 31, 2020 was approximately \$25.6 billion.

Teva operates its business through three reporting segments: North America, Europe and International Markets. Each of these business segments is a reporting unit. Additional reporting units include Teva's production and sale of APIs to third parties ("Teva API") and an out-licensing platform offering a portfolio of products to other pharmaceutical companies through its affiliate Medis. The Teva API and Medis reporting units are included under "Other" in the above table. See note 15 for additional segment information.

Teva determines the fair value of its reporting units using the income approach. The income approach is a forward-looking approach for estimating fair value. Within the income approach, the method used is the discounted cash flow method. Teva starts with a forecast of all the expected net cash flows associated with the reporting unit, which includes the application of a terminal value, and then applies a discount rate to arrive at a net present value amount. Cash flow projections are based on Teva's estimates of revenue growth rates and operating margins, taking into consideration industry and market conditions. The discount rate used is based on the weighted average cost of capital ("WACC"), adjusted for the relevant risk associated with country-specific and business-specific characteristics. If any of these expectations were to vary materially from Teva's assumptions, Teva may record an impairment of goodwill allocated to these reporting units in the future. The current projections related to AUSTEDO are a significant assumption in Teva's future projections. Additionally, certain parts of its business volumes were impacted by the COVID-19 pandemic. Management continues to analyze the expected pace of recovery of volumes and the related impact of the COVID-19 pandemic on Teva's business.

First Quarter Developments

During the first quarter of 2021, management assessed developments that occurred during the quarter to determine if it was more likely than not that the fair value of any of its reporting units was below its carrying amount.

Based on this assessment, management concluded that it was not more likely than not that the fair value of any of the reporting units was below its carrying value as of March 31, 2021 and, therefore, no quantitative assessment was performed.

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Second Quarter Developments

During the second quarter of 2021, Teva 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.

Additionally, Teva conducted a quantitative analysis of all reporting units as part of its annual goodwill impairment test with the assistance of an independent valuation expert. Based on this analysis, no goodwill impairment charge was recorded during the second quarter of 2021. Changes to Teva’s current assessment regarding the impact of the COVID-19 pandemic on its projections and its long-term forecast related to AUSTEDO could result in future impairments.

NOTE 7 – Debt obligations:

a. Short-term debt:

	Weighted average interest rate as of June 30, 2021	Maturity	June 30, 2021	December 31, 2020
(U.S. \$ in millions)				
Convertible senior debentures	0.25%	2026	\$ 23	\$ 514
Current maturities of long-term liabilities (1)			3,507	2,674
Total short-term debt			\$ 3,530	\$ 3,188

(1) In July 2021, Teva repaid \$ 1,475 million of its 2.2 % senior notes at maturity.

Convertible senior debentures

The principal amount of Teva’s 0.25% convertible senior debentures due 2026, was \$23 million as of June 30, 2021 and \$514 million as of December 31, 2020. These convertible senior debentures include a “net share settlement” feature according to which the principal amount will be paid in cash and in case of conversion, only the residual conversion value above the principal amount will be paid in Teva shares. Due to the “net share settlement” feature, exercisable at any time, these convertible senior debentures are classified in the Balance Sheet under short-term debt. Holders of the convertible senior debentures exercised their optional repurchase right and redeemed \$491 million of the convertible senior debentures on February 1, 2021, which was the date to exercise this right.

b. Long-term debt:

	Weighted average interest rate as of June 30, 2021	Maturity	June 30, 2021	December 31, 2020
(U.S. \$ in millions)				
Senior notes EUR 1,500 million	1.13%	2024	\$ 1,780	\$ 1,839
Senior notes EUR 1,300 million	1.25%	2023	1,544	1,595
Senior notes EUR 1,000 million	6.00%	2025	1,190	1,230
Senior notes EUR 900 million	4.50%	2025	1,071	1,107
Senior notes EUR 750 million	1.63%	2028	885	916
Senior notes EUR 700 million	3.25%	2022	832	861
Senior notes EUR 700 million	1.88%	2027	832	860
Senior notes USD 3,500 million	3.15%	2026	3,495	3,495
Senior notes USD 1,475 million (1)	2.20%	2021	1,474	1,472
Senior notes USD 3,000 million	2.80%	2023	2,997	2,996
Senior notes USD 2,000 million	4.10%	2046	1,986	1,986
Senior notes USD 1,250 million	6.00%	2024	1,250	1,250
Senior notes USD 1,250 million	6.75%	2028	1,250	1,250
Senior notes USD 1,000 million	7.13%	2025	1,000	1,000
Senior notes USD 844 million	2.95%	2022	851	853
Senior notes USD 789 million	6.15%	2036	783	783
Senior notes USD 613 million	3.65%	2021	614	616
Senior notes USD 588 million	3.65%	2021	588	586
Senior notes CHF 350 million	0.50%	2022	380	397
Senior notes CHF 350 million	1.00%	2025	381	398
Total senior notes			25,183	25,490
Other long-term debt	1.10%	2026	1	1
Less current maturities			(3,507)	(2,674)
Less debt issuance costs			(75)	(86)
Total senior notes and loans			\$ 21,602	\$ 22,731

(1) In July 2021, Teva repaid \$ 1,475 million of its 2.2 % senior notes at maturity.

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

Long-term debt as of June 30, 2021 is effectively denominated in the following currencies: 63% in U.S. dollar, 34% in euro and 3% in Swiss franc.

Teva's principal sources of short-term liquidity are its cash on hand, existing cash investments, liquid securities and available credit facilities, primarily its \$2.3 billion unsecured syndicated revolving credit facility entered into in April 2019 ("RCF").

The RCF agreement provides for two separate tranches, a \$1.15 billion tranche A and a \$1.15 billion tranche B. Tranche A had a maturity date of April 8, 2022, of which an amount of \$1.065 billion was extended twice, initially to April 8, 2023 and then to April 8, 2024. Tranche B has a maturity date of April 8, 2024. Loans and letters of credit will be available from time to time under each tranche for Teva's general corporate purposes.

The RCF contains certain covenants, including certain limitations on incurring liens and indebtedness and maintenance of certain financial ratios, including the requirement to maintain compliance with a net debt to EBITDA ratio, which becomes more restrictive over time. The net debt to EBITDA ratio limit was 5.50x through June 30, 2021, gradually declines to 5.00x in the third and fourth quarters of 2021, 4.50x in the first and second quarters of 2022, and continues to gradually decline over the remaining term of the RCF to 3.50x in the first quarter of 2023.

The RCF can be used for general corporate purposes, including repaying existing debt. As of June 30, 2021, no amounts were outstanding under the RCF. During July 2021, \$500 million was drawn down under the RCF. Based on current and forecasted results, the Company expects that it will not exceed the financial covenant thresholds set forth in the RCF within one year from the date these financial statements are issued.

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

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

NOTE 8 – Derivative instruments and hedging activities:

a. Foreign exchange risk management:

In the first six months of 2021, approximately 47% of Teva's revenues were denominated in currencies other than the U.S. dollar. As a result, Teva is subject to significant foreign currency risks.

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The Company enters into forward exchange contracts, purchases and writes options in order to hedge the currency exposure on balance sheet items, revenues and expenses. In addition, the Company takes measures to reduce exposure by using natural hedging. The Company also acts to offset risks in opposite directions among the subsidiaries within Teva. The currency hedged items are usually denominated in the following main currencies: the euro, the Swiss franc, the Japanese yen, the British pound, the Russian ruble, the Canadian dollar, the Polish zloty, the Indian rupee and other European and Latin American currencies. Depending on market conditions, foreign currency risk is also managed through the use of foreign currency debt.

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

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

b. Interest risk management:

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

c. Derivative instruments outstanding:

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

<u>Reported under</u>	<u>Fair value</u>	
	<u>Not designated as hedging instruments</u>	
	<u>June 30, 2021</u>	<u>December 31, 2020</u>
	<u>(U.S. \$ in millions)</u>	
Asset derivatives:		
Other current assets:		
Option and forward contracts	\$ 30	\$ 24
Liability derivatives:		
Other current liabilities:		
Option and forward contracts	(25)	(79)

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

<u>Reported under</u>	<u>Financial expenses, net</u>		<u>Other comprehensive income (loss)</u>	
	<u>Three months ended,</u>		<u>Three months ended,</u>	
	<u>June 30, 2021</u>	<u>June 30, 2020</u>	<u>June 30, 2021</u>	<u>June 30, 2020</u>
	<u>(U.S. \$ in millions)</u>			
Line items in which effects of hedges are recorded	\$ 274	\$ 223	\$ 87	\$ 151
Cross-currency swaps - net investment hedge (1)	—	—	—	—

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	Financial expenses, net		Other comprehensive income (loss)	
	Six months ended,		Six months ended,	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Reported under	(U.S. \$ in millions)			
Line items in which effects of hedges are recorded	\$ 564	\$ 448	\$ (115)	\$ (379)
Cross-currency swaps - net investment hedge (1)	—	(2)	—	(21)

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

	Financial expenses, net		Net revenues	
	Three months ended,		Three months ended,	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Reported under	(U.S. \$ in millions)			
Line items in which effects of hedges are recorded	\$ 274	\$ 223	\$ (3,910)	\$ (3,870)
Option and forward contracts (2)	27	13	—	—
Option and forward contracts economic hedge (3)	—	—	15	20

	Financial expenses, net		Net revenues	
	Six months ended,		Six months ended,	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Reported under	(U.S. \$ in millions)			
Line items in which effects of hedges are recorded	\$ 564	\$ 448	\$ (7,892)	\$ (8,227)
Option and forward contracts (2)	(43)	37	—	—
Option and forward contracts economic hedge (3)	—	—	(13)	(40)

- (1) In each of the first and second quarters of 2017, Teva entered into a cross currency swap agreement with a notional amount of \$500 million maturing in 2020. These cross currency swaps were designated as a net investment hedge of Teva's foreign subsidiaries euro denominated net assets, in order to reduce the risk of adverse exchange rate fluctuations. With respect to these cross currency swap agreements, Teva recognized gains which mainly reflect the differences between the float-for-float interest rates paid and received. In the first quarter of 2020, these cross-currency swap agreements expired. The settlement of these transactions resulted in cash proceeds of \$3 million.
- (2) Teva uses foreign exchange contracts (mainly option and forward contracts) to hedge balance sheet items from currency exposure. These foreign exchange contracts are not designated as hedging instruments for accounting purposes. In connection with these foreign exchange contracts, Teva recognizes gains or losses that offset the revaluation of the balance sheet items also recorded under financial expenses, net.

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- (3) Teva entered into option and forward contracts designed to limit the exposure of foreign exchange fluctuations on projected revenues and expenses recorded in euro, the Swiss franc, the Japanese yen, the British pound, the Russian ruble, the Canadian dollar and some other currencies to protect its projected operating results for 2021. These derivative instruments do not meet the criteria for hedge accounting, however, they are accounted for as an economic hedge. These derivative instruments, which may include hedging transactions against future projected revenues and expenses, are recognized on the balance sheet at their fair value on a quarterly basis, while the foreign exchange impact on the underlying revenues and expenses may occur in subsequent quarters. In 2020, Teva recognized a loss of \$27 million in relation with the 2021 hedging program Teva entered into in the second half of 2020. In the first six months of 2021, the positive impact from these derivatives recognized under revenues was \$13 million. Changes in the fair value of the derivative instruments are recognized in 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.

d. Amortizations due to terminated derivative instruments:

Forward starting interest rate swaps and treasury lock agreements

In 2015, Teva entered into forward starting interest rate swaps and treasury lock agreements to protect the Company from interest rate fluctuations in

connection with a future debt issuance the Company was planning. These forward starting interest rate swaps and treasury lock agreements were terminated in July 2016 upon the debt issuance. The termination of these transactions resulted in a loss position of \$493 million, which was recorded in other comprehensive income (loss) and is amortized under financial expenses, net over the life of the debt.

With respect to these forward starting interest rate swaps and treasury lock agreements, losses of \$8 million were recognized under financial expenses, net for each of the three months ended June 30, 2021 and 2020, respectively, and losses of \$16 million were recognized under financial expenses, net for each of the six months ended June 30, 2021 and 2020, respectively.

Fair value hedge

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

In the third quarter of 2019, Teva terminated \$500 million interest rate swap agreements designated as a fair value hedge relating to its 2.8% senior notes due 2023 with respect to \$3,000 million notional amount. Settlement of these transactions resulted in cash proceeds of \$10 million. The fair value hedge accounting adjustments of these instruments, which are recorded under senior notes and loans, are amortized under financial expenses, net over the life of the debt.

Cash flow hedge

In the fourth quarter of 2019, Teva terminated \$588 million cross-currency swap agreements against its outstanding 3.65% senior notes maturing in November 2021. Settlement of these transactions resulted in cash proceeds of \$95 million. The cash flow hedge accounting adjustments of these instruments, which are recorded under senior notes and loans, are amortized under financial expenses, net over the life of the debt.

With respect to the interest rate swap and cross-currency swap agreements, gains of \$1 million were recognized under financial expenses, net for each of the three months ended June 30, 2021 and 2020, respectively, and gains of \$1 million and \$2 million were recognized under financial expenses, net for the six months ended June 30, 2021 and 2020, respectively.

NOTE 9 – Legal settlements and loss contingencies:

In the second quarter of 2021, Teva recorded an expense of \$6 million in legal settlements and loss contingencies, compared to \$13 million in the second quarter of 2020. The expense in the second quarter of 2020 was mainly due to an increase in a provision for settlement of certain product liability claims in the United States and other minor provisions, partially offset by proceeds received following a settlement of the FCPA derivative proceedings in Israel.

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In the first six months of 2021, Teva recorded an expense of \$110 million in legal settlements and loss contingencies, compared to income of \$12 million in the first six months of 2020. The expense in the first six months of 2021 was mainly due to the provision for the carvedilol patent litigation (see note 10). The income in the first six months of 2020 was mainly due to proceeds received following a settlement of the FCPA derivative proceedings in Israel and settlement of an action brought against the sellers of Auden McKenzie (an acquisition made by Actavis Generics), partially offset by an increase in a provision for settlement of certain products liability claims in the United States and other minor provisions.

As of June 30, 2021 and December 31, 2020, Teva's provision for legal settlements and loss contingencies recorded under accrued expenses and other taxes and long-term liabilities was \$1,737 million and 1,625 million, respectively.

NOTE 10 – 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.

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 where the exposures were fully resolved in the prior year, or determined to no longer meet the materiality threshold for disclosure, or were substantially resolved.

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, enforceability or infringement of the originator's patents. Teva may also be involved in patent litigation involving the extent to which its product or manufacturing process techniques may infringe other originator or third-party patents.

Additionally, depending upon a complex analysis of a variety of legal and commercial factors, Teva may, in certain circumstances, elect to market a generic version even though litigation is still pending. To the extent Teva elects to proceed in this manner, it could face substantial liability for patent infringement if the final court decision is adverse to Teva, which could be material to its results of operations and cash flows in a given period.

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Teva could also be sued for patent infringement outside of the context of the Hatch-Waxman Act. For example, Teva could be sued for patent infringement after commencing sales of a product. In addition, for biosimilar products, Teva could be sued according to the “patent dance” procedures of the Biologics Price Competition and Innovation Act (BPCIA).

The general rule for damages in patent infringement cases in the United States is that the patentee should be compensated by no less than a reasonable royalty and it may also be able, in certain circumstances, to be compensated for its lost profits. The amount of a reasonable royalty award would generally be calculated based on the sales of Teva’s product. The amount of lost profits would generally be based on the lost sales of the patentee’s product. In addition, the patentee may seek consequential damages as well as enhanced damages of up to three times the profits lost by the patent holder for willful infringement, although courts have typically awarded much lower multiples.

Teva is also involved in litigation regarding patents in other countries where it does business, particularly in Europe. The laws concerning generic pharmaceuticals and patents differ from country to country. Damages for patent infringement in Europe may include lost profits or a reasonable royalty, but enhanced damages for willful infringement are generally not available.

In July 2014, GlaxoSmithKline (“GSK”) sued Teva in Delaware federal court for infringement of a patent directed to using carvedilol in a specified manner to decrease the risk of mortality in patients with congestive heart failure. Teva and eight other generic producers began selling their carvedilol tablets (the generic version of GSK’s Coreg[®]) in September 2007. A jury trial was held and the jury returned a verdict in GSK’s favor finding Teva liable for induced infringement, including willful infringement, and assessing damages of \$235.5 million, not including pre- or post-judgment interest or a multiplier for willfulness. Thereafter, the judge overturned the jury verdict, finding no induced infringement by Teva and that Teva did not owe any damages. On October 2, 2020, in a two-to-one decision, the Court of Appeals for the Federal Circuit, overturned the judge’s ruling and reinstated the jury verdict. Teva’s request for rehearing was granted, and the October 2020 decision was vacated. On February 23, 2021, the same three-judge panel of the Federal Circuit heard additional oral argument on the issue of whether there is enough evidence to support the jury’s verdict of induced infringement during the period from January 8, 2008 through April 30, 2011 (the “skinny label” period). If further appeals are decided against Teva, the case would be remanded to the district court for it to consider Teva’s other legal and equitable defenses that have not yet been considered by the district court. In the first quarter of 2021, Teva recognized a provision based on its offer to settle such matter.

Product Liability Litigation

Teva’s business inherently exposes it to potential product liability claims. Teva maintains a program of insurance, which may include commercial insurance, self-insurance (including direct risk retention), or a combination of both approaches, in amounts and on terms that it believes are reasonable and prudent in light of its business and related risks. However, Teva sells, and will continue to sell, pharmaceuticals that are not covered by its product liability insurance; in addition, it may be subject to claims for which insurance coverage is denied as well as claims that exceed its policy limits. Product liability coverage for pharmaceutical companies is becoming more expensive and increasingly difficult to obtain. As a result, Teva may not be able to obtain the type and amount of insurance it desires, or any insurance on reasonable terms, in all of its markets.

Teva and its subsidiaries are parties to litigation relating to previously unknown nitrosamine impurities discovered in certain products. The discovery led to a global recall of single and combination valsartan medicines around the world starting in July 2018 and to subsequent recalls on other products. The nitrosamine impurities in valsartan are allegedly found in the active pharmaceutical ingredient (API) supplied by multiple API manufacturers. Teva’s products allegedly at issue in the various nitrosamine-related litigations pending in the United States include valsartan, losartan, metformin and ranitidine. There are currently two Multi-District Litigations (“MDL”) pending in the United States District Courts against Teva and numerous other manufacturers. One MDL is pending in the United States District Court for the District of New Jersey for valsartan, losartan and irbesartan. Teva is not named in complaints with respect to irbesartan. The second MDL is pending in the United States District Court for the Southern District of Florida for ranitidine. The lawsuits against Teva in the MDLs consist of individual personal injury and/or product liability claims and economic damages claims brought by consumers and end payors on behalf of purported classes of other consumers and end payors as well as medical monitoring class claims. Defendants’ motions to dismiss in the valsartan, losartan and irbesartan MDL were denied in part and granted in part. Plaintiffs have moved to file amended complaints, which defendants have opposed. On December 31, 2020, the court in the ranitidine MDL granted the generic defendants’ motion to dismiss on the grounds of preemption and deficient pleading, allowing plaintiffs to re-plead certain claims. Certain plaintiffs appealed the decision. Plaintiffs in the ranitidine MDL filed amended complaints, and on March 24, 2021, defendants moved to dismiss those amended complaints. On July 8, 2021, the district court entered an order granting dismissal of the generic manufacturer defendants, including Teva and its affiliates, without leave to further amend. Teva was also recently named in a consolidated proceeding in California state court with similar allegations as the ranitidine MDL. In addition to these MDLs, Teva has also been named in a consolidated proceeding pending in the United States District Court for the District of New Jersey brought by individuals and end payors seeking economic damages on behalf of purported classes of consumers and end payors who purchased Teva’s, as well as other generic manufacturers’ metformin products. The defendants’ motion to dismiss the metformin complaint was granted, and on June 21, 2021, plaintiffs filed an amended complaint. Teva has also been named in one personal injury metformin case in Florida state court. Similar lawsuits are pending in Canada and Germany.

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Competition Matters

As part of its generic pharmaceuticals business, Teva has challenged a number of patents covering branded pharmaceuticals, some of which are among the most widely-prescribed and well-known drugs on the market. Many of Teva's patent challenges have resulted in litigation relating to Teva's attempts to market generic versions of such pharmaceuticals under the federal Hatch-Waxman Act. Some of this litigation has been resolved through settlement agreements in which Teva obtained a license to market a generic version of the drug, often years before the patents expire.

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

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

In June 2013, the U.S. Supreme Court held, in Federal Trade Commission ("FTC") 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 May 2015, Cephalon Inc., a Teva subsidiary ("Cephalon"), entered into a consent decree with the FTC (the "Modafinil Consent Decree") under which the FTC dismissed antitrust claims against Cephalon related to certain finished modafinil products (marketed as PROVIGIL[®]) in exchange for Cephalon and Teva agreeing to, among other things, abide by certain restrictions and limitations, for a period of ten years, when entering into settlement agreements to resolve patent litigation in the United States. Those restrictions and limitations were further refined in connection with the settlement of other unrelated FTC antitrust lawsuits, as described below, and the term of the Modafinil Consent Decree was extended until 2029.

In November 2020, the European Commission issued a final decision in its proceedings against both Cephalon and Teva, finding that the 2005 settlement agreement between the parties had the object and effect of hindering the entry of generic modafinil, and imposed fines totaling €60.5 million on Teva and Cephalon. Teva and Cephalon filed an appeal against the decision in February 2021. A provision for this matter was included in the financial statements. Teva has provided the European Commission with a bank guarantee in the amount of the imposed fines.

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Teva and its affiliates have been named as defendants in lawsuits alleging that multiple patent litigation settlement agreements relating to AndroGel® 1% (testosterone gel) violate the antitrust laws. The first of these lawsuits (the “Georgia AndroGel Litigation”) was filed in January 2009 in California federal court, and later transferred to Georgia federal court, with the FTC and the State of California, and later private plaintiffs, challenging a September 2006 patent litigation settlement between Watson Pharmaceuticals, Inc. (“Watson”), from which Teva later acquired certain assets and liabilities, and Solvay Pharmaceuticals, Inc. (“Solvay”). The second lawsuit (the “Philadelphia AndroGel Litigation”) was filed by the FTC in September 2014 in federal court in Philadelphia, challenging Teva’s December 2011 patent litigation settlement with AbbVie. The FTC stipulated to dismiss Teva from both litigations, in exchange for Teva’s agreement to amend the Modafinil Consent Decree, as described above. On July 16, 2018, the direct purchaser plaintiffs’ motion for class certification in the Georgia AndroGel Litigation was denied and Teva later settled with the retailer plaintiffs in the Georgia AndroGel Litigation as well as the three direct purchasers that had sought class certification, thus leaving no remaining claims in the Georgia AndroGel Litigation. In August 2019, certain other direct-purchaser plaintiffs (who would have been members of the direct purchaser class in the Georgia AndroGel Litigation, had it been certified) filed their own claims in the federal court in Philadelphia (where the Philadelphia AndroGel Litigation has been pending), challenging (in one complaint) both the September 2006 settlement between Watson and Solvay, and the December 2011 settlement between Teva and AbbVie. Those claims remain pending. Annual sales of AndroGel® 1% were approximately \$ 350 million at the time of the earlier Watson/Solvay settlement and approximately \$ 140 million at the time Actavis launched its generic version of AndroGel® 1 % in November 2015 . A provision for these matters was included in the financial statements.

In December 2011, three groups of plaintiffs sued Wyeth and Teva for alleged violations of the antitrust laws in connection with their settlement of patent litigation involving extended release venlafaxine (generic Effexor XR®) entered into in November 2005. The cases were filed by a purported class of direct purchasers, by a purported class of indirect purchasers and by certain chain pharmacies in the U.S. District Court for the District of New Jersey. The plaintiffs claim that the settlement agreement between Wyeth and Teva unlawfully delayed generic entry. In October 2014, the court granted Teva’s motion to dismiss in the direct purchaser cases, after which the parties agreed that the court’s reasoning applied equally to the indirect purchaser cases. Plaintiffs appealed and, in August 2017, the Third Circuit reversed the district court’s decision and remanded for further proceedings. In March 2020, the district court temporarily stayed discovery and referred the case to mediation, and discovery remains stayed. Annual sales of Effexor XR® were approximately \$2.6 billion at the time of settlement and at the time Teva launched its generic version of Effexor XR® in July 2010.

In February 2012, two purported classes of direct-purchaser plaintiffs sued GSK and Teva in New Jersey federal court for alleged violations of the antitrust laws in connection with their settlement of patent litigation involving lamotrigine (generic Lamictal®) entered into in February 2005. The plaintiffs claim that the settlement agreement unlawfully delayed generic entry and seek unspecified damages. In December 2018, the district court granted the direct-purchaser plaintiffs’ motion for class certification, but on April 22, 2020, the Third Circuit reversed that ruling and remanded for further class certification proceedings. On April 9, 2021, the district court denied the direct purchaser plaintiffs’ renewed motion for class certification, but allowed additional briefing on whether plaintiffs can still meet the class certification standard on certain of their claims. Annual sales of Lamictal® were approximately \$950 million at the time of the settlement and approximately \$2.3 billion at the time Teva launched its generic version of Lamictal® in July 2008.

In April 2013, purported classes of direct purchasers of, and end payers for, Niaspan® (extended release niacin) sued Teva and Abbott for violating the antitrust laws by entering into a settlement agreement in April 2005, to resolve patent litigation over the product. A multidistrict litigation has been established in the U.S. District Court for the Eastern District of Pennsylvania. Throughout 2015 and in January 2016, several individual direct-purchaser opt-out plaintiffs filed complaints with allegations nearly identical to those of the direct purchasers’ class. In August 2019, the district court certified the direct-purchaser class, but in June 2020, the court denied the indirect purchasers’ motion for class certification without prejudice. On September 4, 2020, the indirect purchasers filed a renewed motion for class certification, which remains pending. In October 2016, the District Attorney for Orange County, California, filed a similar complaint in California state court, which has since been amended, alleging violations of state law. Defendants moved to strike the District Attorney’s claims for restitution and civil penalties to the extent not limited to alleged activity occurring in Orange County. The Superior Court denied that motion. The Court of Appeals subsequently reversed the decision and in June 2020, the California Supreme Court reversed the Court of Appeals’ decision, allowing the District Attorney’s claims to proceed. Annual sales of Niaspan® were approximately \$416 million at the time of the settlement and approximately \$1.1 billion at the time Teva launched its generic version of Niaspan® in September 2013.

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Since January 2014, numerous lawsuits have been filed in the U.S. District Court for the Southern District of New York by purported classes of end-payers for, and direct-purchasers of, Actos[®] and Actoplus Met (pioglitazone and pioglitazone plus metformin) against Takeda, the innovator, and several generic manufacturers, including Teva, Actavis and Watson. The lawsuits allege, among other things, that the settlement agreements between Takeda and the generic manufacturers violated the antitrust laws. The court dismissed the end-payers' lawsuits against all defendants in September 2015. On February 8, 2017, the Court of Appeals for the Second Circuit affirmed the dismissal in part and vacated and remanded the dismissal in part with respect to the claims against Takeda. The direct purchasers' case had been stayed pending resolution of the appeal in the end payer matter and the direct purchasers amended their complaint for a second time following the Second Circuit's decision, but on October 8, 2019, the district court dismissed, with prejudice, the direct purchasers' claims against the generic manufacturers (including Teva, Actavis, and Watson). At the time of Teva's settlement, annual sales of Actos[®] and Actoplus Met were approximately \$3.7 billion and approximately \$500 million, respectively. At the time Teva launched its authorized generic version of Actos[®] and Actoplus Met in August 2012, annual sales of Actos[®] and Actoplus Met were approximately \$2.8 billion and approximately \$430 million, respectively.

In January 2019, generic manufacturer Cipla Limited filed a lawsuit against Amgen, which was later amended to include Teva as a defendant, in Delaware federal court, alleging, among other things, that a January 2, 2019 settlement agreement between Amgen and Teva, resolving patent litigation over cinacalcet (generic Sensipar[®]), violated the antitrust laws. On August 14, 2020, Cipla Limited agreed to dismiss its claims against Teva, with prejudice, and those claims have since been dismissed. Putative classes of direct-purchaser and end-payer plaintiffs have also filed antitrust lawsuits (which have since been coordinated in federal court in Delaware) against Amgen and Teva related to the January 2, 2019 settlement. On July 22, 2020, a magistrate judge recommended that plaintiffs' claims be dismissed and on November 30, 2020, the district court overruled the magistrate judge's recommendation, denied Teva's motion to dismiss in part, and instructed plaintiffs to file amended complaints, which plaintiffs filed on February 16, 2021. Teva again moved to dismiss those complaints on March 30, 2021, based on plaintiffs' failure to allege both (a) that the settlement violated the antitrust laws and (b) that the settlement caused any actual injury to plaintiffs, and Teva's motions remain pending. Annual sales of Sensipar[®] in the United States were approximately \$1.4 billion at the time Teva launched its generic version of Sensipar[®] in December 2018, and at the time of the January 2, 2019 settlement.

On July 15, 2021, the U.K. Competition and Markets Authority ("CMA") issued a decision imposing fines for breaches of U.K. competition law by Allergan, Actavis UK and Auden Mckenzie and a number of other companies in connection with the supply of 10mg and 20mg hydrocortisone tablets in the U.K. The decision combines the CMA's three prior investigations into the supply of hydrocortisone tablets in the U.K. and encompasses those allegations which were subject to prior statements of objections (a provisional finding of breach of the Competition Act), in particular those under case 50277-1 (unfair pricing, originally subject to a statement of objections on December 16, 2016), case 50277-2 (anti-competitive agreement with AMCo, originally subject to a statement of objections on March 3, 2017) as well as the CMA's subsequent investigation relating to an anti-competitive agreement with Waymade. On January 9, 2017, Teva completed the sale of Actavis UK to Accord Healthcare Limited, in connection with which Teva will indemnify Accord Healthcare for potential fines imposed by the CMA and/or damages awarded by a court against Actavis UK in relation to the December 16, 2016 and March 3, 2017 statements of objections, and resulting from conduct prior to the closing date of the sale. In addition, Teva agreed to indemnify Allergan against losses arising from this matter in the event of any such fines or damages. A provision for the estimated exposure for Teva related to the fines and/or damages has been recorded in the financial statements.

In March 2021, following the 2019 European Commission's inspection of Teva and subsequent request for information, the European Commission opened a formal antitrust investigation to assess whether Teva may have abused a dominant position by delaying the market entry and uptake of medicines that compete with COPAXONE. Annual sales of COPAXONE in the European Economic Area for the past calendar year were approximately \$380 million.

Between September 1, 2020 and December 20, 2020, separate plaintiffs purporting to represent putative classes of direct and indirect purchasers and opt-out retailer purchasers of Bystolic[®] (nebivolol hydrochloride) filed separate complaints in the U.S. District Court for the Southern District of New York against several generic manufacturers, including Teva, Actavis, and Watson, alleging, among other things, that the settlement agreements these generic manufacturers entered into with Forest Laboratories, Inc., the innovator, to resolve patent litigation over Bystolic[®] violated the antitrust laws. The cases were coordinated and on March 15, 2021, plaintiffs filed amended complaints, which Teva, Actavis, and Watson have moved to dismiss on the grounds (among others) that the allegations do not plausibly demonstrate any improper payment from Forest to Watson that could create antitrust liability. Those motions remain pending. Annual sales of Bystolic[®] in the United States were approximately \$700 million at the time of Watson's 2013 settlement with Forest.

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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.

In 2015 and 2016, Actavis and Teva USA each respectively received subpoenas from the U.S. Department of Justice (“DOJ”) Antitrust Division seeking documents and other information relating to the marketing and pricing of certain Teva USA generic products and communications with competitors about such products. On August 25, 2020, a federal grand jury in the Eastern District of Pennsylvania returned a three count indictment charging Teva USA with criminal felony Sherman Act violations. See No. 20-cr-200 (E.D. Pa.). The indictment alleges Teva USA participated in a conspiracy with certain other generic drug manufacturers to maintain and fix prices, allocate customers, and other alleged antitrust offenses concerning the sale of generic drugs. The indictment identified the following generic drugs: Pravastatin, Carbamazepine, Clotrimazole, Etodolac (IR and ER), Fluocinonide (Cream E-Cream, Gel, and Ointment), Warfarin, Etodolac (IR), Nadolol, Temozolomide, and Tobramycin. On September 8, 2020, Teva USA pled not guilty to all counts. A tentative trial date is yet to be scheduled. While the Company is unable to estimate a range of loss at this time, a conviction on these criminal charges could have a material adverse impact on the Company’s business, including monetary penalties and debarment from federally funded health care programs.

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. An adverse resolution of this matter may include fines, penalties, financial forfeiture and compliance conditions.

In 2015 and 2016, Actavis and Teva USA each respectively received a subpoena from the Connecticut Attorney General seeking documents and other information relating to potential state antitrust law violations. Subsequently, on December 15, 2016, a civil action was brought by the attorneys general of twenty states against Teva USA and several other companies asserting claims under federal antitrust law alleging price fixing of generic products in the United States. That complaint was later amended to add new states as named plaintiffs, as well as new allegations and new state law claims, and on June 18, 2018, the attorneys general of 49 states plus Puerto Rico and the District of Columbia filed a consolidated amended complaint against Actavis and Teva, as well as other companies and individuals. On May 10, 2019, most (though not all) of these attorneys general filed another antitrust complaint against Actavis, Teva and other companies and individuals, alleging price-fixing and market allocation with respect to additional generic products. On November 1, 2019, the state attorneys general filed an amended complaint, bringing the total number of plaintiff states and territories to 54. The amended complaint alleges that Teva was at the center of a conspiracy in the generic pharmaceutical industry, and asserts that Teva and others fixed prices, rigged bids, and allocated customers and market share with respect to certain additional products. On June 10, 2020, most, but not all, of the same states, with the addition of the U.S. Virgin Islands, filed a third complaint in the District of Connecticut naming, among other defendants, Actavis, but not Teva USA in a similar complaint relating to dermatological generics products. In the various complaints described above, the states seek a finding that the defendants’ actions violated federal antitrust law and state antitrust and consumer protection laws, as well as injunctive relief, disgorgement, damages on behalf of various state and governmental entities and consumers, civil penalties and costs. All such complaints have been transferred to the generic drug multidistrict litigation in the Eastern District of Pennsylvania (“Pennsylvania MDL”). On July 13, 2020, the court overseeing the Pennsylvania MDL chose the attorneys’ general November 1, 2019 amended complaint, referenced above, along with three complaints filed by private plaintiffs, to proceed first in the litigation as bellwether complaints. Teva moved the court to reconsider that ruling. The motion was granted on February 9, 2021 and on May 7, 2021, the Court chose the attorneys’ general third complaint (from June 10, 2020) to serve as a bellwether complaint in the Pennsylvania MDL. In June 2021, Teva settled with the State of Mississippi for \$925,000, and the State dismissed its claims against Actavis and Teva USA, as well as certain former employees of Actavis and Teva USA, pursuant to that settlement.

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Beginning on March 2, 2016, and continuing through December 2020, 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 and indirect purchaser opt-out plaintiffs. These complaints, which allege that the defendants engaged in conspiracies to fix prices and/or allocate market share of generic products have been brought against various manufacturer defendants, including Teva USA and Actavis. The plaintiffs generally seek injunctive relief and damages under federal antitrust law, and damages under various state laws. On October 16, 2018, the court denied certain of the defendants' motions to dismiss as to certain federal claims, pending as of that date, and on February 15, 2019, the court granted in part and denied in part defendants' motions to dismiss as to certain state law claims. On July 18, 2019, and again on May 6, 2020, certain individual plaintiffs commenced a civil action in the Pennsylvania Court of Common Pleas of Philadelphia County against many of the defendants in the Pennsylvania MDL, including Teva and Actavis, but no complaint has been filed in either action and, both cases have been placed in deferred status. On November 13, 2019, and again on August 24, 2020, certain counties in New York commenced civil actions against many of the defendants in the Pennsylvania MDL, including Teva and Actavis, and the complaints have been transferred to the Pennsylvania MDL. On December 15, 2020, several additional New York counties filed suit in New York state court raising similar allegations, and the case was removed to federal court on March 26, 2021 and has been transferred to the Pennsylvania MDL. On March 1, 2020, Harris County in Texas filed a complaint against several generic manufacturers including Teva and Actavis in the District Court for the Southern District of Texas, which has been transferred to the Pennsylvania MDL. There is also one similar complaint brought in Canada, which alleges that the defendants engaged in conspiracies to fix prices and/or allocate market share of generic drug products to the detriment of a class of private payors. The action is in its early stages.

In March 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. Subsequently, in August 2020, the U.S. Attorney's office in Boston, Massachusetts brought a civil action in the U.S. District Court for the District of Massachusetts alleging violations of the federal Anti-Kickback Statute, and asserting causes of action under the federal False Claims Act and state law. It is alleged that Teva caused the submission of false claims to Medicare through Teva's donations to bona fide independent charities that provide financial assistance to patients. An adverse judgment may involve damages, civil penalties and injunctive remedies. On October 19, 2020, Teva filed a motion to dismiss the complaint on the grounds that it fails to state a claim, and that motion remains pending. Additionally, on January 8, 2021, Humana, Inc. filed an action against Teva in the United States District Court for the Middle District of Florida based on the allegations raised in the August 2020 complaint filed by the U.S. Attorney's Office in Boston. On April 2, 2021, Teva filed a motion to dismiss the claims on the grounds that the claims are time-barred and/or insufficiently pled, and that motion remains pending.

In April 2021, a city and county in Washington sued Teva in the United States District Court for the Western District of Washington for alleged violations of the Racketeer Influenced and Corrupt Organizations Act, Washington's Consumer Protection Act, and unjust enrichment concerning Teva's sale of COPAXONE. Plaintiffs purport to represent a nationwide class of health plans and a subclass of Washington-based health plans that purchased and/or reimbursed health plan members for COPAXONE. Plaintiffs allege that Teva engaged in several fraudulent schemes that resulted in plaintiffs and the putative class members purchasing and/or reimbursing plan members for additional prescriptions of COPAXONE and/or at inflated COPAXONE prices. Plaintiffs seek treble damages for the excess reimbursements and inflated costs, as well as injunctive relief. On July 2, 2021, Teva moved to dismiss the suit arguing that plaintiffs' claims are barred by the applicable statutes of limitations, plaintiffs cannot recover under the direct purchaser rule, and that plaintiffs failed to plausibly allege fraud or other elements of their claims. That motion remains pending.

On June 29, 2021, Mylan Pharmaceuticals sued Teva in District Court for the District of New Jersey for alleged violations of the Lanham Act, unfair competition, monopolization, tortious interference, and trade libel. Plaintiffs claim Teva was involved in an unlawful scheme to delay and hinder generic competition concerning COPAXONE sales. Plaintiffs seek damages for lost profits and expenses, disgorgement, treble damages, attorneys' fees and costs, and injunctive relief.

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Opioids Litigation

Since May 2014, more than 3,500 complaints have been filed with respect to opioid sales and distribution against various Teva affiliates, along with several other pharmaceutical companies, by a number of cities, counties, states, other governmental agencies, tribes and private plaintiffs (including various putative class actions of individuals) in both state and federal courts. Most of the federal cases have been consolidated into a multidistrict litigation in the Northern District of Ohio (“MDL Opioid Proceeding”) and many of the cases filed in state court have been removed to federal court and consolidated into the MDL Opioid Proceeding. Two cases that were included in the MDL Opioid Proceeding were transferred back to federal district court for additional discovery, pre-trial proceedings and trial. Those cases are: *City of Chicago v. Purdue Pharma L.P. et al.*, No. 14-cv-04361 (N.D. Ill.) and *City and County of San Francisco v. Purdue Pharma L.P. et al.*, No. 18-cv-07591-CRB (N.D. Cal.). Other cases remain pending in various states. In some jurisdictions, such as Illinois, New York, Pennsylvania, South Carolina, Texas, Utah and West Virginia, certain state court cases have been transferred to a single court within their respective state court systems for coordinated pretrial proceedings. 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, over 950 personal injury plaintiffs, including various putative class actions of individuals, have asserted personal injury and wrongful death claims in over 600 complaints, nearly all of which are consolidated in the MDL Opioid Proceeding. Furthermore, approximately 700 complaints have named Anda, Inc. (and other distributors and manufacturers) alleging that Anda failed to develop and implement systems sufficient to identify suspicious orders of opioid products and prevent the abuse and diversion of such products to individuals who used them for other than legitimate medical purposes. Plaintiffs seek a variety of remedies, including restitution, civil penalties, disgorgement of profits, treble damages, attorneys’ fees and injunctive relief. Certain plaintiffs assert that the measure of damages is the entirety of the costs associated with addressing the abuse of opioids and opioid addiction and certain plaintiffs specify multiple billions of dollars in the aggregate as alleged damages. The individual personal injury plaintiffs further seek non-economic damages. In many of these cases, plaintiffs are seeking joint and several damages among all defendants.

On April 19, 2021, a bench trial in California (*The People of the State of California, acting by and through Santa Clara County Counsel James R. Williams, et. al. v. Purdue Pharma L.P., et. al.*) commenced with Teva and other defendants focused on the marketing of branded opioids. On June 29, 2021, a jury trial in New York (*In re Opioid Litigation*, Index No. 400000/2017)) commenced, with Teva and other defendants, focused on the marketing and distribution of opioids. Absent resolutions, additional trials are expected to proceed in several states in 2022.

In May 2019, Teva settled the Oklahoma litigation brought by the Oklahoma Attorney General (State of Oklahoma, ex. rel. Mike Hunter, Attorney General of Oklahoma vs. Purdue Pharma L.P., et. al.) for \$85 million. The settlement did not include any admission of violation of law for any of the claims or allegations made. As the Company demonstrated a willingness to settle part of the litigation, for accounting purposes, management considered a portion of opioid-related cases as probable and, as such, recorded an estimated provision in the second quarter of 2019. Given the relatively early stage of the cases, management viewed no amount within the range to be the most likely outcome. Therefore, management recorded a provision for the reasonably estimable minimum amount in the assessed range for such opioid-related cases in accordance with Accounting Standards Codification 450 “Accounting for Contingencies.”

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

Also on October 21, 2019, Teva and certain other defendants reached an agreement in principle with a group of Attorneys General from North Carolina, Pennsylvania, Tennessee and Texas for a nationwide settlement. This nationwide settlement was designed to provide a mechanism by which the Company attempts to seek resolution of remaining potential and pending opioid claims by both the U.S. states and political subdivisions (i.e., counties, tribes and other plaintiffs) thereof. Under this nationwide settlement, Teva would provide buprenorphine naloxone (sublingual tablets) with an estimated value of up to approximately \$23 billion at wholesale acquisition cost over a ten year period. In addition, Teva would also provide cash payments of up to \$250 million over a ten year period.

During the passage of time since then, the Company has continued to negotiate the terms and conditions of a nationwide settlement. On July 21, 2021, it was announced that four other defendants (not including Teva) have reached a nationwide settlement, subject to certain conditions, which includes payment of up to approximately \$26 billion spread over up to 18 years. The achievement of this settlement may similarly present an opportunity for Teva to arrive at a settlement, although there do remain many complex financial and legal issues still outstanding, including indemnification claims by Allergan against the Company, arising from the acquisition of the Actavis Generics business. The Company cannot predict if a settlement will be finalized.

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The Company considered a range of potential settlement outcomes. The current provision remains a reasonable estimate of the ultimate costs if a settlement is finalized based on the Company's most recent offer to settle. However, if not finalized for the entirety of the cases, a reasonable upper end of a range of loss cannot be determined. An adverse resolution of any of these lawsuits or investigations may involve large monetary penalties, damages, and/or other forms of monetary and non-monetary relief and could have a material and adverse effect on Teva's reputation, business, results of operations and cash flows.

Separately, on April 27, 2018, Teva received subpoena requests from the United States Attorney's office in the Western District of Virginia and the Civil Division seeking documents relating to the manufacture, marketing and sale of branded opioids. In August 2019, Teva received a grand jury subpoena from the United States Attorney's Office for the Eastern District of New York for documents related to the Company's anti-diversion policies and procedures and distribution of its opioid medications, in what the Company understands to be part of a broader investigation into manufacturers' and distributors' monitoring programs and reporting under the Controlled Substances Act. In September 2019, Teva received subpoenas from the New York State Department of Financial Services (NYDFS) as part of an industry-wide inquiry into the effect of opioid prescriptions on New York health insurance premiums. This was followed by a Statement of Charges and Notice of Hearing filed by the NYDFS, although no hearing date is currently set. Currently, Teva cannot predict how a nationwide settlement (if finalized) will affect these investigations and administrative actions. In addition, a number of state attorneys general, including a coordinated multistate effort, have initiated investigations into sales and marketing practices of Teva and its affiliates with respect to opioids. Other states are conducting their own investigations outside of the multistate group. Teva is cooperating with these ongoing investigations and cannot predict their outcome at this time.

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

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. Those lawsuits were consolidated and transferred to the U.S. District Court for the District of Connecticut (the "Ontario Teachers Securities Litigation"). On December 13, 2019, the lead plaintiff in that action filed an amended complaint, purportedly on behalf of purchasers of Teva's securities between February 6, 2014 and May 10, 2019. The amended complaint asserts that Teva and certain of its current and former officers and directors violated federal securities and common 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. The amended complaint seeks unspecified damages, legal fees, interest, and costs. In July 2017, August 2017, and June 2019, other putative securities class actions were filed in other federal courts based on similar allegations, and those cases have been transferred to the U.S. District Court for the District of Connecticut. Between August 2017 and October 2020, twenty complaints were filed against Teva and certain of its current and former officers and directors seeking unspecified compensatory damages, legal fees, costs and expenses. The similar claims in these complaints have been brought on behalf of plaintiffs, in various forums across the country, who have indicated that they intend to "opt-out" of the Ontario Teachers Securities Litigation. On March 10, 2020, the Court consolidated the Ontario Teachers Securities Litigation with all of the above-referenced putative class actions for all purposes and the "opt-out" cases for pretrial purposes. The case is now in discovery. Pursuant to that consolidation order, plaintiffs in several of the "opt-out" cases filed amended complaints on May 28, 2020. On January 22, 2021, the Court dismissed the "opt-out" plaintiffs' claims arising from statements made prior to the five year statute of repose, but denied Teva's motion to dismiss their claims under Israeli laws. Those "opt-out" plaintiffs moved for reconsideration, which was denied on March 30, 2021. On May 24, 2021, Teva moved to dismiss a majority of the "opt-out" complaints on various other grounds. The Ontario Teachers Securities Litigation plaintiffs' Motion for Class Certification and Appointment of Class Representatives and Class Counsel was granted on March 9, 2021, to which Teva's appeal was denied. Motions to approve securities class actions were also filed in the Tel Aviv District Court in Israel with similar allegations to those made in the Ontario Teachers Securities Litigation.

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On September 23, 2020, a putative securities class action was filed in the U.S. District Court for the Eastern District of Pennsylvania against Teva and certain of its former officers alleging, among other things, violations of Section 10(b) of the Securities and Exchange Act of 1934, as amended and SEC Rule 10b-5. The complaint, purportedly filed on behalf of persons who purchased or otherwise acquired Teva securities between October 29, 2015 and August 18, 2020, alleges that Teva and certain of its former officers violated federal securities laws by allegedly making false and misleading statements regarding the commercial performance of COPAXONE, namely, by failing to disclose that Teva had caused the submission of false claims to Medicare through Teva's donations to bona fide independent charities that provide financial assistance to patients, which allegedly impacted COPAXONE's commercial success and the sustainability of its revenues and resulted in the above referenced August 2020 False Claims Act complaint filed by the DOJ. On March 26, 2021, the Court appointed lead plaintiff and lead counsel. On May 25, 2021, lead plaintiff filed an amended class action complaint, which names four additional former and current officers as defendants. The amended complaint seeks unspecified damages, legal fees, interest, and costs. Defendants' response to the amended complaint is currently due by August 13, 2021. A motion to approve a securities class action was also filed in the Central District Court in Israel, which has been stayed pending the U.S. litigation, with similar allegations to those made in the above complaint filed in the U.S. District Court for the Eastern District of Pennsylvania.

Motions to approve derivative actions against certain past and present directors and officers have been filed in Israeli Courts alleging negligence and recklessness with respect to the acquisition of the Rimsa business, the acquisition of Actavis Generics and the patent settlement relating to Lidoderm®. Motions for document disclosure prior to initiating derivative actions were filed with respect to several U.S. and EU settlement agreements, opioids, the U.S. price-fixing investigations and allegations related to the DOJ's complaint regarding Copaxone patient assistance program in the U.S. as well as allegations related to the European Commission investigation. In June 2021, the Tel Aviv District Court approved the settlement reached with respect to the derivative proceeding with regard to the acquisition of Actavis Generics and two related actions, including the derivative proceedings related to allegations in connection with the Lidoderm® patent settlement agreement.

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.

Item 103 of Regulation S-K promulgated by the SEC requires disclosure of certain environmental matters when a governmental authority is a party to the proceedings and such proceedings involve potential monetary sanctions, unless the Company reasonably believes that the matter will result in no monetary sanctions, or in monetary sanctions, exclusive of interest and costs, of less than \$300,000. The following matter is disclosed in accordance with that requirement. On July 8, 2021, the National Green Tribunal Principal Bench, New Delhi, issued an order against Teva's subsidiary in India, Teva API India Private Limited, finding non-compliance with environmental laws and assessed a penalty of \$1.4 million. The Company expects to dispute certain of the findings and the amount of the penalty and file an appeal before the Supreme Court in India. The Company does not believe that the eventual outcome of such matter will have a material effect on its business.

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Other Matters

On February 1, 2018, former shareholders of Ception Therapeutics, Inc., a company that was acquired by and merged into Cephalon in 2010, prior to Cephalon's acquisition by Teva, filed breach of contract and other related claims against the Company, Teva USA and Cephalon in the Delaware Court of Chancery. Among other things, the plaintiffs allege that Cephalon breached the terms of the 2010 Ception-Cephalon merger agreement by failing to exercise commercially reasonable efforts to develop and commercialize CINQAIR[®] (reslizumab) for the treatment of eosinophilic esophagitis ("EE"). The plaintiffs claim damages of at least \$200 million, an amount they allege is equivalent to the milestones payable to the former shareholders of Ception in the event Cephalon were to obtain regulatory approval for EE in the United States (\$150 million) and Europe (\$50 million). Defendants moved to dismiss the complaint and on December 28, 2018, the court granted the motion in part and dismissed all of plaintiffs' claims, except for their claim against Cephalon for breach of contract. Trial in this matter is currently scheduled for June 2022.

NOTE 11 – Income taxes:

In the second quarter of 2021, Teva recognized a tax expense of \$98 million, on pre-tax income of \$308 million. In the second quarter of 2020, Teva recognized a tax benefit of \$104 million, on pre-tax loss of \$51 million. Teva's tax rate for the second quarter of 2021 was mainly affected by impairments, amortization and interest expense disallowance.

In the first six months of 2021, Teva recognized a tax expense of \$159 million, on pre-tax income of \$451 million. In the first six months of 2020, Teva recognized a tax benefit of \$163 million, on pre-tax loss of \$84 million. Teva's tax rate for the first six months of 2021 was mainly affected by impairments, amortization, legal settlements and interest expense disallowance.

The statutory Israeli corporate tax rate is 23% in 2021. Teva's tax rate differs from the Israeli statutory tax rate, mainly due to generation of profits in various jurisdictions in which tax rates are different than the Israeli tax rate, tax benefits in Israel and other countries, as well as infrequent or non-recurring items.

Teva filed a claim seeking the refund of withholding taxes paid to the Indian tax authorities in 2012. Trial in this case is scheduled to begin in September 2021. A final and binding decision against Teva in this case may lead to an asset write off of \$ 139 million.

The Israeli tax authorities issued tax assessment decrees for 2008-2012 and 2013-2016, challenging the Company's positions on several issues. Teva has protested the 2008-2012 and 2013-2016 decrees before the Central District Court in Israel. The Company believes it has adequately provided for these items, however, adverse results could be material.

NOTE 12 – Other assets impairments, restructuring and other items:

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
	(U.S. \$ in millions)		(U.S. \$ in millions)	
Impairments of long-lived tangible assets (1)	\$ 32	\$ 277	\$ 80	\$ 352
Contingent consideration	(19)	76	(16)	83
Restructuring	(13)	33	69	73
Other	28	(6)	33	(5)
Total	\$ 28	\$ 381	\$ 165	\$ 502

(1) Including impairments related to exit and disposal activities

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Impairments

Impairments of tangible assets for the three months ended June 30, 2021 and 2020 were \$32 million and \$277 million, respectively. The impairment for the three months ended June 30, 2021 was mainly related to certain assets in Europe. The impairment for the three months ended June 30, 2020 was mainly related to the agreement to sell certain assets from Teva's business venture in Japan, which was completed in February 2021.

Impairments of tangible assets for the six months ended June 30, 2021 and 2020 were \$80 million and \$352 million, respectively. The impairment for the six months ended June 30, 2021 was mainly related to certain assets in Europe. The impairment for the six months ended June 30, 2020 was mainly related to the agreement to sell certain assets from Teva's business venture in Japan, which was completed in February 2021 and plant rationalization. See note 2.

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

Contingent consideration

In the three months ended June 30, 2021, Teva recorded income of \$19 million for contingent consideration, compared to an expense of \$76 million in the three months ended June 30, 2020. The income in the second quarter of 2021 was mainly related to a change in the estimated future royalty payments to Allergan in connection with lenalidomide (generic equivalent of Revlimid®), which was part of the Actavis Generics acquisition. The expense in the second quarter of 2020 was mainly related to a change in the estimated future royalty payments to Eagle Pharmaceuticals, Inc. ("Eagle") in connection with expected future bendamustine sales.

In the six months ended June 30, 2021, Teva recorded income of \$16 million for contingent consideration, compared to an expense of \$83 million in the six months ended June 30, 2020. The income in the first six months of 2021 was mainly related to a change in the estimated future royalty payments to Allergan in connection with lenalidomide (generic equivalent of Revlimid®), which was part of the Actavis Generics acquisition. The expense in the first six months of 2020 was mainly related to a change in the estimated future royalty payments to Eagle in connection with expected future bendamustine sales.

Restructuring

In the three months ended June 30, 2021, Teva recorded \$13 million of restructuring income, compared to \$33 million of restructuring expenses in the three months ended June 30, 2020. The income for the three months ended June 30, 2021 was primarily related to reassessment of the estimate of a prior employee termination provision.

In the six months ended June 30, 2021, Teva recorded \$69 million of restructuring expenses, compared to \$73 million in the six months ended June 30, 2020. The expenses for the six months ended June 30, 2021 were primarily related to network consolidation activities and residual expenses of the restructuring plan announced in 2017.

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

	Three months ended June 30,	
	2021	2020
	(U.S. \$ in millions)	
Restructuring		
Employee termination	\$ (19)	\$ 3
Other	6	30
Total	<u>\$ (13)</u>	<u>\$ 33</u>

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	Six months ended June 30,	
	2021	2020
	(U.S. \$ in millions)	
Restructuring		
Employee termination	\$ 61	\$ 36
Other	8	36
Total	\$ 69	\$ 73

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

	Employee termination costs	Other	Total
	(U.S. \$ in millions)		
Balance as of January 1, 2021	\$ (115)	\$ (7)	\$(122)
Provision	(61)	(8)	(69)
Utilization and other*	56	8	64
Balance as of June 30, 2021	<u>\$ (120)</u>	<u>\$ (7)</u>	<u>\$(127)</u>
	Employee termination costs	Other	Total
	(U.S. \$ in millions)		
Balance as of January 1, 2020	\$ (208)	\$ (7)	\$(215)
Provision	(36)	(36)	(73)
Utilization and other*	114	36	150
Balance as of June 30, 2020	<u>\$ (130)</u>	<u>\$ (7)</u>	<u>\$(137)</u>

* Includes adjustments for foreign currency translation.

Significant regulatory and other events

In July 2018, the FDA completed an inspection of Teva's manufacturing plant in Davie, Florida in the United States, and issued a Form FDA-483 to the site. In October 2018, the FDA notified Teva that the inspection of the site is classified as "official action indicated" ("OAI"). On February 5, 2019, Teva received a warning letter from the FDA that contained four additional enumerated concerns related to production, quality control and investigations at this site. Teva has been working diligently to address the FDA's concerns in a manner consistent with current good manufacturing practice (cGMP) requirements as quickly and as thoroughly as possible. An FDA follow up inspection occurred in January 2020, resulting in some follow up findings and Teva received a letter from the FDA dated April 24, 2020 notifying it that the site continues to be classified as OAI. A subsequent FDA inspection in May 2021 concluded with five observations, which Teva addressed in its response. The response is pending with the FDA. If Teva is unable to remediate the findings to the FDA's satisfaction, Teva may face additional consequences. These would potentially include continued delays in FDA approval for future products from the site, financial implications due to loss of revenues, impairments, inventory write-offs, customer penalties, idle capacity charges, costs of additional remediation and possible FDA enforcement action. Teva expects to generate approximately \$46.3 million in revenues from this site during the remainder of 2021, assuming remediation or enforcement does not cause any unscheduled slowdown or stoppage at the facility, however, delays in FDA approvals of future products from the site may occur.

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In July 2018, Teva announced the voluntary recall of valsartan and certain combination valsartan medicines in various countries due to the detection of trace amounts of a previously unknown nitrosamine impurity called NDMA found in valsartan API supplied by Zhejiang Huahai Pharmaceuticals Co. Ltd. ("Huahai"). Since July 2018, Teva has been actively engaged with global regulatory authorities in reviewing its sartan and other products to determine whether NDMA and/or other related nitrosamine impurities are present in specific products. Where necessary, Teva has initiated additional voluntary recalls. In December 2019, Teva reached a settlement with Huahai resolving Teva's claims related to certain sartan API supplied by Huahai. Under the settlement agreement, Huahai agreed to compensate Teva for some of its direct losses and provide it with prospective cost reductions for API. The settlement does not release Huahai from liability for any losses Teva may incur as a result of third party personal injury or product liability claims relating to the sartan API at issue. In addition, multiple lawsuits have been filed in connection with this matter, which may lead to additional customer penalties, impairments and litigation costs.

In the second quarter of 2020, Teva's operations in its manufacturing facilities in Goa, India were temporarily suspended due to a water supply issue. During the second half of 2020, Teva completed partial remediation of this issue and restarted limited supply from its Goa facilities. The site experienced some additional delays in the first quarter of 2021 due to labor related issues, but the situation stabilized during the second quarter of 2021. The impact to Teva's financial results for the six months ended June 30, 2021 was immaterial, however, if the full remediation takes longer than expected there may be further loss of sales, customer penalties or impairments to related assets.

In June 2021, the Company temporarily paused manufacturing at its Irvine, California facility pending completion of an open manufacturing investigation. In July 2021, the FDA initiated an establishment inspection at the facility. During the inspection, the Company opened additional investigations, and considered proactively to suspend distribution of product from the Irvine facility until completion of these investigations. Teva continues to manage the ongoing FDA inspection, and will address any concerns raised by FDA. A decision to suspend distribution for an extended period or if Teva is unable to address additional inspection issues satisfactorily, could subject Teva to additional consequences. Teva has considered these developments and has not recorded an impairment or other loss in the financial statements. Teva will continue to assess potential financial implications, including due to loss of revenues, impairments, inventory write offs, customer penalties, idle capacity charges, costs of additional remediation and/or FDA enforcement actions.

NOTE 13 – Earnings (Loss) per share:

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

In computing diluted earnings per share for the three months ended June 30, 2021 and June 30, 2020, basic earnings per share were adjusted to take into account the potential dilution that could occur upon the exercise of options and non-vested RSUs granted under employee stock compensation plans. No account was taken of the potential dilution by the convertible senior debentures, since they had an anti-dilutive effect on earnings per share.

In computing diluted earnings per share for the six months ended June 30, 2021 and June 30, 2020, basic earnings per share were adjusted to take into account the potential dilution that could occur upon the exercise of options and non-vested RSUs granted under employee stock compensation plans. No account was taken of the potential dilution by the convertible senior debentures, since they had an anti-dilutive effect on earnings per share.

Basic and diluted earnings per share were \$ 0.19 for the three months ended June 30, 2021, compared to basic and diluted earnings per share of \$ 0.13 for the three months ended June 30, 2020.

Basic and diluted earnings per share were \$ 0.26 for the six months ended June 30, 2021, compared to basic and diluted earnings per share of \$ 0.19 for the six months ended June 30, 2020.

NOTE 14 – Accumulated other comprehensive income (loss):

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

	Net Unrealized Gains (Losses)		Benefit Plans	
	Foreign currency translation adjustments	Derivative financial instruments	Actuarial gains (losses) and prior service (costs) credits	Total
	(U.S. \$ in millions)			
Balance as of December 31, 2020, net of taxes	\$ (1,919)	\$ (363)	\$ (117)	\$ (2,399)
Other comprehensive income (loss) before reclassifications	(77)	—	—	(77)
Amounts reclassified to the statements of income	—	18	1	19
Net other comprehensive income (loss) before tax	(77)	18	1	(58)
Corresponding income tax	15	(4)	—	11
Net other comprehensive income (loss) after tax*	(62)	14	1	(47)
Balance as of June 30, 2021, net of taxes	\$ (1,981)	\$ (349)	\$ (116)	\$ (2,446)

* Amounts do not include a \$68 million loss from foreign currency translation adjustments attributable to non-controlling interests.

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	Net Unrealized Gains (Losses)		Benefit Plans	
	Foreign currency translation adjustments	Derivative financial instruments	Actuarial gains (losses) and prior service (costs) credits	Total
	(U.S. \$ in millions)			
Balance as of December 31, 2019, net of taxes	\$ (1,794)	\$ (420)	\$ (98)	\$ (2,312)
Other comprehensive income (loss) before reclassifications	(432)	19	—	(413)
Amounts reclassified to the statements of income	—	18	—	18
Net other comprehensive income (loss) before tax	(432)	37	—	(395)
Corresponding income tax	4	—	—	4
Net other comprehensive income (loss) after tax*	(428)	37	—	(391)
Balance as of June 30, 2020, net of taxes	\$ (2,222)	\$ (383)	\$ (98)	\$ (2,703)

* Amounts do not include a \$12 million gain from foreign currency translation adjustments attributable to non-controlling interests.

NOTE 15 – Segments:

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

- (a) North America segment, which includes the United States and Canada.
- (b) Europe segment, which includes the European Union and certain other European countries.
- (c) International Markets segment, which includes all countries other than those in the North America and Europe segments.

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

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

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

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

Teva's CEO may review its strategy and organizational structure from time to time. Any changes in strategy may lead to a reevaluation of the Company's segments and goodwill allocation to reporting units, as well as fair value attributable to its reporting units. See note 3 and note 6.

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

a. Segment information:

	Three months ended June 30,		
	2021		
	North America	Europe	International Markets
	(U.S. \$ in millions)		
Revenues	\$ 1,943	\$ 1,184	\$ 485
Gross profit	1,040	661	270
R&D expenses	162	63	18
S&M expenses	255	209	105
G&A expenses	106	47	25
Other income	(5)	\$	(1)
Segment profit	<u>\$ 521</u>	<u>\$ 343</u>	<u>\$ 123</u>

§ Represents an amount less than \$1 million.

	Three months ended June 30,		
	2020		
	North America	Europe	International Markets
	(U.S. \$ in millions)		
Revenues	\$ 2,047	\$ 1,001	\$ 488
Gross profit	1,090	548	247
R&D expenses	154	65	19
S&M expenses	254	188	105
G&A expenses	110	52	29
Other income	(2)	(1)	(2)
Segment profit	<u>\$ 573</u>	<u>\$ 244</u>	<u>\$ 97</u>

	Six months ended June 30,		
	2021		
	North America	Europe	International Markets
	(U.S. \$ in millions)		
Revenues	\$ 3,932	\$ 2,398	\$ 975
Gross profit	2,114	1,349	530
R&D expenses	322	129	35
S&M expenses	483	424	201
G&A expenses	218	117	51
Other income	(7)	(1)	(3)
Segment profit	<u>\$ 1,098</u>	<u>\$ 680</u>	<u>\$ 245</u>

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
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(Unaudited)

	Six months ended June 30,		
	2020		
	North America	Europe	International Markets
	(U.S. \$ in millions)		
Revenues	\$ 4,129	\$2,404	\$ 1,053
Gross profit	2,152	1,371	552
R&D expenses	300	120	34
S&M expenses	505	390	211
G&A expenses	228	118	63
Other income	(4)	(2)	(8)
Segment profit	\$ 1,123	\$ 746	\$ 253

The following table presents a reconciliation of Teva's segment profits to its consolidated operating income (loss) and to consolidated income (loss) before income taxes for the three and six months ended June 30, 2021 and 2020:

	Three months ended		Six months ended	
	June 30,		June 30,	
	2021	2020	2021	2020
	(U.S. \$ in millions)		(U.S. \$ in millions)	
North America profit	\$ 521	\$ 573	\$1,098	\$1,123
Europe profit	343	244	680	746
International Markets profit	123	97	245	253
Total reportable segments profit	987	914	2,023	2,121
Profit of other activities	47	66	87	102
Total segments profit	1,034	979	2,111	2,223
Amounts not allocated to segments:				
Amortization	173	249	414	507
Other assets impairments, restructuring and other items	28	381	165	502
Goodwill impairment	—	—	—	—
Intangible asset impairments	195	120	274	768
Legal settlements and loss contingencies	6	13	110	(12)
Other unallocated amounts	50	44	132	93
Consolidated operating income (loss)	582	173	1,015	364
Financial expenses, net	274	223	564	448
Consolidated income (loss) before income taxes	\$ 308	\$ (51)	\$ 451	\$ (84)

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
Notes to Consolidated Financial Statements
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b. Segment revenues by major products and activities:

The following tables present revenues by major products and activities for the th r ee and six months ended June 30, 2021 and 2020:

North America	Three months ended	
	June 30,	
	2021	2020
	(U.S. \$ in millions)	
Generic products	\$ 951	\$ 923
AJOVY	46	34
AUSTEDO	174	161
BENDEKA [®] /TREANDA [®]	106	103
COPAXONE	152	238
ProAir [®] *	55	66
Anda	316	374
Other	144	147
Total	<u>\$1,943</u>	<u>\$2,047</u>

* Does not include revenues from the ProAir authorized generic, which are included under generic products.

North America	Six months ended	
	June 30,	
	2021	2020
	(U.S. \$ in millions)	
Generic products	\$2,004	\$1,875
AJOVY	77	63
AUSTEDO	320	283
BENDEKA/TREANDA	197	208
COPAXONE	315	435
ProAir*	109	125
Anda	605	800
Other	305	338
Total	<u>\$ 3,932</u>	<u>\$ 4,129</u>

* Does not include revenues from the ProAir authorized generic, which are included under generic products.

Europe	Three months ended	
	June 30,	
	2021	2020
	(U.S. \$ in millions)	
Generic products	\$ 878	\$ 737
AJOVY	19	5
COPAXONE	100	84
Respiratory products	85	80
Other	102	95
Total	<u>\$1,184</u>	<u>\$1,001</u>

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
Notes to Consolidated Financial Statements
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Europe	Six months ended June 30,	
	2021	2020
	(U.S. \$ in millions)	
Generic products	\$1,742	\$1,769
AJOVY	35	9
COPAXONE	201	193
Respiratory products	179	186
Other	242	246
Total	<u>\$2,398</u>	<u>\$2,404</u>

International markets	Three months ended June 30,	
	2021	2020
	(U.S. \$ in millions)	
Generic products	\$ 407	\$ 426
COPAXONE	7	12
Other	71	50
Total	<u>\$ 485</u>	<u>\$ 488</u>

International markets	Six months ended June 30,	
	2021	2020
	(U.S. \$ in millions)	
Generic products	\$799	\$ 875
COPAXONE	19	23
Other	157	154
Total	<u>\$975</u>	<u>\$1,053</u>

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Notes to Consolidated Financial Statements
(Unaudited)

NOTE 16 – Fair value measurement:

Financial items carried at fair value on a recurring basis as of June 30, 2021 and December 31, 2020 are classified in the tables below in one of the three categories of fair value levels:

	June 30, 2021			Total
	Level 1	Level 2	Level 3	
	(U.S. \$ in millions)			
Cash and cash equivalents:				
Money markets	\$ 278	\$ —	\$ —	\$ 278
Cash, deposits and other	2,158	—	—	2,158
Investment in securities:				
Equity securities*	35	—	—	35
Other, mainly debt securities	5	—	1	6
Derivatives:				
Asset derivatives—options and forward contracts	—	30	—	30
Liability derivatives—options and forward contracts	—	(25)	—	(25)
Contingent consideration**	—	—	(205)	(205)
Total	<u>\$2,476</u>	<u>\$ 5</u>	<u>\$ (204)</u>	<u>\$2,277</u>

	December 31, 2020			Total
	Level 1	Level 2	Level 3	
	(U.S. \$ in millions)			
Cash and cash equivalents:				
Money markets	\$ 367	\$ —	\$ —	\$ 367
Cash, deposits and other	1,810	—	—	1,810
Investment in securities:				
Equity securities*	25	259	—	284
Other, mainly debt securities	5	—	10	15
Derivatives:				
Asset derivatives—options and forward contracts	—	24	—	24
Liability derivatives—options and forward contracts	—	(79)	—	(79)
Contingent consideration**	—	—	(268)	(268)
Total	<u>\$2,207</u>	<u>\$ 204</u>	<u>\$ (258)</u>	<u>\$2,153</u>

* During the first quarter of 2021, Teva's shares in American Well Corporation ("American Well") moved from a Level 2 measurement to a Level 1 measurement within the fair value hierarchy, since they are no longer subject to a sale restriction. As of June 30, 2021, Teva sold most of its holdings in American Well, and subsequently sold its remaining holdings.

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

Teva determined the fair value of the liabilities for the contingent consideration based on a probability-weighted discounted cash flow analysis. This fair value measurement is based on significant unobservable inputs in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value of the contingent consideration is based on several factors, such as: the cash flows projected from the success of unapproved product candidates; the probability of success of product candidates, including risks associated with uncertainty regarding achievement and payment of milestone events; the time and resources needed to complete the development and approval of product candidates; the life of the potential commercialized products and associated risks of obtaining regulatory approvals in the United States and Europe, and the risk adjusted discount rate for fair value measurement. A probability of success factor ranging from 90% to 100% was used in the fair value calculation to reflect inherent regulatory and commercial risk of the contingent payments and IPR&D. The discount rate applied ranged from 7.5% to 7.8%. The weighted average discount rate, calculated based on the relative fair value of Teva's contingent consideration liabilities, was 7.7%. The contingent consideration is evaluated quarterly, or more frequently, if circumstances dictate. Changes in the fair value of contingent consideration are recorded in consolidated statements of income. Significant changes in unobservable inputs, mainly the probability of success and cash flows projected, could result in material changes to the contingent consideration liabilities.

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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:

	Six months ended June 30, 2021	Six months ended June 30, 2020
	(U.S. \$ in millions)	
Fair value at the beginning of the period	\$ (258)	(448)
Redemption of debt securities	(9)	—
Revaluation of debt securities	—	1
Adjustments to provisions for contingent consideration:		
Actavis Generics transaction	22	(15)
Eagle transaction	(7)	(67)
Settlement of contingent consideration:		
Eagle transaction	48	58
Fair value at the end of the period	<u>\$ (204)</u>	<u>\$ (471)</u>

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 (see note 7) and are presented in the table below in terms of fair value (level 1 inputs):

	Estimated fair value*	
	June 30, 2021	December 31, 2020
	(U.S. \$ in millions)	
Senior notes included under senior notes and loans	\$21,449	\$ 22,684
Senior notes and convertible senior debentures included under short-term debt	3,548	3,207
Total	<u>\$24,997</u>	<u>\$ 25,891</u>

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

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

Business Overview

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

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

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

Our Business Segments

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

In addition to these three segments, we have other activities, primarily the sale of API to third parties, certain contract manufacturing services and an out-licensing platform offering a portfolio of products to other pharmaceutical companies through our affiliate Medis.

The COVID-19 Pandemic

As a leading global pharmaceutical company, Teva provides essential medicines to millions of patients around the world every day. Our priorities remain focused on the health and well-being of our employees and on our responsibility to continue to provide our medicines to the nearly 200 million patients who depend on us every day.

During the second quarter of 2021, we have not experienced material delays in development, production and distribution of medicines or disruptions in our supply chains. The supply chain supporting our key products – specialty, generics and API – remains largely uninterrupted, with adequate product inventory across our network and redundancy plans in place to address potential shortfalls, if any. All our facilities that research, manufacture, order, pack, distribute and provide critical customer and patient services are currently functioning to meet demand for essential medicines for patients throughout the world.

We did not have and do not expect to have a material impact on our ongoing clinical research programs and product launches as a result of the COVID-19 pandemic; however, during the second quarter of 2021, we have experienced minimal delays in clinical trials due to cessation or slow-downs of recruitment for patient studies and suspended regulatory inspections, raw material supply issues, delays in regulatory approvals of new products due to reduced capacity or re-prioritization of regulatory agencies and delays in pre-commercial launch activities. We may experience further delays if the pandemic continues for an extended period of time. All of our new product launches have been risk-assessed based on upcoming manufacturing and regulatory inspections.

The long-term effects of the pandemic cannot be predicted at this time and would depend on the duration and severity of the pandemic and the restrictive measures put in place to control its impact. In the first quarter of 2020, we experienced increasing demand for certain medicines, as would be expected during a global crisis of this nature. We saw a compensating effect with lower demand for certain medicines during the second quarter of 2020 and continuing slightly lower demand due to less physician and hospital activity in certain regions and for certain medicines in the second half of 2020. Although no one can predict future demand for pharmaceutical products, market dynamics or the scope or duration of the financial and other challenges arising from the pandemic, it is possible that we will continue to see variable demand during the remainder of 2021. While COVID-19 continues to impact sales in certain markets and for certain products, we do not currently anticipate a material negative impact on our 2021 financial results due to the ongoing global pandemic.

Highlights

Significant highlights in the second quarter of 2021 included:

- Revenues in the second quarter of 2021 were \$3,910 million, an increase of 1%, or a decrease of 2% in local currency terms, compared to the second quarter of 2020, mainly due to lower revenues in our North America segment, mainly related to COPAXONE and Anda, partially offset by positive foreign currency impacts as well as higher revenues from generic products, OTC, AJOVY and COPAXONE in our Europe segment. Revenues were also affected by changes in demand for certain products resulting from the impact of the COVID-19 pandemic.
- Our North America segment generated revenues of \$1,943 million and profit of \$521 million in the second quarter of 2021. Revenues decreased by 5% compared to the second quarter of 2020, mainly due to a decrease in revenues from COPAXONE and Anda, partially offset by higher revenues from generic products, AUSTEDO and AJOVY. Our North America segment has experienced some reductions in volume due to less physician and hospital activity during the COVID-19 pandemic, but has also experienced increase in demand for certain products related to the treatment of COVID-19 and its symptoms. In addition, the ability to promote certain specialty products has been impacted by less physician visits by patients and less physician interactions by our sales personnel. Profit decreased by 9% compared to the second quarter of 2020, mainly due to lower gross profit, as well as higher R&D expenses.
- Our Europe segment generated revenues of \$1,184 million and profit of \$343 million in the second quarter of 2021. Revenues increased by 18%, or 8% in local currency terms, compared to the second quarter of 2020. This increase was mainly due to changed buying patterns in the second quarter of 2020 as a result of significant customer stocking due to the COVID-19 pandemic in March 2020, and a decline in doctor and hospital visits by patients resulting in fewer prescriptions during the second quarter of 2020. Profit increased by 41%, mainly due to higher revenues.
- Our International Markets segment generated revenues of \$485 million and profit of \$123 million in the second quarter of 2021. Revenues decreased by 1%, or 3% in local currency terms, compared to the second quarter of 2020, mainly due to lower revenues in Japan resulting from the divestment of the majority of the generic and operational assets of our Japanese business venture, as well as regulatory price reductions and generic competition to off-patented products in Japan and a negative impact from hedging activity, partially offset by higher revenues in most other markets as well as lower revenues in certain markets in the second quarter of 2020 resulting from reduced demand due to the impact the COVID-19 pandemic had on purchasing patterns. Profit increased by 27%, mainly due to the divestment in Japan mentioned above and a change in product portfolio mix.
- Impairments of identifiable intangible assets were \$195 million in the second quarter of 2021, compared to \$120 million in the second quarter of 2020. See note 5 to our consolidated financial statements.
- No goodwill impairments were recorded in the second quarters of both 2021 and 2020.
- We recorded other asset impairments, restructuring and other items expenses of \$28 million in the second quarter of 2021, compared to expenses of \$381 million in the second quarter of 2020. See note 12 to our consolidated financial statements.
- Legal settlements and loss contingencies expenses were \$6 million in the second quarter of 2021, compared to \$13 million in the second quarter of 2020. See note 9 to our consolidated financial statements.
- Operating income was \$582 million in the second quarter of 2021, compared to \$173 million in the second quarter of 2020. This increase was mainly due to lower other assets impairments, restructuring and other items charges and higher profit in our Europe segment, partially offset by higher intangible asset impairment charges.
- Financial expenses were \$274 million in the second quarter of 2021, compared to \$223 million in the second quarter of 2020. Financial expenses in the second quarter of 2021 were mainly comprised of interest expenses of \$240 million and loss on revaluations of marketable securities of \$34 million (see note 16 to our consolidated financial statements). Financial expenses in the second quarter of 2020 were mainly comprised of interest expenses of \$241 million.
- In the second quarter of 2021, we recognized a tax expense of \$98 million, on pre-tax income of \$308 million. In the second quarter of 2020, we recognized a tax benefit of \$104 million, on pre-tax loss of \$51 million. Our tax rate for the second quarter of 2021 was mainly affected by impairments, amortization and interest expense disallowance.

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- Exchange rate movements during the second quarter of 2021, including hedging effects, positively impacted revenues by \$135 million and operating income by \$26 million, compared to the second quarter of 2020.
- As of June 30, 2021, our debt was \$25,132 million, compared to \$24,986 million as of March 31, 2021. This increase was mainly due to exchange rate fluctuations. In July 2021, we repaid \$1,475 million of our 2.2% senior notes at maturity. During July 2021, \$500 million was drawn down under the RCF.
- Cash flow generated from operating activities during the second quarter of 2021 was \$218 million, compared to \$273 million in the second quarter of 2020. The decrease in the second quarter of 2021 was mainly due to favorable collection of payments from customers in the second quarter of 2020, which resulted from increased sales in the first quarter of 2020.
- During the second quarter of 2021, we generated free cash flow of \$625 million, which we define as comprising \$218 million in cash flow generated from operating activities, \$405 million in beneficial interest collected in exchange for securitized accounts receivables and \$115 million in proceeds from divestitures of businesses and other assets, partially offset by \$113 million in cash used for capital investment. During the second quarter of 2020, we generated free cash flow of \$582 million, comprising \$273 million in cash flow generated from operating activities, \$401 million in beneficial interest collected in exchange for securitized accounts receivables and \$39 million in proceeds from sale of property, plant and equipment and intangible assets, partially offset by \$131 million in cash used for capital investment. The increase in the second quarter of 2021, resulted mainly from higher proceeds from divestitures of businesses and other assets, partially offset by lower cash flow from operating activities.

Results of Operations

Comparison of Three Months Ended June 30, 2021 to Three Months Ended June 30, 2020

Segment Information

North America Segment

The following table presents revenues, expenses and profit for our North America segment for the three months ended June 30, 2021 and 2020:

	Three months ended June 30,			
	2021		2020	
	(U.S. \$ in millions / % of Segment Revenues)			
Revenues	\$ 1,943	100%	\$ 2,047	100%
Gross profit	1,040	53.5%	1,090	53.3%
R&D expenses	162	8.4%	154	7.5%
S&M expenses	255	13.1%	254	12.4%
G&A expenses	106	5.5%	110	5.4%
Other income	(5)	\$	(2)	\$
Segment profit*	\$ 521	26.8%	\$ 573	28.0%

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

§ Represents an amount less than 0.5%.

North America Revenues

Our North America segment includes the United States and Canada. Revenues from our North America segment in the second quarter of 2021 were \$1,943 million, a decrease of \$104 million, or 5%, compared to the second quarter of 2020, mainly due to a decrease in revenues from COPAXONE and Anda, partially offset by higher revenues from generic products, AUSTEDO and AJOVY. Our North America segment has experienced some reductions in volume due to less physician and hospital activity during the COVID-19 pandemic, but has also experienced increase in demand for certain products related to the treatment of COVID-19 and its symptoms. In addition, the ability to promote certain specialty products has been impacted by less physician visits by patients and less physician interactions by our sales personnel.

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Revenues by Major Products and Activities

The following table presents revenues for our North America segment by major products and activities for the three months ended June 30, 2021 and 2020:

	Three months ended June 30,		Percentage Change 2020-2021
	2021	2020	
	(U.S. \$ in millions)		
Generic products	\$ 951	\$ 923	3%
AJOVY	46	34	32%
AUSTEDO	174	161	8%
BENDEKA/TREANDA	106	103	3%
COPAXONE	152	238	(36%)
ProAir*	55	66	(16%)
Anda	316	374	(16%)
Other	144	147	(2%)
Total	<u>\$ 1,943</u>	<u>\$ 2,047</u>	(5%)

* Does not include revenues from the ProAir authorized generic, which are included under generic products.

Generic products revenues in our North America segment (including biosimilars) in the second quarter of 2021 were \$951 million, an increase of 3% compared to the second quarter of 2020, mainly due to higher revenues from epinephrine injectable solution (the generic equivalent of EpiPen[®] and EpiPen Jr.[®]), Truxima (the biosimilar to Rituxan[®]) and ProAir[®] authorized generic, partially offset by lower volume and pricing of other generic products.

Among the most significant generic products we sold in North America in the second quarter of 2021 were Truxima (the biosimilar to Rituxan[®]), epinephrine injectable solution (the generic equivalent of EpiPen[®] and EpiPen Jr.[®]), albuterol sulfate inhalation aerosol (our ProAir authorized generic) and lidocaine transdermal patch (the generic equivalent of Lidoderm Patch[®]).

In the second quarter of 2021, our total prescriptions were approximately 314 million (based on trailing twelve months), representing 8.8% of total U.S. generic prescriptions according to IQVIA data.

AJOVY revenues in our North America segment in the second quarter of 2021 increased by 32% to \$46 million, compared to the second quarter of 2020, mainly due to growth in volume. In the second quarter of 2021, AJOVY's exit market share in the United States in terms of total number of prescriptions was 21.2%, compared to 16.1% in the second quarter of 2020.

AJOVY is indicated for the preventive treatment of migraine in adults. AJOVY was launched in the U.S. in 2018, and was approved in Canada in April 2020. Our auto-injector device for AJOVY became commercially available in the U.S. in April 2020 and in Canada in April 2021. AJOVY is the only anti-CGRP product indicated for quarterly treatment and in January 2021 we launched a new product offering, providing a quarterly dose.

AJOVY is protected by patents expiring in 2026 in Europe and in 2027 in the United States. Applications for patent term extensions have been submitted in various markets around the world, and certain extensions in Europe and other countries have already been granted until 2031. Additional patents relating to the use of AJOVY in the treatment of migraine have also been issued in the United States and will expire in 2035 and 2037. Such patents are also pending in other countries. AJOVY will also be protected by regulatory exclusivity for 12 years from marketing approval in the United States and 10 years from marketing approval in Europe. We have filed a lawsuit in the U.S. District Court for the District of Massachusetts alleging that Eli Lilly & Co.'s ("Lilly") marketing and sale of its galcanezumab product for the treatment of migraine infringes nine Teva patents. Lilly then submitted IPR (inter partes review) petitions to the Patent Trial and Appeal Board, challenging the validity of the nine patents asserted against it in the litigation.

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The litigation in the district court was stayed pending resolution of the IPR petitions. On February 18, 2020, the Patent Trial and Appeal Board issued decisions on the first six IPRs, finding the six composition of matter patents invalid as being obvious. On April 21, 2020, we filed notices of appeal in connection with these decisions. On March 31, 2020 the Patent Trial and Appeal Board (“PTAB”) issued a decision upholding the three method of treatment patents and on June 1, 2020, Lilly filed notices of appeal in connection with the decisions on these three patents. The Court of Appeals for the Federal Circuit heard oral argument for the IPR appeals on June 7, 2021 and we await those decisions. The litigation stay ended following the IPR decisions by the PTAB, and the parties are proceeding with the litigation. We also filed another suit against Lilly on June 8, 2021, asserting two patents which issued that same day and relate to the treatment of refractory migraine. The case has been assigned to the same judge in the U.S. District Court for the District of Massachusetts and Lilly’s response to our complaint is due on August 27, 2021. In addition, in 2018 we entered into separate agreements with Alder Biopharmaceuticals, Inc. and Lilly, resolving the European Patent Office oppositions that they filed against our AJOVY patents. The settlement agreement with Lilly also resolved Lilly’s action to revoke the patent protecting AJOVY in the United Kingdom.

AUSTEDO revenues in our North America segment in the second quarter of 2021 increased by 8%, to \$174 million, compared to \$161 million in the second quarter of 2020. This increase was mainly due to growth in volume.

AUSTEDO was launched in the U.S. in 2017. It is indicated for the treatment of chorea associated with Huntington disease and for the treatment of tardive dyskinesia in adults.

AUSTEDO is protected in the United States by six Orange Book patents expiring between 2031 and 2036 and in Europe by two patents expiring in 2029. We received notice letters from two ANDA filers regarding the filing of their ANDAs with paragraph (IV) certifications for certain of the patents listed in the Orange Book for AUSTEDO. On July 1, 2021, we filed a complaint against Aurobindo, asserting all six of the Orange Book patents, and a separate complaint against Lupin, asserting four of the Orange Book patents. The suits were filed in the U.S. District Court for the District of New Jersey.

BENDEKA and **TREANDA** combined revenues in our North America segment in the second quarter of 2021 increased by 3% to \$106 million, compared to the second quarter of 2020, mainly due to higher sales of oncology products compared to sales in the second quarter of 2020, which were impacted by the COVID-19 pandemic, partially offset by the availability of alternative therapies and continued competition from Belrapzo[®] (a ready-to-dilute bendamustine hydrochloride product from Eagle Pharmaceuticals, Inc. (“Eagle”).

In July 2018, Eagle prevailed in its suit against the FDA to obtain seven years of orphan drug exclusivity in the United States for BENDEKA. On March 13, 2020, this decision was upheld in the appellate court. As things currently stand, drug applications referencing BENDEKA, TREANDA or any other bendamustine product will not be approved by the FDA until the orphan drug exclusivity expires in December 2022. In April 2019, we signed an amendment to the license agreement with Eagle extending the royalty term applicable to the United States to the full period for which we sell BENDEKA and increased the royalty rate. In consideration, Eagle agreed to assume a portion of BENDEKA-related patent litigation expenses.

There are 15 patents listed in the U.S. Orange Book for BENDEKA with expiry dates in 2026 and 2031. In September 2019, a patent infringement action against four of six ANDA filers for generic versions of BENDEKA was tried in the United States District Court for the District of Delaware. On April 27, 2020, the District Court upheld the validity of all of the asserted patents and found that all four ANDA filers infringe at least one of the patents. Three of the four ANDA filers have appealed the district court decision, but barring an adverse appellate decision, these ANDA filers should be enjoined until the patents expire in 2031. A litigation against the fifth ANDA filer was dismissed after the withdrawal of its patent challenge, and the case against a sixth ANDA filer is in the early stages of litigation. Recent suits against two filers of 505(b)(2) NDAs referencing BENDEKA are also in the initial stages of litigation.

Additionally, in July 2018, Teva and Eagle filed suit against Hospira, Inc. (“Hospira”) related to its 505(b)(2) new drug application (“NDA”) referencing BENDEKA in the U.S. District Court for the District of Delaware. On December 16, 2019, the Delaware District Court dismissed the case against Hospira on all but one of the asserted patents, which expires in 2031. Trial against Hospira on that patent is scheduled to begin on November 15, 2021.

In addition to the settlement with Eagle regarding its bendamustine 505(b)(2) NDA, between 2015 and 2020, we reached final settlements with 22 ANDA filers for generic versions of the lyophilized form of TREANDA and one 505(b)(2) NDA filer for a generic version of the liquid form of TREANDA, providing for the launch of generic versions of TREANDA prior to patent expiration.

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COPAXONE revenues in our North America segment in the second quarter of 2021 decreased by 36% to \$152 million, compared to the second quarter of 2020, mainly due to generic competition in the United States.

The market for MS treatments continues to develop, particularly with the approval of generic versions of COPAXONE. Additionally, oral treatments for MS, such as Tecfidera[®], Gilenya[®] and Aubagio[®], continue to present significant and increasing competition. COPAXONE also continues to face competition from existing injectable products, as well as from monoclonal antibodies, such as Ocrevus[®].

ProAir (HFA and RespiClick) revenues in our North America segment in the second quarter of 2021 were \$55 million, a decrease of 16% compared to the second quarter of 2020. In January 2019, we launched our own ProAir authorized generic in the United States, following the launch of a generic version of Ventolin[®] HFA, another albuterol inhaler. Revenues from our ProAir authorized generic are included in “generic products” above. During the second quarter of 2021, the exit market share of our overall albuterol product, including our ProAir authorized generic was 41.4%, making it the second largest in the market, compared to 34.9% in the second quarter of 2020. Other generic versions of ProAir were launched in 2020.

Anda revenues in our North America segment in the second quarter of 2021 decreased by 16% to \$316 million, compared to \$374 million in the second quarter of 2020, mainly due to lower demand by Anda’s customers for generic products. Anda, our distribution business in the United States, distributes generic, specialty and OTC pharmaceutical products from various third party manufacturers to independent retail pharmacies, pharmacy retail chains, hospitals and physician offices in the United States. Anda is able to compete in the secondary distribution market by maintaining high inventory levels for a broad offering of products, competitive pricing and offering next day delivery throughout the United States.

Product Launches and Pipeline

In the second quarter of 2021, we launched the generic version of the following branded products in North America:

Product Name	Brand Name	Launch Date	Total Annual U.S. Branded Sales at Time of Launch (U.S. \$ in millions (IQVIA)) *
Mesalamine Suppositories	Canasa [®]	April	\$ 66
Isotretinoin Capsules, USP	Absorica [®]	April	\$ 156
Erythromycin Tablets, USP	n/a	May	\$ 45
Tiopronin Tablets	Thiola [®]	May	\$ 81**
Ivermectin Cream, 1%	Soolantra [®]	June	\$ 111
Formoterol Fumarate Inhalation Solution	Perforomist [®]	June	\$ 300

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

** Limited data is available for this product in IQVIA and as a result Teva estimated the brand market based on data available in Travele Therapeutic’s 10-K for the year ended December 31, 2020.

Our generic products pipeline in the United States includes, as of June 30, 2021, 207 product applications awaiting FDA approval, including 72 tentative approvals. This total reflects all pending ANDAs, supplements for product line extensions and tentatively approved applications and includes some instances where more than one application was submitted for the same reference product. Excluding overlaps, the branded products underlying these pending applications had U.S. sales for the twelve months ended March 31, 2021 exceeding \$106 billion, according to IQVIA. Approximately 72% of pending applications include a paragraph IV patent challenge, and we believe we are first to file with respect to 77 of these products, or 103 products including final approvals where launch is pending a settlement agreement or court decision. Collectively, these first to file opportunities represent over \$76 billion in U.S. brand sales for the twelve months ended March 31, 2021, according to IQVIA.

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IQVIA reported brand sales are one of the many indicators of future potential value of a launch, but equally important are the mix and timing of competition, as well as cost effectiveness. The potential advantages of being the first filer with respect to some of these products may be subject to forfeiture, shared exclusivity or competition from so-called “authorized generics,” which may ultimately affect the value derived.

In the second quarter of 2021, we received tentative approvals for generic equivalents of the products listed in the table below, excluding overlapping applications. A “tentative approval” indicates that the FDA has substantially completed its review of an application and final approval is expected once the relevant patent expires, a court decision is reached, a 30-month regulatory stay lapses or a 180-day exclusivity period awarded to another manufacturer either expires or is forfeited.

<u>Generic Name</u>	<u>Brand Name</u>	<u>Total Annual U.S. Branded Market (U.S. \$ in millions (IQVIA)) *</u>
Lenalidomide Capsules, 2.5 mg and 20 mg	Revlimid®	\$ 179
Pimavanserin Capsules, 34 mg	Nuplazid®	\$ 173

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

We have additional biosimilar products in development in various stages of clinical trials and regulatory review.

Below is a description of key products in our specialty pipeline as of June 30, 2021:

	<u>Phase 2</u>	<u>Phase 3</u>	<u>Pre-Submission</u>
Novel Biologics	<i>Fremanezumab</i> Fibromyalgia <i>TEV-48574</i> Respiratory <i>TEV-53275</i> Respiratory	<i>Fasinumab</i> Osteoarthritic Pain (March 2016) ⁽¹⁾	
Small Molecules		<i>Deutetrabenazine</i> Dyskinesia in Cerebral Palsy (September 2019)	<i>Risperidone LAI</i> Schizophrenia ⁽²⁾
Digital Respiratory			<i>Digihaler</i> ® (budesonide and formoterol fumarate dihydrate) (EU) <i>QVAR</i> ® <i>Digihaler</i> ® (beclomethasone dipropionate HFA) (U.S.)

- (1) Developed in collaboration with Regeneron Pharmaceuticals, Inc. (“Regeneron”). Results for two phase 3 clinical trials, FACT OA1 and FACT OA2, were released on August 5, 2020, indicating that the co-primary endpoints for fasinumab 1 mg monthly were achieved. Fasinumab 1 mg monthly demonstrated significant improvements in pain and physical function over placebo at week 16 and week 24, respectively. Fasinumab 1 mg monthly also showed nominally significant benefits in physical function in two trials and pain in one trial, when compared to the maximum FDA-approved prescription doses of non-steroidal anti-inflammatory drugs for osteoarthritis. The FACT OA1 trial included an additional treatment arm, fasinumab 1 mg every two months, which showed numerical benefit over placebo, but did not reach statistical significance. In initial safety analyses from the phase 3 trials, there was an increase in arthropathies reported with fasinumab. In a sub-group of patients from one phase 3 long-term safety trial, there was an increase in joint replacement with fasinumab 1 mg monthly treatment during the off-drug follow-up period, although this increase was not seen in the other trials to date.

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Active treatment of patients with fasinumab, which only involved dosing in an optional second-year extension phase of one trial, has been discontinued following a recommendation from the fasinumab program's Independent Data Monitoring Committee that the program should be terminated, based on available evidence obtained to date. The core efficacy data has already been obtained to support potential fasinumab regulatory filings. Long-term safety data continues to be gathered, and is expected to be reported in 2021. Currently, all non-essential activities and related expenditures for fasinumab have been put on hold. Next steps will be assessed together with Regeneron, with the intention of discussing data with the FDA.

- (2) In January 2021, we announced positive results for a phase 3 clinical trial designed to evaluate the efficacy of risperidone LAI. No new safety signals were identified that are inconsistent with the known safety profile of other risperidone formulations. The second phase 3 study evaluating long-term safety and tolerability is ongoing.

Discontinued Project

During the second quarter of 2021, development of fremanezumab for an additional indication was discontinued.

North America Gross Profit

Gross profit from our North America segment in the second quarter of 2021 was \$1,040 million, a decrease of 5%, compared to \$1,090 million in the second quarter of 2020. This decrease was mainly due to lower gross profit from Anda and COPAXONE.

Gross profit margin for our North America segment in the second quarter of 2021 increased to 53.5%, compared to 53.3% in the second quarter of 2020. This increase was mainly due to a change in the mix of products.

North America R&D Expenses

R&D expenses relating to our North America segment in the second quarter of 2021 were \$162 million, an increase of 5%, compared to \$154 million in the second quarter of 2020.

For a description of our R&D expenses in the second quarter of 2021, see “—Teva Consolidated Results—Research and Development (R&D) Expenses” below.

North America S&M Expenses

S&M expenses relating to our North America segment in the second quarter of 2021 were \$255 million, flat compared to the second quarter of 2020.

North America G&A Expenses

G&A expenses relating to our North America segment in the second quarter of 2021 were \$106 million, a decrease of 4%, compared to \$110 million in the second quarter of 2020.

North America Profit

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

Profit from our North America segment in the second quarter of 2021 was \$521 million, a decrease of 9% compared to \$573 million in the second quarter of 2020, mainly due to lower gross profit, as discussed above, as well as higher R&D expenses.

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Europe Segment

The following table presents revenues, expenses and profit for our Europe segment for the three months ended June 30, 2021 and 2020:

	Three months ended June 30,			
	2021		2020	
	(U.S. \$ in millions / % of Segment Revenues)			
Revenues	\$ 1,184	100%	\$ 1,001	100%
Gross profit	661	55.8%	548	54.7%
R&D expenses	63	5.3%	65	6.5%
S&M expenses	209	17.7%	188	18.8%
G&A expenses	47	4.0%	52	5.2%
Other income	\$	\$	(1)	\$
Segment profit*	\$ 343	28.9%	\$244	24.3%

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

\$ Represents an amount less than \$1 million or 0.5%, as applicable.

Europe Revenues

Our Europe segment includes the European Union and certain other European countries. Revenues from our Europe segment in the second quarter of 2021 were \$1,184 million, an increase of 18% or \$183 million, compared to the second quarter of 2020. In local currency terms, revenues increased by 8%, mainly due to changed buying patterns in the second quarter of 2020 as a result of significant customer stocking due to the COVID-19 pandemic in March 2020, and a decline in doctor and hospital visits by patients resulting in fewer prescriptions during the second quarter of 2020.

Revenues by Major Products and Activities

The following table presents revenues for our Europe segment by major products and activities for the three months ended June 30, 2021 and 2020:

	Three months ended June 30,		Percentage Change 2020-2021
	2021	2020	
	(U.S. \$ in millions)		
Generic products	\$ 878	\$ 737	19%
AJOVY	19	5	302%
COPAXONE	100	84	19%
Respiratory products	85	80	7%
Other	102	95	7%
Total	<u>\$ 1,184</u>	<u>\$ 1,001</u>	18%

Generic products revenues in our Europe segment in the second quarter of 2021, including OTC products, increased by 19% to \$878 million, compared to the second quarter of 2020. In local currency terms, revenues increased by 9% compared to the second quarter of 2020, mainly due lower revenues in the second quarter of 2020, as a result of significant changes in buying patterns and customer stocking due to the COVID-19 pandemic in March 2020. In addition, revenues in the second quarter of 2020 were impacted by lower demand of generic products resulting from a decline in doctor and hospital visits by patients resulting in fewer prescriptions, as well as lower sales of OTC products resulting from lower demand for cough and cold products, both due to the COVID-19 pandemic.

AJOVY revenues in our Europe segment in the second quarter of 2021 were \$19 million, compared to \$5 million in the second quarter of 2020, mainly due to launches and reimbursements in additional European countries.

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By the end of 2020, we launched AJOVY in most European countries and we are moving forward with plans to launch in other European countries. For information about AJOVY patent protection, see “—North America Revenues—Revenues by Major Product” above.

COPAXONE revenues in our Europe segment in the second quarter of 2021 increased by 19% to \$100 million, compared to the second quarter of 2020. In local currency terms, revenues increased by 9%, mainly due to customer stocking due to the COVID-19 pandemic in March 2020 resulting in significant changes in buying patterns in the second quarter of 2020.

One European patent protecting COPAXONE 40 mg/mL was found invalid by the Board of Appeal of the European Patent Office in September 2020. Two additional patents expiring in 2030 are currently under opposition at the European Patent Office. In certain countries, Teva remains in litigation against generic companies on an additional COPAXONE 40 mg/mL patent that expires in 2030.

Respiratory products revenues in our Europe segment in the second quarter of 2021 increased by 7% to \$85 million compared to the second quarter of 2020. In local currency terms, revenues decreased by 4%, mainly due to lower sales in the United Kingdom, partially offset by changes in buying patterns in the second quarter of 2020 as a result of significant customer stocking due to the COVID-19 pandemic in March 2020.

Product Launches and Pipeline

As of June 30, 2021, our generic products pipeline in Europe included 266 generic approvals relating to 50 compounds in 100 formulations, with no European Medicines Agency (“EMA”) approvals received. In addition, approximately 1,161 marketing authorization applications are pending approval in 37 European countries, relating to 118 compounds in 252 formulations. No applications are pending with the EMA.

For information regarding our specialty pipeline, see “—North America Segment —Product Launches and Pipeline” above.

Europe Gross Profit

Gross profit from our Europe segment in the second quarter of 2021 was \$661 million, an increase of 21% compared to \$548 million in the second quarter of 2020.

Gross profit margin for our Europe segment in the second quarter of 2021 increased to 55.8%, compared to 54.7% in the second quarter of 2020. This increase was mainly due to a change in product mix.

Europe R&D Expenses

R&D expenses relating to our Europe segment in the second quarter of 2021 were \$63 million, a decrease of 4% compared to \$65 million in the second quarter of 2020.

For a description of our R&D expenses in the second quarter of 2021, see “—Teva Consolidated Results—Research and Development (R&D) Expenses” below.

Europe S&M Expenses

S&M expenses relating to our Europe segment in the second quarter of 2021 were \$209 million, an increase of 11% compared to \$188 million in the second quarter of 2020. This increase was mainly due to exchange rate fluctuations, as well as lower expenses in the second quarter of 2020 attributed to restrictions related to the COVID-19 pandemic.

Europe G&A Expenses

G&A expenses relating to our Europe segment in the second quarter of 2021 were \$47 million, a decrease of 10% compared to \$52 million in the second quarter of 2020.

Europe Profit

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

Profit from our Europe segment in the second quarter of 2021 was \$343 million, an increase of 41%, compared to \$244 million in the second quarter of 2020. This increase was mainly due to higher revenues, as discussed above.

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International Markets Segment

The following table presents revenues, expenses and profit for our International Markets segment for the three months ended June 30, 2021 and 2020:

	Three months ended June 30,			
	2021		2020	
	(U.S. \$ in millions / % of Segment Revenues)			
Revenues	\$ 485	100%	\$ 488	100%
Gross profit	270	55.7%	247	50.8%
R&D expenses	18	3.6%	19	3.9%
S&M expenses	105	21.7%	105	21.4%
G&A expenses	25	5.1%	29	6.0%
Other income	(1)	\$	(2)	\$
Segment profit*	\$ 123	25.5%	\$ 97	19.9%

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

\$ Represents an amount less than 0.5%.

International Markets Revenues

Our International Markets segment includes all countries in which we operate other than those in our North America and Europe segments. The International Markets segment includes more than 35 countries, covering a substantial portion of the global pharmaceutical market. Our key international markets are Japan, Russia and Israel. The countries in our International Markets segment include highly regulated, pure generic markets, such as Israel, branded generics oriented markets, such as Russia and certain Latin America markets and hybrid markets, such as Japan.

On February 1, 2021, we completed the sale of the majority of the generic and operational assets of our business venture in Japan.

Revenues from our International Markets segment in the second quarter of 2021 were \$485 million, a decrease of \$3 million, or 1%, compared to the second quarter of 2020. In local currency terms, revenues decreased by 3% compared to the second quarter of 2020, mainly due to lower revenues in Japan resulting from the divestment mentioned above, as well as regulatory price reductions and generic competition to off-patented products in Japan, and a negative impact from hedging activity, partially offset by higher revenues in most other markets as well as lower revenues in certain markets in the second quarter of 2020, resulting from reduced demand due to the impact the COVID-19 pandemic had on purchasing patterns.

Revenues by Major Products and Activities

The following table presents revenues for our International Markets segment by major products and activities for the three months ended June 30, 2021 and 2020:

	Three months ended June 30,		Percentage Change 2020-2021
	2021	2020	
	(U.S. \$ in millions)		
Generic products	\$ 407	\$ 426	(5%)
COPAXONE	7	12	(35%)
Other	71	50	42%
Total	<u>\$ 485</u>	<u>\$ 488</u>	(1%)

Generic products revenues in our International Markets segment in the second quarter of 2021, which include OTC products, decreased by 5% in both U.S. dollar and local currency terms, to \$407 million, compared to the second quarter of 2020. This decrease was mainly due to lower sales in Japan resulting from the divestment mentioned above, as well as regulatory price reductions and generic competition to off-patented products in Japan, partially offset by higher revenues in most other markets as well as lower revenues in certain markets in the second quarter of 2020, resulting from reduced demand due to the impact the COVID-19 pandemic had on purchasing patterns.

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COPAXONE revenues in our International Markets segment in the second quarter of 2021 were \$7 million, a decrease of 35% compared to the second quarter of 2020. In local currency terms, revenues decreased by 33%.

AJOVY was launched in certain markets in our International Markets segment and we are moving forward with plans to launch in other markets. On June 23, 2021, AJOVY was approved for the preventive treatment of migraine in adults in Japan.

AUSTEDO was launched in China for the treatment of chorea associated with Huntington disease and for the treatment of tardive dyskinesia in early 2021. We continue with additional submissions in various other countries.

International Markets Gross Profit

Gross profit from our International Markets segment in the second quarter of 2021 was \$270 million, an increase of 9% compared to \$247 million in the second quarter of 2020.

Gross profit margin for our International Markets segment in the second quarter of 2021 increased to 55.7%, compared to 50.8% in the second quarter of 2020. This increase was mainly due to the divestment in Japan mentioned above and a change in product portfolio mix.

International Markets R&D Expenses

R&D expenses relating to our International Markets segment in the second quarter of 2021 were \$18 million, a decrease of 8% compared to \$19 million in the second quarter of 2020.

For a description of our R&D expenses in the second quarter of 2021, see “—Teva Consolidated Results—Research and Development (R&D) Expenses” below.

International Markets S&M Expenses

S&M expenses relating to our International Markets segment in the second quarter of 2021 were \$105 million, flat compared to the second quarter of 2020.

International Markets G&A Expenses

G&A expenses relating to our International Markets segment in the second quarter of 2021 were \$25 million, a decrease of 15% compared to \$29 million in the second quarter of 2020.

International Markets Profit

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

Profit from our International Markets segment in the second quarter of 2021 was \$123 million, an increase of 27%, compared to \$97 million in the second quarter of 2020. This increase was mainly due to higher gross profit as discussed above.

Other Activities

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

Our revenues from other activities in the second quarter of 2021 were \$298 million, a decrease of 11% compared to the second quarter of 2020. In local currency terms, revenues decreased by 13% compared to the second quarter of 2020, mainly due to a decrease in volumes from API and Medis resulting from the COVID-19 pandemic.

API sales to third parties in the second quarter of 2021 were \$199 million, a decrease of 6% in both U.S. dollar and local currency terms compared to the second quarter of 2020.

Teva Consolidated Results

Revenues

Revenues in the second quarter of 2021 were \$3,910 million, an increase of 1%, or a decrease of 2% in local currency terms, compared to the second quarter of 2020. This decrease was mainly due to lower revenues in our North America segment, mainly related to COPAXONE and Anda, partially offset by positive foreign currency impacts as well as higher revenues from generic products, OTC, AJOVY and COPAXONE in our Europe segment. Revenues were also affected by changes in demand for certain products resulting from the impact of the COVID-19 pandemic. See “—North America Revenues,” “—Europe Revenues,” “—International Markets Revenues” and “—Other Activities” above.

Exchange rate movements during the second quarter of 2021, including hedging effects, positively impacted revenues by \$135 million, compared to the second quarter of 2020. See note 8c to our consolidated financial statements.

Gross Profit

Gross profit in the second quarter of 2021 was \$1,873 million, an increase of 6% compared to the second quarter of 2020. This increase was mainly a result of the factors discussed above under “—North America Gross Profit,” “—Europe Gross Profit” and “—International Markets Gross Profit.”

Gross profit margin was 47.9% in the second quarter of 2021, compared to 45.5% in the second quarter of 2020.

The increase in gross profit margin was mainly driven by higher profitability in North America resulting from the change in mix of products sold as well as network optimization activities, partially offset by lower sales of COPAXONE.

Research and Development (R&D) Expenses

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

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

R&D expenses in the second quarter of 2021 were \$248 million, an increase of 10% compared to the second quarter of 2020.

In the second quarter of 2021, our R&D expenses related primarily to specialty product candidates in the respiratory, migraine and headache therapeutic areas, with additional activities in selected other areas and generic products including biosimilars.

Our higher R&D expenses in the second quarter of 2021, compared to the second quarter of 2020, were mainly due to an increase in respiratory and biosimilar projects as well as various generics projects.

R&D expenses as a percentage of revenues were 6.3% in the second quarter of 2021, compared to 5.8% in the second quarter of 2020.

Selling and Marketing (S&M) Expenses

S&M expenses in the second quarter of 2021 were \$615 million, an increase of 3% compared to the second quarter of 2020. Our S&M expenses were primarily the result of the factors discussed above under “—North America Segment— S&M Expenses,” “—Europe Segment— S&M Expenses” and “—International Markets Segment— S&M Expenses.”

S&M expenses as a percentage of revenues were 15.7% in the second quarter of 2021, compared to 15.4% in the second quarter of 2020.

General and Administrative (G&A) Expenses

G&A expenses in the second quarter of 2021 were \$242 million, a decrease of 8% compared to the second quarter of 2020.

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G&A expenses as a percentage of revenues were 6.2% in the second quarter of 2021, compared to 6.8% in the second quarter of 2020.

Intangible Asset Impairments

We recorded expenses of \$195 million for identifiable intangible asset impairments in the second quarter of 2021, compared to expenses of \$120 million in the second quarter of 2020. See note 5 to our consolidated financial statements.

Goodwill Impairment

No goodwill impairments were recorded in the second quarters of both 2021 and 2020.

Other Asset Impairments, Restructuring and Other Items

We recorded expenses of \$28 million for other asset impairments, restructuring and other items in the second quarter of 2021, compared to expenses of \$381 million in the second quarter of 2020. For further details, as well as a description of significant regulatory and other events, see note 12 to our consolidated financial statements.

Legal Settlements and Loss Contingencies

In the second quarter of 2021, we recorded an expense of \$6 million in legal settlements and loss contingencies, compared to income of \$13 million in the second quarter of 2020. See note 9 to our consolidated financial statements.

Other Income

Other income in the second quarter of 2021 was \$43 million, compared to \$9 million in the second quarter of 2020. The income in the second quarter of 2021 was mainly due to capital gains related to the sale of certain OTC assets.

Operating Income (Loss)

Operating income was \$582 million in the second quarter of 2021, compared to \$173 million in the second quarter of 2020.

Operating income as a percentage of revenues was 14.9% in the second quarter of 2021, compared to 4.5% in the second quarter of 2020. This increase was mainly due to lower other assets impairments, restructuring and other items charges and higher profit in our Europe segment, partially offset by higher intangible asset impairment charges.

Financial Expenses, Net

Financial expenses were \$274 million in the second quarter of 2021, compared to \$223 million in the second quarter of 2020. Financial expenses in the second quarter of 2021 were mainly comprised of interest expenses of \$240 million and loss on revaluations of marketable securities of \$34 million (see note 16 to our consolidated financial statements). Financial expenses in the second quarter of 2020 were mainly comprised of interest expenses of \$241 million.

The following table presents a reconciliation of our segment profits to our consolidated operating income (loss) and to consolidated income (loss) before income taxes for the three months ended June 30, 2021 and 2020:

	Three months ended	
	June 30,	
	2021	2020
	(U.S. \$ in millions)	
North America profit	\$ 521	\$ 573
Europe profit	343	244
International Markets profit	123	97
Total reportable segments profit	987	914
Profit of other activities	47	66
Total segments profit	1,034	979
Amounts not allocated to segments:		
Amortization	173	249
Other assets impairments, restructuring and other items	28	381
Goodwill impairment	—	—
Intangible asset impairments	195	120
Legal settlements and loss contingencies	6	13
Other unallocated amounts	50	44
Consolidated operating income (loss)	582	173
Financial expenses, net	274	223
Consolidated income (loss) before income taxes	\$ 308	\$ (51)

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Tax Rate

In the second quarter of 2021, we recognized a tax expense of \$98 million, on pre-tax income of \$308 million. In the second quarter of 2020, we recognized a tax benefit of \$104 million, on pre-tax loss of \$51 million. Our tax rate for the second quarter of 2021 was mainly affected by impairments, amortization and interest expense disallowance.

The statutory Israeli corporate tax rate is 23% in 2021. Our tax rate differs from the Israeli statutory tax rate, mainly due to generation of profits in various jurisdictions in which tax rates are different than the Israeli tax rate, tax benefits in Israel and other countries, as well as infrequent or nonrecurring items.

Share In (Profits) Losses of Associated Companies, Net

Share in losses of associated companies, net in the second quarter of 2021 was \$11 million. We did not have any share in (profits) losses of associated companies, net in the second quarter of 2020.

Net Income (Loss) Attributable to Teva

Net income was \$207 million in the second quarter of 2021, compared to \$140 million in the second quarter of 2020. This increase was mainly due to the increase in operating income, as discussed above.

Diluted Shares Outstanding and Earnings (Loss) per Share

The weighted average diluted shares outstanding used for the fully diluted share calculation for the three months ended June 30, 2021 and 2020 were 1,109 million and 1,100 million shares, respectively.

In computing diluted earnings per share for the three months ended June 30, 2021 and June 30, 2020, basic earnings per share were adjusted to take into account the potential dilution that could occur upon the exercise of options and non-vested RSUs granted under employee stock compensation plans. No account was taken of the potential dilution by the convertible senior debentures, since they had an anti-dilutive effect on earnings per share.

Diluted earnings per share were \$0.19 in the second quarter of 2021, compared to diluted earnings per share of \$0.13 in the second quarter of 2020.

Share Count for Market Capitalization

We calculate share amounts using the outstanding number of shares (i.e., excluding treasury shares) plus shares that would be outstanding upon the exercise of options and vesting of RSUs and performance share units and the conversion of our convertible senior debentures, in each case, at period end.

As of June 30, 2021 and 2020, the fully diluted share count for purposes of calculating our market capitalization was approximately 1,129 million and 1,119 million, respectively.

Impact of Currency Fluctuations on Results of Operations

In the second quarter of 2021, approximately 47% of our revenues were denominated in currencies other than the U.S. dollar. Because our results are reported in U.S. dollars, we are subject to significant foreign currency risks. Accordingly, changes in the rate of exchange between the U.S. dollar and the local currencies in the markets in which we operate (primarily the euro, British pound, Japanese yen, new Israeli shekel, Canadian dollar and Russian ruble) impact our results.

During the second quarter of 2021, the following main currencies relevant to our operations decreased in value against the U.S. dollar (each on a quarterly average compared to quarterly average basis): Argentinian peso by 28%, Turkish lira by 18%, Russian ruble by 2% and Japanese yen by 2%. The following main currencies relevant to our operations increased in value against the U.S. dollar: Australian dollar by 17%, Mexican peso by 16%, Swedish krona by 15%, Chilean peso by 15%, British pound by 13%, Canadian dollar by 13%, euro by 9% and Israeli shekel by 8%.

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As a result, exchange rate movements during the second quarter of 2021, including hedging effects, positively impacted overall revenues by \$135 million and our operating income by \$26 million, in comparison with the second quarter of 2020.

In the second quarter of 2021, a negative hedging impact of \$15 million was recognized under revenues, and a minimal negative impact was recognized under cost of sales. In the second quarter of 2020, a negative hedging impact of \$20 million was recognized under revenues and a negative impact of \$1 million was recognized under cost of sales.

Hedging transactions against future projected revenues and expenses are recognized on the balance sheet at their fair value on a quarterly basis, while the foreign exchange impact on the underlying revenues and expenses may occur in subsequent quarters. See note 8c to our consolidated financial statements.

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

Comparison of Six Months Ended June 30, 2021 to Six Months Ended June 30, 2020

Unless specified otherwise, the factors used to explain quarterly changes on a year-over-year basis are also relevant for the comparison of the results for the six months ended June 30, 2021 and 2020. Where there are different factors affecting the six months comparison, we have described them below.

Segment Information

North America Segment

The following table presents revenues, expenses and profit for our North America segment for the six months ended June 30, 2021 and 2020:

	Six months ended June 30,			
	2021		2020	
	(U.S. \$ in millions / % of Segment Revenues)			
Revenues	\$ 3,932	100%	\$ 4,129	100%
Gross profit	2,114	53.8%	2,152	52.1%
R&D expenses	322	8.2%	300	7.3%
S&M expenses	483	12.3%	505	12.2%
G&A expenses	218	5.5%	228	5.5%
Other income	(7)	\$	(4)	\$
Segment profit*	\$ 1,098	27.9%	\$ 1,123	27.2%

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

§ Represents an amount less than 0.5%.

North America Revenues

Our North America segment includes the United States and Canada. Revenues from our North America segment in the first six months of 2021 were \$3,932 million, a decrease of 4.8% compared to \$4,129 million in the first six months of 2020.

Revenues by Major Products and Activities

The following table presents revenues for our North America segment by major products and activities for the six months ended June 30, 2021 and 2020:

	Six months ended June 30,		Percentage Change 2020-2021
	2021	2020	
	(U.S. \$ in millions)		
Generic products	\$ 2,004	\$ 1,875	7%
AJOVY	77	63	21%
AUSTEDO	320	283	13%
BENDEKA/TREANDA	197	208	(6%)
COPAXONE	315	435	(28%)
ProAir*	109	125	(13%)
Anda	605	800	(24%)
Other	305	338	(10%)
Total	\$ 3,932	\$ 4,129	(5%)

* Does not include revenues from the ProAir authorized generic, which are included under generic products.

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North America Gross Profit

Gross profit from our North America segment in the first six months of 2021 was \$2,114 million, a decrease of 2%, compared to \$2,152 million in the first six months of 2020.

Gross profit margin for our North America segment in the first six months of 2021 increased to 53.8% compared to 52.1% in the first six months of 2020.

North America R&D Expenses

R&D expenses relating to our North America segment in the first six months of 2021 were \$322 million, an increase of 7%, compared to \$300 million in the first six months of 2020.

North America S&M Expenses

S&M expenses relating to our North America segment in the first six months of 2021 were \$483 million, a decrease of 4% compared to \$505 million in the first six months of 2020. This decrease was mainly due to lower S&M expenses related to Anda and additional efficiency measures.

North America G&A Expenses

G&A expenses relating to our North America segment in the first six months of 2021 were \$218 million, a decrease of 4%, compared to \$228 million in the first six months of 2020.

North America Profit

Profit from our North America segment in the first six months of 2021 was \$1,098 million, a decrease of 2%, compared to \$1,123 million in the first six months of 2020.

Europe Segment

The following table presents revenues, expenses and profit for our Europe segment for the six months ended June 30, 2021 and 2020:

	Six months ended June 30,			
	2021		2020	
	(U.S. \$ in millions / % of Segment Revenues)			
Revenues	\$ 2,398	100%	\$ 2,404	100%
Gross profit	1,349	56.2%	1,371	57.0%
R&D expenses	129	5.4%	120	5.0%
S&M expenses	424	17.7%	390	16.2%
G&A expenses	117	4.9%	118	4.9%
Other (income) expense	(1)	\$	(2)	\$
Segment profit*	\$ 680	28.4%	\$ 746	31.0%

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

§ Represents an amount less than 0.5%.

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Europe Revenues

Our Europe segment includes the European Union and certain other European countries. Revenues from our Europe segment in the first six months of 2021 were \$2,398 million, flat compared to the first six months of 2020. In local currency terms, revenues decreased by 8%, compared to the first six months of 2020, as a result of significant customer stocking due to the COVID-19 pandemic in March 2020, partially offset by changes in buying patterns in the second quarter of 2020.

Revenues by Major Products and Activities

The following table presents revenues for our Europe segment by major products and activities for the six months ended June 30, 2021 and 2020:

	Six months ended June 30,	
	2021	2020
	(U.S. \$ in millions)	
Generic products	\$ 1,742	\$ 1,769
AJOVY	35	9
COPAXONE	201	193
Respiratory products	179	186
Other	242	246
Total	<u>\$ 2,398</u>	<u>\$ 2,404</u>

Europe Gross Profit

Gross profit from our Europe segment in the first six months of 2021 was \$1,349 million, a decrease of 2% compared to \$1,371 million in the first six months of 2020.

Gross profit margin for our Europe segment in the first six months of 2021 decreased to 56.2% compared to 57.0% in the first six months of 2020, mainly due to a change in the mix of products.

Europe R&D Expenses

R&D expenses relating to our Europe segment in the first six months of 2021 were \$129 million, an increase of 8% compared to \$120 million in the first six months of 2020.

Europe S&M Expenses

S&M expenses relating to our Europe segment in the first six months of 2021 were \$424 million, an increase of 9% compared to \$390 million in the first six months of 2020.

Europe G&A Expenses

G&A expenses relating to our Europe segment in the first six months of 2021 were \$117 million, a decrease of 1% compared to \$118 million in the first six months of 2020.

Europe Profit

Profit from our Europe segment in the first six months of 2021 was \$680 million, a decrease of 9% compared to first six months of 2020, mainly due to lower revenues, as discussed above.

International Markets Segment

The following table presents revenues, expenses and profit for our International Markets segment for the six months ended June 30, 2021 and 2020:

	2021		2020	
	(U.S. \$ in millions / % of Segment Revenues)			
Revenues	\$ 975	100%	\$ 1,053	100%
Gross profit	530	54.4%	552	52.5%
R&D expenses	35	3.6%	34	3.3%
S&M expenses	201	20.7%	211	20.0%
G&A expenses	51	5.2%	63	6.0%
Other (income) expense	(3)	\$	(8)	(0.8%)
Segment profit*	\$ 245	25.2%	\$ 253	24.0%

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

\$ Represents an amount less than 0.5%.

International Markets Revenues

Our International Markets segment includes all countries other than those in our North America and Europe segments. Revenues from our International Markets segment in the first six months of 2021 were \$975 million, a decrease of \$78 million, or 7%, compared to the first six months of 2020. In local currency terms, revenues decreased by 5% compared to the first six months of 2020. Revenues in the first six months of 2020 included \$20 million from a positive hedging impact, which are included in “Other” in the table below. The hedging impact in the first six months of 2021 was immaterial. See note 8c to our consolidated financial statements.

Revenues by Major Products and Activities

The following table presents revenues for our International Markets segment by major products and activities for the six months ended June 30, 2021 and 2020:

	Six months ended June 30,		Percentage Change 2020-2021
	2021	2020	
	(U.S. \$ in millions)		
Generic products	\$ 799	\$ 875	(9%)
COPAXONE	19	23	(18%)
Other	157	154	2%
Total	<u>\$ 975</u>	<u>\$ 1,053</u>	(7%)

International Markets Gross Profit

Gross profit from our International Markets segment in the first six months of 2021 was \$530 million, a decrease of 4% compared to \$552 million in the first six months of 2020, mainly due to a negative impact from hedging activity as well as regulatory price reductions and generic competition to off-patented products in Japan.

Gross profit margin for our International Markets segment in the first six months of 2021 increased to 54.4%, compared to 52.5% in the first six months of 2020.

International Markets R&D Expenses

R&D expenses relating to our International Markets segment in the first six months of 2021 were \$35 million, an increase of 3% compared to \$34 million in the first six months of 2020.

International Markets S&M Expenses

S&M expenses relating to our International Markets segment in the first six months of 2021 were \$201 million, a decrease of 4% compared to \$211 million in the first six months of 2020.

International Markets G&A Expenses

G&A expenses relating to our International Markets segment in the first six months of 2021 were \$51 million, a decrease of 19% compared to \$63 million in the first six months of 2020.

International Markets Profit

Profit from our International Markets segment in the first six months of 2021 was \$245 million, a decrease of 3%, compared to \$253 million in the first six months of 2020. This decrease was mainly due to lower gross profit, partially offset by lower S&M and G&A expenses.

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Other Activities

Our revenues from other activities in the first six months of 2021 decreased by 9% to \$587 million, compared to the first six months of 2020. In local currency terms, revenues decreased by 11%.

API sales to third parties in the first six months of 2021 were \$376 million, a decrease of 3% in both U.S dollar and local currency terms, compared to the first six months of 2020.

Teva Consolidated Results

Revenues

Revenues in the first six months of 2021 were \$7,892 million, a decrease of 4%, or 7% in local currency terms, compared to the first six months of 2020.

Exchange rate movements during the first six months of 2021, including hedging effects, negatively impacted revenues by \$209 million, compared to the first six months of 2020. See note 8c to our consolidated financial statements.

Gross Profit

Gross profit in the first six months of 2021 was \$3,750 million, a decrease of 2% compared to the first six months of 2020. This decrease was mainly due to lower gross profit from COPAXONE and Anda in our North America segment as well as lower gross profit from generic products in our Europe segment, partially offset by higher gross profit from generic products in our North America segment.

Gross profit margin was 47.5% in the first six months of 2021, compared to 46.5% in the first six months of 2020.

Research and Development (R&D) Expenses

R&D expenses in the first six months of 2021 were \$501 million, an increase of 12% compared to the first six months of 2020.

R&D expenses as a percentage of revenues were 6.4% in the first six months of 2021, compared to 5.4% in the first six months of 2020.

Selling and Marketing (S&M) Expenses

S&M expenses in the first six months of 2021 were \$1,200 million, a decrease of 1% compared to the first six months of 2020. Our S&M expenses were primarily the result of the factors discussed above under “—North America Segment— S&M Expenses,” “—Europe Segment— S&M Expenses” and “—International Markets Segment— S&M Expenses.”

S&M expenses as a percentage of revenues were 15.2% in the first six months of 2021, compared to 14.7% in the first six months of 2020.

General and Administrative (G&A) Expenses

G&A expenses in the first six months of 2021 were \$532 million, a decrease of 6% compared to the first six months of 2020.

G&A expenses as a percentage of revenues were 6.7% in the first six months of 2021, compared to 6.9% in the first six months of 2020.

Intangible Asset Impairments

We recorded expenses of \$274 million for identifiable intangible asset impairments, in the first six months of 2021, compared to expenses of \$768 million in the first six months of 2020. See note 5 to our consolidated financial statements.

Goodwill Impairment

No goodwill impairments were recorded in the first six months of both 2021 and 2020.

Other Asset Impairments, Restructuring and Other Items

We recorded expenses of \$165 million for other asset impairments, restructuring and other items in the first six months of 2021, compared to expenses of \$502 million in the first six months of 2020. See note 12 to our consolidated financial statements.

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Legal Settlements and Loss Contingencies

In the first six months of 2021, we recorded expenses of \$110 million in legal settlements and loss contingencies, compared to income of \$12 million in the first six months of 2020. See note 9 to our consolidated financial statements.

Other Income

Other income in the first six months of 2021 was \$48 million, compared to \$22 million in the first six months of 2020. The income in the second quarter of 2021 was mainly due to capital gains related to the sale of certain OTC assets.

Operating Income (Loss)

Operating income was \$1,015 million in the first six months of 2021, compared to \$364 million in the first six months of 2020.

Operating income as a percentage of revenues was 12.9% in the first six months of 2021, compared to 4.4% in the first six months of 2020.

Financial Expenses, Net

Financial expenses were \$564 million in the first six months of 2021, compared to \$448 million in the first six months of 2020. Financial expenses in the first six months of 2021 were mainly comprised of interest expenses of \$479 million and loss on revaluations of marketable securities of \$98 million (see note 16 to our consolidated financial statements). Financial expenses in the first six months of 2020 were mainly comprised of interest expenses of \$482 million, partially offset by a gain of \$29 million resulting from our hedging and derivatives activities.

The following table presents a reconciliation of our segment profits to our consolidated operating income (loss) and to consolidated income (loss) before income taxes for the six months ended June 30, 2021 and 2020:

	Six months ended June 30,	
	2021	2020
	(U.S. \$ in millions)	
North America profit	\$ 1,098	\$ 1,123
Europe profit	680	746
International Markets profit	245	253
Total reportable segments profit	2,023	2,121
Profit of other activities	87	102
Total segments profit	2,111	2,223
Amounts not allocated to segments:		
Amortization	414	507
Other assets impairments, restructuring and other items	165	502
Goodwill impairment	—	—
Intangible asset impairments	274	768
Legal settlements and loss contingencies	110	(12)
Other unallocated amounts	132	93
Consolidated operating income (loss)	1,015	364
Financial expenses, net	564	448
Consolidated income (loss) before income taxes	\$ 451	\$ (84)

Tax Rate

In the first six months of 2021, we recognized a tax expense of \$159 million, on pre-tax income of \$451 million. In the first six months of 2020, we recognized a tax benefit of \$163 million, on pre-tax loss of \$84 million. Our tax rate in the first six months of 2021 was mainly affected by impairments, amortization, legal settlements and interest expense disallowance.

Share in (Profits) Losses of Associated Companies, Net

Share in loss of associated companies, net in the first six months of 2021 was \$14 million. We did not have any share in (profits) losses of associated companies, net in the first six months of 2020.

Net Income (Loss) Attributable to Teva

Net income was \$284 million in the first six months of 2021, compared to \$209 million in the first six months of 2020.

Diluted Shares Outstanding and Earnings (Loss) per Share

The weighted average diluted shares outstanding used for the fully diluted share calculation for the six months ended June 30, 2021 and 2020 was 1,108 million and 1,098 million shares, respectively.

In computing diluted earnings per share for the six months ended June 30, 2021 and June 30, 2020, basic earnings per share were adjusted to take into account the potential dilution that could occur upon the exercise of options and non-vested RSUs granted under employee stock compensation plans. No account was taken of the potential dilution by the convertible senior debentures, since they had an anti-dilutive effect on earnings per share.

Diluted earnings per share were \$0.26 in the first six months of 2021, compared to diluted earnings per share of \$0.19 in the first six months of 2020.

Impact of Currency Fluctuations on Results of Operations

In the first six months of 2021, approximately 47% of our revenues were denominated in currencies other than the U.S. dollar. Because our results are reported in U.S. dollars, we are subject to significant foreign currency risks and, accordingly, changes in the exchange rate between the U.S. dollar and local currencies in markets in which we operate (primarily the euro, British pound, Japanese yen, Israeli shekel, Canadian dollar and Russian ruble) impact our results. During the first six months of 2021, the following main currencies relevant to our operations decreased in value against the U.S. dollar: Argentinian peso by 29%, Turkish lira by 18%, Brazilian real by 10%, Russian ruble by 7% and Ukrainian hryvnia by 7% (all compared on a six-month average basis). The following main currencies relevant to our operations increased in value against the U.S. dollar: Australian dollar by 17%, Swedish krona by 15%, Chilean peso by 13%, British pound by 10%, euro by 9%, Canadian dollar by 9% and new Israeli shekel by 7%.

As a result, exchange rate movements during the first six months of 2021 positively impacted overall revenues by \$209 million and our operating income by \$12 million, in comparison to the first six months of 2020.

In the first six months of 2021, a positive hedging impact of \$13 million was recognized under revenues, and a minimal negative impact was recognized under cost of sales. In the first six months of 2020, a positive hedging impact of \$40 million was recognized under revenues and a positive impact of \$4 million was recognized under cost of sales.

Hedging transactions against future projected revenues and expenses are recognized on the balance sheet at their fair value on a quarterly basis, while the foreign exchange impact on the underlying revenues and expenses may occur in subsequent quarters. See note 8c to our consolidated financial statements.

Liquidity and Capital Resources

Total balance sheet assets were \$49,195 million as of June 30, 2021, compared to \$49,004 million as of March 31, 2021.

Our working capital balance, which includes accounts receivables net of SR&A, inventories, prepaid expenses and other current assets, accounts payables, employee-related obligations, accrued expenses and other current liabilities, was \$1,196 million as of June 30, 2021, compared to \$1,179 million as of March 31, 2021.

Cash investment in property, plant and equipment in the second quarter of 2021 was \$113 million, compared to \$150 million in the first quarter of 2021. Depreciation in both the second and first quarters of 2021 was \$134 million.

Cash and cash equivalents and short-term and long-term investments as of June 30, 2021 were \$2,479 million, compared to \$1,933 million as of March 31, 2021. The increase in the second quarter of 2021 was mainly due to cash flow generated during the quarter.

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

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Our principal sources of short-term liquidity are our cash on hand, existing cash investments, liquid securities and available credit facilities, primarily our \$2.3 billion unsecured syndicated revolving credit facility entered into in April 2019 (“RCF”).

The RCF agreement provides for two separate tranches, a \$1.15 billion tranche A and a \$1.15 billion tranche B. Tranche A has a maturity date of April 8, 2022, of which an amount of \$1.065 billion was extended twice, initially to April 8, 2023 and then to April 8, 2024. Tranche B has a maturity date of April 8, 2024. Loans and letters of credit will be available from time to time under each tranche for Teva’s general corporate purposes.

The RCF contains certain covenants, including certain limitations on incurring liens and indebtedness and maintenance of certain financial ratios, including the requirement to maintain compliance with a net debt to EBITDA ratio, which becomes more restrictive over time. The net debt to EBITDA ratio limit was 5.50x through June 30, 2021, gradually declines to 5.00x in the third and fourth quarters of 2021, 4.50x in the first and second quarters of 2022, and continues to gradually decline over the remaining term of the RCF to 3.50x in the first quarter of 2023.

The RCF can be used for general corporate purposes, including repaying existing debt. As of June 30, 2021, no amounts were outstanding under the RCF. During July 2021, \$500 million was drawn down under the RCF. Based on current and forecasted results, we expect that we will not exceed the financial covenant thresholds set forth in the RCF within one year from the date the financial statements are issued.

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

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

Debt Balance and Movements

As of June 30, 2021, our debt was \$25,132 million, compared to \$24,986 million as of March 31, 2021. This increase was mainly due to exchange rate fluctuations.

In July 2021, we repaid \$1,475 million of our 2.2% senior notes at maturity.

Our debt as of June 30, 2021 was effectively denominated in the following currencies: 65% in U.S. dollars, 32% in euros and 3% in Swiss francs.

The portion of total debt classified as short-term as of June 30, 2021 was 14%, compared to 11% as of March 31, 2021.

Our financial leverage was 69% as of June 30, 2021 and as of March 31, 2021.

Our average debt maturity was approximately 5.3 years as of June 30, 2021, compared to 5.6 years as of March 31, 2021.

Total Equity

Total equity was \$11,311 million as of June 30, 2021, compared to \$10,975 million as of March 31, 2021. This increase was mainly due to net income of \$221 million and a positive impact of \$79 million from exchange rate fluctuations.

Exchange rate fluctuations affected our balance sheet, as approximately 56% of our net assets in the second quarter of 2021 (including both non-monetary and monetary assets) were in currencies other than the U.S. dollar. When compared to March 31, 2021, changes in currency rates had a positive impact of \$79 million on our equity as of June 30, 2021, mainly due to the changes in value against the U.S. dollar of: the Japanese yen by 7%, the Swiss franc by 4%, the euro by 3%, the Croatian kuna by 3%, the Polish zloty by 2% and the Chilean peso by 2%. All comparisons are on a quarter-end to quarter-end basis.

Cash Flow

We seek to continually improve the efficiency of our working capital management. From time to time, as part of our cash management activities, we may make decisions in our commercial and supply chain activities which may drive an acceleration of receivable payments from customers or deceleration of payments to vendors, having the effect of increasing or decreasing cash from operations in an individual period. Such decisions had no material impact on our year-to-date operating cash flow measurement, but may impact quarter-to-quarter results.

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Cash flow generated from operating activities during the second quarter of 2021 was \$218 million, compared to \$273 million in the second quarter of 2020. The decrease in the second quarter of 2021 was mainly due to favorable collection of payments from customers in the second quarter of 2020, which resulted from increased sales in the first quarter of 2020.

During the second quarter of 2021, we generated free cash flow of \$625 million, which we define as comprising \$218 million in cash flow generated from operating activities, \$405 million in beneficial interest collected in exchange for securitized accounts receivables and \$115 million in proceeds from divestitures of businesses and other assets, partially offset by \$113 million in cash used for capital investment. During the second quarter of 2020, we generated free cash flow of \$582 million, comprising \$273 million in cash flow generated from operating activities, \$401 million in beneficial interest collected in exchange for securitized accounts receivables and \$39 million in proceeds from sale of property, plant and equipment and intangible assets, partially offset by \$131 million in cash used for capital investment. The increase in the second quarter of 2021 resulted mainly from higher proceeds from divestitures of businesses and other assets, partially offset by lower cash flow from operating activities.

Dividends

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

Commitments

In addition to financing obligations under short-term debt and long-term senior notes and loans, debentures and convertible debentures, our major contractual obligations and commercial commitments include leases, royalty payments, contingent payments pursuant to acquisition agreements and participation in joint ventures associated with R&D activities.

In August 2020, we entered into a partnership agreement with biopharmaceutical company Alvotech for the exclusive commercialization in the U.S. of five biosimilar product candidates. The initial pipeline for this partnership contains biosimilar candidates addressing multiple therapeutic areas, including a proposed biosimilar to Humira[®]. Under this agreement, Alvotech is responsible for the development, registration and supply of the biosimilar product candidates and Teva will exclusively commercialize the products in the United States. We paid an upfront payment in the third quarter of 2020 and additional upfront and milestone payments in the second quarter of 2021 that were recorded as R&D expenses. Additional development and commercial milestone payments of up to \$450 million, as well as royalty payments, may be payable by Teva over the next few years. Teva and Alvotech will share profit from the commercialization of these biosimilars. In March 2021, Abbvie sued Alvotech for allegedly misappropriating confidential information relating to Humira[®]. Alvotech has disputed these claims. In addition, there is pending patent litigation between Abbvie and Alvotech.

In September 2016, we entered into a collaborative agreement with Regeneron to develop and commercialize Regeneron's pain medication product, fasinumab. We share in the global commercial rights to this product with Regeneron (excluding Japan, Korea and nine other Asian countries), as well as ongoing associated R&D costs of approximately \$1 billion. We made an upfront payment of \$250 million to Regeneron in the third quarter of 2016 and additional payments for achievement of development milestones in an aggregate amount of \$120 million were paid during 2017 and 2018. The agreement stipulates additional development and commercial milestone payments of up to \$2,230 million, as well as future royalties. For information regarding fasinumab, see "—North America Segment —Product Launches and Pipeline" above.

In October 2016, we entered into a collaborative agreement with Celltrion to commercialize Truxima[®] and Herzuma[®], two biosimilar products for the U.S. and Canadian markets. We paid Celltrion \$160 million, of which we received an aggregate credit of \$60 million as of March 31, 2021. We share the profit from the commercialization of these products with Celltrion. These two products, Truxima and Herzuma, were approved by the FDA in November and December 2018, respectively and were launched in the United States in November 2019 and March 2020, respectively. No additional milestone payments are expected.

We are committed to pay royalties to owners of know-how, partners in alliances and certain other arrangements, and to parties that financed R&D at a wide range of rates as a percentage of sales of certain products, as defined in the agreements. In some cases, the royalty period is not defined; in other cases, royalties will be paid over various periods not exceeding 20 years.

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In connection with certain development, supply and marketing, and research and collaboration or services agreements, we are required to indemnify, in unspecified amounts, the parties to such agreements against third-party claims relating to (i) infringement or violation of intellectual property or other rights of such third party; or (ii) damages to users of the related products. Except as described in our financial statements, we are not aware of any material pending action that may result in the counterparties to these agreements claiming such indemnification.

2021 Aggregated Contractual Obligations

There have not been any material changes in our assessment of material contractual obligations and commitments as set forth in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2020.

Supplemental Non-GAAP Income Data

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

- our management and Board of Directors use the non-GAAP measures to evaluate our operational performance, to compare against work plans and budgets, and ultimately to evaluate the performance of management;
- our annual budgets are prepared on a non-GAAP basis; and
- senior management's annual compensation is derived, in part, using these non-GAAP measures. While qualitative factors and judgment also affect annual bonuses, the principal quantitative element in the determination of such bonuses is performance targets tied to the work plan, which is based on the non-GAAP presentation set forth below.

Non-GAAP financial measures have no standardized meaning and accordingly have limitations in their usefulness to investors. We provide such non-GAAP data because management believes that such data provide useful information to investors. However, investors are cautioned that, unlike financial measures prepared in accordance with U.S. GAAP, non-GAAP measures may not be comparable with the calculation of similar measures for other companies. These non-GAAP financial measures are presented solely to permit investors to more fully understand how management assesses our performance. The limitations of using non-GAAP financial measures as performance measures are that they provide a view of our results of operations without including all events during a period and may not provide a comparable view of our performance to other companies in the pharmaceutical industry.

Investors should consider non-GAAP financial measures in addition to, and not as replacements for, or superior to, measures of financial performance prepared in accordance with GAAP.

In arriving at our non-GAAP presentation, we exclude items that either have a non-recurring impact on the income statement or which, in the judgment of our management, are items that, either as a result of their nature or size, could, were they not singled out, potentially cause investors to extrapolate future performance from an improper base. In addition, we also exclude equity compensation expenses to facilitate a better understanding of our financial results, since we believe that such exclusion is important for understanding the trends in our financial results and that these expenses do not affect our business operations. While not all inclusive, examples of these items include:

- amortization of purchased intangible assets;
- legal settlements and/or loss contingencies, due to the difficulty in predicting their timing and scope;
- impairments of long-lived assets, including intangibles, property, plant and equipment and goodwill;
- restructuring expenses, including severance, retention costs, contract cancellation costs and certain accelerated depreciation expenses primarily related to the rationalization of our plants or to certain other strategic activities, such as the realignment of R&D focus or other similar activities;
- acquisition- or divestment- related items, including changes in contingent consideration, integration costs, banker and other professional fees, inventory step-up and in-process R&D acquired in development arrangements;
- expenses related to our equity compensation;
- significant one-time financing costs and marketable securities investment valuation gains/losses;
- unusual tax items;

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- other awards or settlement amounts, either paid or received;
- other exceptional items that we believe are sufficiently large that their exclusion is important to facilitate an understanding of trends in our financial results, such as impacts due to changes in accounting, significant costs for remediation of plants, such as inventory write-offs or related consulting costs, or other unusual events; and
- corresponding tax effects of the foregoing items.

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

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

Three Months Ended June 30, 2021											
U.S. \$ and shares in millions (except per share amounts)											
GAAP	Excluded for non-GAAP measurement									Non-GAAP	
	Amortization of purchased intangible assets	Legal settlements and loss contingencies	Impairment of long lived assets	Restructuring costs	Costs related to regulatory actions taken in facilities	Equity compensation	Contingent consideration	Other non-GAAP items*	Other items		
Net revenues	3,910									3,910	
Cost of sales	2,037	148			8	6		50		1,826	
Gross profit	1,873	148			8	6		50		2,084	
Gross profit margin	47.9%									53.3%	
R&D expenses	248						5			243	
S&M expenses	615	25					8			582	
G&A expenses	242					11				231	
Other income	(43)							(37)		(6)	
Legal settlements and loss contingencies	6		6							—	
Other assets impairments, restructuring and other items	28			32	(13)			(19)	28	—	
Intangible assets impairments	195			195						—	
Operating income (loss)	582	173	6	226	(13)	8	29	(19)	42	1,034	
Financial expenses, net	274								34	240	
Income (loss) before income taxes	308	173	6	226	(13)	8	29	(19)	42	34	794
Income taxes	98								(36)		133
Share in (profits) losses of associated companies – net	(11)									(3)	(8)
Net income (loss)	221	173	6	226	(13)	8	29	(19)	42	(5)	669
Net income (loss) attributable to non-controlling interests	14									(3)	18
Net income (loss) attributable to Teva	207	173	6	226	(13)	8	29	(19)	42	(8)	651
EPS - Basic	0.19									0.40	0.59
EPS - Diluted	0.19									0.40	0.59

The non-GAAP diluted weighted average number of shares was 1,109 million for the three months ended June 30, 2021.

Non-GAAP income taxes for the three months ended June 30, 2021 were 17% on pre-tax non-GAAP income.

- * Other non-GAAP items include other exceptional items that we believe are sufficiently large that their exclusion is important to facilitate an understanding of trends in our financial results, such as certain accelerated depreciation expenses and inventory write offs, primarily related to the rationalization of our plants and other unusual events.

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Three Months Ended June 30, 2020
U.S. \$ and shares in millions (except per share amounts)

	GAAP	Excluded for non-GAAP measurement									Non-GAAP	
		Amortization of purchased intangible assets	Legal settlements and loss contingencies	Impairment of long lived assets	Other R&D expenses	Restructuring costs	Costs related to regulatory actions taken in facilities	Equity compensation	Contingent consideration	Other non-GAAP items*	Other items	
Net revenues	3,870											3,870
Cost of sales	2,107	219					6	6		16		1,859
Gross profit	1,763	219					6	6		16		2,011
Gross profit margin	45.5%											52.0%
R&D expenses	225				(13)			5				233
S&M expenses	597	30						8				559
G&A expenses	264							11		8		245
Other income	(9)									(4)		(6)
Legal settlements and loss contingencies	13		13									—
Other assets impairments, restructuring and other items	381			277		33			76	(6)		—
Intangible assets impairments	120			120								—
Operating income (loss)	173	249	13	396	(13)	33	6	30	76	14		979
Financial expenses, net	223										(5)	229
Income (loss) before income taxes	(51)	249	13	396	(13)	33	6	30	76	14	(5)	751
Income taxes	(104)										(231)	128
Net income (loss)	53	249	13	396	(13)	33	6	30	76	14	(237)	623
Net income (loss) attributable to non-controlling interests	(87)										(105)	19
Net income (loss) attributable to Teva	140	249	13	396	(13)	33	6	30	76	14	(342)	605
EPS - Basic	0.13										0.42	0.55
EPS - Diluted	0.13										0.42	0.55

The non-GAAP diluted weighted average number of shares was 1,100 million for the three months ended June 30, 2020.

Non-GAAP income taxes for the three months ended June 30, 2020 were 17% on pre-tax non-GAAP income.

- * Other non-GAAP items include other exceptional items that we believe are sufficiently large that their exclusion is important to facilitate an understanding of trends in our financial results, such as certain accelerated depreciation expenses and inventory write offs, primarily related to the rationalization of our plants and other unusual events.

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Six Months Ended June 30, 2021 U.S. \$ and shares in millions (except per share amounts)

GAAP	Excluded for non-GAAP measurement									Non-GAAP
	Amortization of purchased intangible assets	Legal settlements and loss contingencies	Impairment of long-lived assets	Restructuring costs	Costs related to regulatory actions taken in facilities	Equity compensation	Contingent consideration	Other non-GAAP items*	Other items	
Net revenue	7,892									7,892
Cost of sales	4,141	363			13	12		91		3,663
Gross profit	3,750	363			13	12		91		4,228
Gross profit margin	47.5%									53.6%
R&D expenses	501					10		5		487
S&M expenses	1,200	52				18		—		1,131
G&A expenses	532					21		0		510
Other (income) expense	(48)							(37)		(11)
Legal settlements and loss contingencies	110		110							—
Other assets impairments, restructuring and other items	165		80	69			(16)	33		—
Intangible assets impairment	274		274							—
Operating income (loss)	1,015	414	110	354	69	13	60	(16)	92	2,111
Financial expenses, net	564								98	467
Income (loss) before income taxes	451	414	110	354	69	13	60	(16)	92	1,644
Income taxes	159								(120)	280
Share in (profits) losses of associated companies – net	(14)								(1)	(13)
Net income (loss)	306	414	110	354	69	13	60	(16)	92	1,377
Net income (loss) attributable to non-controlling interests	21								(6)	28
Net income (loss) attributable to Teva	284	414	110	354	69	13	60	(16)	92	1,350
EPS - Basic	0.26								0.97	1.23
EPS - Diluted	0.26								0.96	1.22

The non-GAAP diluted weighted average number of shares was 1,108 million for the six months ended June 30, 2021.

Non-GAAP income taxes for the six months ended June 30, 2021 were 17% on pre-tax non-GAAP income.

- * Other non-GAAP items include other exceptional items that we believe are sufficiently large that their exclusion is important to facilitate an understanding of trends in our financial results, such as certain accelerated depreciation expenses and inventory write offs, primarily related to the rationalization of our plants and other unusual events.

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Six months ended June 30, 2020
U.S. \$ and shares in millions (except per share amounts)

GAAP	Excluded for non-GAAP measurement									Non-GAAP
	Amortization of purchased intangible assets	Legal settlements and loss contingencies	Impairment of long-lived assets	Restructuring costs	Costs related to regulatory actions taken in facilities	Equity compensation	Contingent consideration	Other non-GAAP items*	Other items	
Net revenue	8,227									8,227
Cost of sales	4,402	443			11	12		32		3,905
Gross profit	3,826	443			11	12		32		4,322
Gross profit margin	46.5%									52.5%
R&D expenses	446					9		(17)		454
S&M expenses	1,210	64				17				1,129
G&A expenses	567					21		12		535
Other (income) expense	(22)							(3)		(19)
Legal settlements and loss contingencies	(12)	(12)								—
Other assets impairments, restructuring and other items	502		352	73			83	(5)		—
Intangible assets impairment	768		768							—
Operating income (loss)	364	507	(12)	1,121	73	11	60	83	18	2,223
Financial expenses, net	448								6	442
Income (loss) before income taxes	(84)	507	(12)	1,121	73	11	60	83	18	1,781
Income taxes	(163)								(465)	303
Net income (loss) attributable to Teva	78	507	(12)	1,121	73	11	60	83	18	1,478
Net income (loss) attributable to non-controlling interests	(131)								(169)	38
Net income (loss)	209	507	(12)	1,121	73	11	60	83	18	1,440
EPS - Basic	0.19									1.32
EPS - Diluted	0.19									1.31

The non-GAAP diluted weighted average number of shares was 1,098 million for the six months ended June 30, 2020.

Non-GAAP income taxes for the six months ended June 30, 2021 were 17% on pre-tax non-GAAP income.

- * Other non-GAAP items include other exceptional items that we believe are sufficiently large that their exclusion is important to facilitate an understanding of trends in our financial results, such as certain accelerated depreciation expenses and inventory write offs, primarily related to the rationalization of our plants and other unusual events.

Non-GAAP Tax Rate

Non-GAAP income taxes in the second quarter of 2021 were \$133 million, or 17%, on pre-tax non-GAAP income of \$794 million. Non-GAAP income taxes in the second quarter of 2020 were \$128 million, or 17%, on pre-tax non-GAAP income of \$751 million. Our non-GAAP tax rate in the second quarter of 2021 was mainly affected by the mix of products we sold and interest expense disallowance.

Non-GAAP income taxes in the first six months of 2021 were \$280 million, or 17%, on pre-tax non-GAAP income of \$1,644 million. Non-GAAP income taxes in the first six months of 2020 were \$303 million, or 17%, on pre-tax non-GAAP income of \$1,781 million.

We expect our annual non-GAAP tax rate for 2021 to be between 17% to 18%, similar to our non-GAAP tax rate for 2020, which was 17%.

Off-Balance Sheet Arrangements

Except for securitization transactions, which are disclosed in note 10(f) to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020, we do not have any material off-balance sheet arrangements.

Critical Accounting Policies

For a summary of our significant accounting policies, see note 1 to our consolidated financial statements and “Critical Accounting Policies” included in our Annual Report on Form 10-K for the year ended December 31, 2020.

Recently Issued Accounting Pronouncements

See note 1 to our consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has not been any material change in our assessment of market risk as set forth in Item 7A to our Annual Report on Form 10-K for the year ended December 31, 2020.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

After evaluating the effectiveness of our disclosure controls and procedures as of June 30, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, Teva’s disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2021, there were no changes in internal control over financial reporting that materially affected or are reasonably likely to materially affect Teva’s internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

There are no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

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

Unregistered Sales of Equity Securities

There were no sales of unregistered equity securities during the three months ended June 30, 2021.

Repurchase of Shares

We did not repurchase any of our shares during the three months ended June 30, 2021 and currently cannot conduct share repurchases or pay dividends due to our accumulated deficit.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

31.1	<u>Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *</u>
31.2	<u>Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *</u>
32	<u>Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 *</u>
101.INS	XBRL Taxonomy Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

SIGNATURES

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

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

Date: July 28, 2021

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

CERTIFICATION OF CHIEF EXECUTIVE OFFICER**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Kåre Schultz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Teva Pharmaceutical Industries Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the company's internal control over financial reporting that occurred during the company's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: July 28, 2021

/s/ Kåre Schultz

Kåre Schultz

President and Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Eli Kalif, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Teva Pharmaceutical Industries Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the company's internal control over financial reporting that occurred during the company's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: July 28, 2021

/s/ Eli Kalif

Eli Kalif

Executive Vice President, Chief Financial Officer

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER**PURSUANT TO 18 U.S.C. SECTION 1350,****AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Teva Pharmaceutical Industries Limited (the “Company”) on Form 10-Q for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), we, Kåre Schultz, President and Chief Executive Officer of the Company, and Eli Kalif, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: July 28, 2021

/s/ Kåre Schultz

Kåre Schultz

President and Chief Executive Officer

/s/ Eli Kalif

Eli Kalif

Executive Vice President, Chief Financial Officer