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

FORM 10-Q

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

For the quarterly period ended September 30, 2022

OR

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

Commission file number 001-16174

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
(Exact name of registrant as specified in its charter)

Israel	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification Number)**
124 Dvora HaNevi'a St., Tel Aviv, ISRAEL	**6944020**
(Address of principal executive offices)	**(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 September 30, 2022, the registrant had 1,110,644,809 ordinary shares outstanding.

INDEX

INTRODUCTION AND USE OF CERTAIN TERMS

Unless otherwise indicated, all references to the "Company," "we," "our" and "Teva" refer to Teva Pharmaceutical Industries Limited and its subsidiaries, and references to "revenues" refer to net revenues. References to "U.S. dollars," "dollars," "U.S. $" and "$" are to the lawful currency of the United States of America, and references to "NIS" are to new Israeli shekels. References to "ADS(s)" are to Teva's American Depositary Share(s). References to "MS" are to multiple sclerosis. Market data, including both sales and share data, is based on information provided by IQVIA, 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 the governmental and societal responses thereto; 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, including to finalize settlement documentation and obtain sufficient participation of plaintiffs for the proposed nationwide settlement to take effect; 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; environmental risks; and the impact of Environmental, Social and Governance ("ESG") issues;
- other financial and economic risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; potential impairments of our intangible assets; the impact of other macroeconomic developments such as rising inflation and geopolitical conflicts including the ongoing conflict between Russia and Ukraine; 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;

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, 2021, including in the sections captioned "Risk Factors." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,225	$ 2,165
Accounts receivables, net of allowance for credit losses of $94 million and $90 million as of September 30, 2022 and December 31, 2021	3,730	4,529
Inventories	3,859	3,818
Prepaid expenses	1,045	1,075
Other current assets	579	965
Assets held for sale	16	19
Total current assets	11,453	12,573
Deferred income taxes	1,546	596
Other non-current assets	438	515
Property, plant and equipment, net	5,568	5,982
Operating lease right-of-use assets	422	495
Identifiable intangible assets, net	6,393	7,466
Goodwill	18,433	20,040
Total assets	$ 44,252	$ 47,666
LIABILITIES AND EQUITY		
Current liabilities:		
Short-term debt	$ 2,769	$ 1,426
Sales reserves and allowances	3,648	4,241
Accounts payables	1,635	1,686
Employee-related obligations	496	563
Accrued expenses	2,041	2,208
Other current liabilities	945	903
Total current liabilities	11,534	11,027
Long-term liabilities:		
Deferred income taxes	503	784
Other taxes and long-term liabilities	3,846	2,578
Senior notes and loans	18,497	21,617
Operating lease liabilities	354	416
Total long-term liabilities	23,200	25,395
Commitments and contingencies, see note 10		
Total liabilities	34,734	36,422
Equity:		
Teva shareholders' equity:		
Ordinary shares of NIS 0.10 par value per share; September 30, 2022 and December 31, 2021: authorized 2,495 million shares; issued 1,216 million shares and 1,209 million shares, respectively.	57	57
Additional paid-in capital	27,652	27,561
Accumulated deficit	(11,660)	(10,529)
Accumulated other comprehensive loss	(3,153)	(2,683)
Treasury shares as of September 30, 2022 and December 31, 2021: 106 million ordinary shares	(4,128)	(4,128)
	8,767	10,278
Non-controlling interests	751	966
Total equity	9,519	11,244
Total liabilities and equity	$ 44,252	$ 47,666

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Net revenues	$3,595	$3,887	$11,041	$11,778
Cost of sales	1,926	2,093	5,839	6,234
Gross profit	1,669	1,794	5,203	5,544
Research and development expenses	175	222	628	723
Selling and marketing expenses	539	597	1,716	1,798
General and administrative expenses	283	291	892	822
Intangible assets impairments	24	21	223	295
Goodwill impairment	—	—	745	—
Other assets impairments, restructuring and other items	36	62	282	227
Legal settlements and loss contingencies	195	3	2,048	113
Other income	(2)	(25)	(88)	(73)
Operating income (loss)	419	623	(1,244)	1,638
Financial expenses, net	252	241	721	805
Income (loss) before income taxes	166	382	(1,964)	833
Income taxes (benefit)	107	76	(792)	235
Share in (profits) losses of associated companies, net	1	5	(20)	(9)
Net income (loss)	58	302	(1,152)	608
Net income (loss) attributable to non-controlling interests	3	11	(21)	32
Net income (loss) attributable to Teva	56	292	(1,132)	576
Earnings (loss) per share attributable to ordinary shareholders:				
Basic	$ 0.05	$ 0.26	$ (1.02)	$ 0.52
Diluted	$ 0.05	$ 0.26	$ (1.02)	$ 0.52
Weighted average number of shares (in millions):				
Basic	1,111	1,103	1,109	1,102
Diluted	1,119	1,109	1,109	1,109

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Net income (loss)	$ 58	$ 302	$(1,152)	$ 608
Other comprehensive income (loss), net of tax:				
Currency translation adjustment	(402)	(195)	(684)	(325)
Unrealized gain (loss) from derivative financial instruments, net	7	7	21	21
Unrealized loss on defined benefit plans	—	1	—	2
Total other comprehensive income (loss)	(395)	(187)	(663)	(302)
Total comprehensive income (loss)	(337)	115	(1,815)	306
Comprehensive income (loss) attributable to non-controlling interests	(40)	(3)	(214)	(49)
Comprehensive income (loss) attributable to Teva	$ (297)	$ 118	$(1,601)	$ 355

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

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Teva shareholders' equity								
	Ordinary shares								
	Number of shares (in millions)	Stated value	Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	(U.S. dollars in millions)								
Balance at June 30, 2022	1,216	57	27,625	(11,716)	(2,801)	(4,128)	9,037	791	9,828
Net Income (loss)				56			56	3	58
Other comprehensive income (loss)					(352)		(352)	(43)	(395)
Issuance of Shares	*	*					*		*
Stock-based compensation expense			26				26		26
Balance at September 30, 2022	1,216	$ 57	$ 27,652	$ (11,660)	$ (3,153)	$(4,128)	$ 8,767	$ 751	$9,519

* Represents an amount less than $0.5 million.

	Teva shareholders' equity								
	Ordinary shares								
	Number of shares (in millions)	Stated value	Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	(U.S. dollars in millions)								
Balance at June 30, 2021	1,209	57	27,503	(10,662)	(2,446)	(4,128)	10,324	987	11,311
Net Income (loss)				292			292	11	302
Other comprehensive income (loss)					(174)		(174)	(13)	(187)
Issuance of Shares	*	*					*		*
Stock-based compensation expense			26				26		26
Balance at September 30, 2021	1,209	$ 57	$ 27,529	$ (10,370)	$ (2,620)	$(4,128)	$ 10,467	$ 984	$11,451

* Represents an amount less than $0.5 million.

	Teva shareholders' equity								
	Ordinary shares								
	Number of shares (in millions)	Stated value	Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	(U.S. dollars in millions)								
Balance at December 31, 2021	1,209	57	27,561	(10,529)	(2,683)	(4,128)	10,278	966	11,244
Net Income (loss)				(1,132)			(1,132)	(21)	(1,152)
Other comprehensive income (loss)					(470)		(470)	(193)	(663)
Issuance of Shares	7	*	1				1		1
Stock-based compensation expense			88				88		88
Balance at September 30, 2022	1,216	$ 57	$ 27,652	$ (11,660)	$ (3,153)	$(4,128)	$ 8,767	$ 751	$ 9,519

* 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 shareholders' equity								
	Ordinary shares								
	Number of shares (in millions)	Stated value	Additional paid-in capital	Retained earnings (accumulated deficit)	Accumulated other comprehensive (loss)	Treasury shares	Total Teva shareholders' equity	Non-controlling interests	Total equity
	(U.S. dollars in millions)								
Balance at December 31, 2020	1,202	57	27,443	(10,946)	(2,399)	(4,128)	10,026	1,035	11,061
Net Income (loss)				576			576	32	608
Other comprehensive income (loss)					(221)		(221)	(81)	(302)
Issuance of shares	7	*					*		*
Stock-based compensation expense			86				86		86
Balance at September 30, 2021	1,209	$ 57	$ 27,529	$ (10,370)	$ (2,620)	$(4,128)	$ 10,467	$ 984	$11,451

* Represents an amount less than $0.5 million.

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

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

	Nine months ended September 30,	
	2022	2021
Operating activities:		
Net income (loss)	$(1,152)	$ 608
Adjustments to reconcile net income (loss) to net cash provided by operations:		
Depreciation and amortization	1,002	1,010
Impairment of goodwill, long-lived assets and assets held for sale	1,002	401
Net change in operating assets and liabilities	1,007	(1,881)
Deferred income taxes – net and uncertain tax positions	(1,214)	13
Stock-based compensation	88	86
Other items	(117)	(4)
Net loss (gain) from investments and from sale of long lived assets	1	109
Net cash provided by (used in) operating activities	617	342
Investing activities:		
Beneficial interest collected in exchange for securitized trade receivables	854	1,278
Purchases of property, plant and equipment	(406)	(409)
Proceeds from sale of business and long lived assets	45	269
Acquisition of businesses, net of cash acquired	(7)	—
Proceeds from sale of investments	4	172
Purchases of investments and other assets	(2)	(36)
Other investing activities	—	3
Net cash provided by (used in) investing activities	488	1,277
Financing activities:		
Redemption of convertible senior notes	—	(491)
Proceeds from short term debt	—	500
Repayment of short term debt	—	(200)
Repayment of senior notes and loans	(661)	(1,475)
Other financing activities	(115)	(5)
Net cash provided by (used in) financing activities	(776)	(1,671)
Translation adjustment on cash and cash equivalents	(269)	(80)
Net change in cash, cash equivalents and restricted cash	60	(132)
Balance of cash, cash equivalents and restricted cash at beginning of period	2,198	2,177
Balance of cash, cash equivalents and restricted cash at end of period	$ 2,258	$ 2,045
Reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets:		
Cash and cash equivalents	2,225	2,045
Restricted cash included in other current assets . .	33	—
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	2,258	2,045
Non-cash financing and investing activities:		
Beneficial interest obtained in exchange for securitized accounts receivables	$ 883	$ 1,310

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

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, 2021, 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, 2021, 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 inflation expectations on its critical and significant accounting estimates. The most significant estimates relate to sales, reserves and allowances, IPR&D assets, marketed product rights and goodwill. These estimates could be impacted by higher costs and the ability to pass on such higher costs to customers, which is highly uncertain. The actions taken to address macroeconomic developments, as well as the economic impact on Teva's third-party manufacturers and suppliers, customers and markets could also impact such estimates and may change in future periods. Actual results could differ from those estimates.

In February 2022, Russia launched an invasion of Ukraine. As of the date of this Quarterly Report on Form 10-Q, sustained conflict and disruption in the region is ongoing. Russia and Ukraine markets are included in Teva's International Markets segment results. Teva has no manufacturing or R&D facilities in these markets. As part of the Company's annual goodwill analysis performed in the second quarter of 2022, it identified an increase in the discount rate, which led to a goodwill impairment charge in its International Markets and Teva's API reporting units. This increase was a result of an increase in certain components of the discount rate that were partially attributed to higher risk associated with country-specific characteristics of several countries, such as Russia, that might be a consequence of the conflict. Other than its impact on the goodwill impairment charge, during the nine months ended September 30, 2022, the impact of this conflict on Teva's results of operation and financial condition was immaterial. See also note 6.

Teva's results of operations for the three and nine months ended September 30, 2022 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 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 did not have a significant impact on the Company's consolidated financial statements.

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 material impact to the Company's consolidated financial statements for the period ended September 30, 2022 as a result of adopting this standard update. The Company has completed negotiations to transform the facility base rate of its securitization program and evaluated the potential impact of the replacement of the LIBOR benchmark on its interest rate risk management activities. 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 September 2022, the FASB issued ASU 2022-04 "Liabilities — Supplier Finance Programs: Disclosure of Supplier Finance Program Obligations (Subtopic 405-50)". This guidance is intended to address requests from stakeholders for information about an entity's use of supplier finance programs and their effect on the entity's working capital, liquidity and cash flows. The guidance is effective for the fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, except for the amendment on roll-forward information requirement, which is effective for the fiscal years beginning after December 15, 2023. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In November 2021, the FASB issued ASU 2021-10 "Government Assistance (Topic 832)," which requires annual disclosures that increase the transparency of transactions involving government grants, including (1) the types of transactions, (2) the accounting for those transactions, and (3) the effect of those transactions on an entity's financial statements. The amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2021, but early adoption is permitted. The Company does not expect the adoption of the ASU to have a material impact on the Company's consolidated financial statements and plans to apply the guidance prospectively to all in-scope transactions beginning fiscal year 2022.

In October 2021, the FASB issued ASU 2021-08 "Business Combinations (Topic 805), Accounting for Contract Assets and Contract Liabilities from Contracts with Customers," which requires contract assets and contract liabilities acquired in a business combination to be recognized and measured by the acquirer on the acquisition date in accordance with ASC 606, Revenue from Contracts with Customers. The guidance will result in the acquirer recognizing contract assets and contract liabilities at the same amounts recorded by the acquiree. The guidance should be applied prospectively to acquisitions occurring on or after the effective date. The guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted, including in interim periods, for any financial statements that have not yet been issued. Adoption in an interim period other than the first fiscal quarter requires an entity to apply the new guidance to all prior business combinations that have occurred since the beginning of the annual period in which the new guidance is adopted. The company will apply the guidance prospectively to acquisitions occurring on or after January 2023.

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.

MODAG

In October 2021, Teva announced a license agreement with MODAG GmbH ("Modag") that will provide Teva an exclusive global license to develop, manufacture and commercialize Modag's lead compound (TEV-56286) and a related compound (TEV-56287). TEV-56286 was initially developed for the treatment of Multiple System Atrophy ("MSA") and Parkinson's disease, and has the potential to be applied to other treatments for neurodegenerative disorders, such as Alzheimer's disease. A phase 1b clinical trial is currently being completed for TEV-56286. In the fourth quarter of 2021, Teva made an upfront payment of $10 million to Modag that was recorded as an R&D expense. Modag may be eligible for future development milestone payments, totaling an aggregate amount of up to $70 million, as well as future commercial milestones and royalties.

Alvotech

In August 2020, Teva entered into an agreement with biopharmaceutical company Alvotech for the exclusive commercialization in the U.S. of five biosimilar product candidates. The initial pipeline for this collaboration contains biosimilar candidates addressing multiple therapeutic areas, including a proposed biosimilar to Humira®. Under the terms of the 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, which were recorded as R&D expenses. Additional development and commercial milestone payments of up to $400 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. Alvotech was previously involved in litigation involving certain IP and trade secrets claims filed by Abbvie in relation to Alvotech's proposed biosimilar to Humira®, all of which were settled on March 8, 2022. Pursuant to that settlement, Alvotech and Teva may sell Alvotech's proposed biosimilar to Humira® in the United States beginning on July 1, 2023, provided that U.S. regulatory approval is obtained by that date. In September 2022, Alvotech announced they received a Complete Response Letter ("CRL") from the FDA with respect to Alvotech's proposed biosimilar to Humira®.

Eli Lilly and Alder BioPharmaceuticals

In December 2018, Teva entered into an agreement with Eli Lilly & Co. ("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. 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.

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 develop and commercialize AJOVY in Japan. Otsuka paid Teva an upfront payment of $50 million in consideration for the transaction. 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. AJOVY was approved in Japan in June 2021 and launched on August 30, 2021. As a result of the launch, Otsuka paid Teva a milestone payment of $35 million, which was recognized as revenue in the third quarter of 2021. Teva may receive additional milestone payments upon achievement of certain revenue targets. Otsuka also pays Teva royalties on AJOVY sales in Japan.

Takeda

In December 2016, Teva entered into a license agreement with a subsidiary of Takeda Pharmaceutical Company Ltd. ("Takeda"), for the research, development, manufacture and commercialization of Attenukine® technology. Teva received a $30 million upfront payment and a milestone payment of $20 million in 2017. During the second quarter of 2022, Takeda initiated its phase 2 study of modakafusp alfa (formerly TAK 573 or TEV 48573) and as a result paid Teva a milestone payment of $25 million, which was recognized as revenues in the second quarter of 2022. The license agreement stipulates additional milestone payments to Teva of up to $519 million with respect to this product candidate, as well as future royalties.

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. In October 2022, development of fasinumab for the treatment of osteoarthritic pain was discontinued.

MedinCell

In November 2013, Teva entered into an agreement with MedinCell for the development and commercialization of multiple long-acting injectable ("LAI") products. The lead product candidate selected was risperidone LAI (TV-46000) suspension for subcutaneous use for the treatment of schizophrenia. In August 2021, the FDA accepted the new drug application ("NDA") for risperidone LAI, based on phase 3 data from two pivotal studies. Teva leads the clinical development and regulatory process and is responsible for commercialization of this product candidate. MedinCell may be eligible for development milestones, and future commercial milestones of up to $112 million in respect of risperidone LAI. Teva will also pay MedinCell royalties on net sales. In April 2022, the FDA issued a CRL regarding the NDA for risperidone LAI. Teva resubmitted the NDA in October 2022 and awaits the FDA's response.

The second selected product candidate is TEV-44749, a LAI for the treatment of schizophrenia. In the third quarter of 2022, Teva decided to progress development of the product to phase 3, as a result of which a $3 million milestone payment was paid to MedinCell. MedinCell may become eligible for further milestones and royalties on sales of TEV-44749.

Assets and Liabilities Held For Sale:

General

Assets held for sale as of September 30, 2022 included certain assets that are expected to be sold within the next year. Assets and liabilities held for sale as of December 31, 2021 included certain manufacturing assets sold during the first and second quarters of 2022. The table below summarizes all of Teva's assets and liabilities included as held for sale as of September 30, 2022 and December 31, 2021:

	September 30, 2022	December 31, 2021
	(U.S. $ in millions)	
Inventories	—	2
Property, plant and equipment, net and others	46	86
Goodwill	—	7
Adjustments of assets held for sale to fair value	(30)	(76)
Total assets of the disposal group classified as held for sale in the consolidated balance sheets	$ 16	$ 19
Total liabilities of the disposal group classified as held for sale in the consolidated balance sheets, recorded under accrued expenses and other long-term liabilities	$ —	$ (43)

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 September 30, 2022				
	North America	Europe	International Markets	Other activities	Total
	(U.S. $ in millions)				
Sale of goods	1,393	1,034	445	149	3,021
Licensing arrangements	37	10	4	1	52
Distribution	371	§	12	—	383
Other	9	26	14	91	139
	$ 1,809	$1,069	$ 475	$ 241	$3,595

§ Represents an amount less than $0.5 million.

	Three months ended September 30, 2021				
	North America	Europe	International Markets	Other activities	Total
	(U.S. $ in millions)				
Sale of goods	1,487	1,197	495	160	3,340
Licensing arrangements	22	11	4	1	38
Distribution	363	§	15	—	378
Other	2	11	15	102	130
	$ 1,875	$1,220	$ 530	$ 262	$3,887

§ Represents an amount less than $0.5 million.

	Nine months ended September 30, 2022				
	North America	Europe	International Markets	Other activities	Total
	(U.S. $ in millions)				
Sale of goods	4,308	3,295	1,338	505	9,447
Licensing arrangements	111	36	12	3	162
Distribution	1,021	1	38	—	1,060
Other	10	65	33	266	373
	$ 5,450	$3,396	$ 1,422	$ 773	11,041

	Nine months ended September 30, 2021				
	North America	Europe	International Markets	Other activities	Total
	(U.S. $ in millions)				
Sale of goods	4,776	3,560	1,397	534	10,268
Licensing arrangements	62	32	9	3	106
Distribution	968	§	49	—	1,018
Other	§	25	50	312	387
	$ 5,807	$3,618	$ 1,505	$ 849	$11,778

§ Represents an amount less than $0.5 million.

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 72% of the Company's total SR&A as of September 30, 2022, with the remaining balance primarily related to customers in Canada and Germany. The changes in SR&A for third-party sales for the nine months ended September 30, 2022 and 2021 were as follows:

	Sales Reserves and Allowances							
	Reserves included in Accounts Receivable, net	Rebates	Medicaid and other governmental allowances	Chargebacks	Returns	Other	Total reserves included in SR&A	Total
	(U.S. $ in millions)							
Balance at December 31, 2021	$ 68	$ 1,655	$ 854	$ 1,085	$ 535	$ 112	$ 4,241	$ 4,309
Provisions related to sales made in current year	269	2,832	684	5,656	219	226	9,617	9,886
Provisions related to sales made in prior periods	—	(103)	(15)	(28)	(9)	(3)	(158)	(158)
Credits and payments	(285)	(2,845)	(762)	(5,826)	(300)	(213)	(9,946)	(10,231)
Translation differences	—	(66)	(11)	(17)	(8)	(4)	(106)	(106)
Balance at September 30, 2022	$ 52	1,473	$ 750	$ 870	$ 437	$ 118	$ 3,648	$ 3,700

	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, 2020	$ 80	$ 2,054	$ 828	$ 1,108	$ 686	$ 148	$ 4,824	$ 4,904
Provisions related to sales made in current year	285	3,060	617	5,949	207	246	10,079	10,364
Provisions related to sales made in prior periods	(5)	(94)	(46)	(31)	(53)	(25)	(249)	(254)
Credits and payments	(293)	(3,286)	(595)	(5,983)	(265)	(247)	(10,376)	(10,669)
Translation differences	—	(22)	(5)	(4)	(4)	(2)	(37)	(37)
Balance at September 30, 2021	$ 67	$ 1,712	$ 799	$ 1,039	$ 571	$ 120	$ 4,241	$ 4,308

NOTE 4 – Inventories:

Inventories, net of reserves, consisted of the following:

	September 30, 2022	December 31, 2021
	(U.S. $ in millions)	
Finished products	$ 1,801	$ 1,932
Raw and packaging materials	1,292	1,136
Products in process	606	587
Materials in transit and payments on account	160	163
Total	$ 3,859	$ 3,818

NOTE 5 – Identifiable intangible assets:

Identifiable intangible assets consisted of the following:

	Gross carrying amount net of impairment		Accumulated amortization		Net carrying amount	
	September 30, 2022	December 31, 2021	September 30, 2022	December 31, 2021	September 30, 2022	December 31, 2021
	(U.S. $ in millions)					
Product rights	$ 17,599	$ 18,815	$ 12,050	$ 12,318	$ 5,548	$ 6,497
Trade names	556	590	216	198	340	392
In process research and development	505	577	—	—	505	577
Total	$ 18,660	$ 19,982	$ 12,267	$ 12,516	$ 6,393	$ 7,466

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.

Amortization of intangible assets was $165 million and $199 million in the three months ended September 30, 2022 and 2021, respectively.

Amortization of intangible assets was $576 million and $613 million in the nine months ended September 30, 2022 and 2021, 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 $479 million. IPR&D carries intrinsic risks that the asset might not succeed in advanced phases and may be impaired in future periods.

Intangible assets impairments

Impairments of long-lived intangible assets for the three months ended September 30, 2022 and 2021 were $24 million and $21 million, respectively.

Impairments of long-lived intangible assets for the nine months ended September 30, 2022 and 2021 were $223 million and $295 million, respectively.

Impairments in the first nine months of 2022 consisted mainly of:

(a) Identifiable product rights of $169 million related to updated market assumptions regarding price and volume of products acquired from Actavis Generics, and

(b) IPR&D assets of $37 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 and launch date).

Impairments in the first nine months of 2021 consisted of:

(a) Identifiable product rights and trade names of $209 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) $179 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 $86 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) in the United States.

The fair value measurement of the impaired intangible assets in the first nine months of 2022 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 8.5%. 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 nine months ended September 30, 2022 were as follows:

	North America	Europe	International Markets	Other	Total
			(U.S. $ in millions)		
Balance as of December 31, 2021 (1)	$ 6,474	$8,544	$ 2,328	$2,694	$20,040
Changes during the period:					
Goodwill impairment	—	—	(479)	(266)	(745)
Goodwill acquired				12	12
Translation differences	(27)	(559)	(67)	(221)	(874)
Balance as of September 30, 2022 (1)	$ 6,447	$7,985	$ 1,782	$2,219	$18,433

(1) Accumulated goodwill impairment as of September 30, 2022 and December 31, 2021 was approximately $26.3 billion and $25.6 billion, respectively.

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.

During the second quarter of 2022, 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.

Teva identified an increase in certain components of the discount rate, mainly attributable to: (i) the risk free interest rate, which resulted in an increase in the WACC; and (ii) the risk associated with country-specific characteristics of several countries.

Based on this quantitative analysis, in the second quarter of 2022, Teva recorded a goodwill impairment charge of $745 million as follows: (i) $479 million related to its International Markets reporting unit, mainly due to the increase in the discount rate; and (ii) $266 million related to its Teva's API reporting unit, mainly due to the increase in the discount rate, as well as updated assumptions supporting the cash flow projections, including certain revenue growth assumptions and the associated operating profit margins. Teva's API reporting unit is included under "Other" in the table above.

Following the goodwill impairment charges recorded in relation to Teva's International Markets and Teva's API reporting units, the carrying values of those reporting units equaled their fair value as of June 30, 2022. Therefore, if business conditions or expectations were to change materially, it may be necessary to record further impairment charges to Teva's International Markets or Teva's API reporting units in the future.

The estimated fair value of Teva's Europe reporting unit exceeded its estimated carrying amount by 9% based on a terminal growth rate of 1.41% and a discount rate of 10.04%. If Teva held all other assumptions constant, a reduction in the terminal growth rate of 0.50% to 0.91% or an increase in the discount rate of 0.50% to 10.54% would have resulted in a reduction of the excess of fair value over carrying amount with respect to Teva's Europe reporting unit to 5%.

Teva's North America and Medis reporting units had a fair value in excess of 10% over their book values as of June 30, 2022.

Teva noted its market capitalization has been below management's assessment of the aggregated fair value of the Company's reporting units. However, as of June 30, 2022, the Company's market capitalization plus a reasonable control premium exceeded its book value.

During the third quarter of 2022, management assessed developments that occurred during the quarter to determine if it is 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 amounts as of September 30, 2022 and, therefore, no quantitative assessment was performed.

NOTE 7 – Debt obligations:

a. Short-term debt:

	Weighted average interest rate as of September 30, 2022	Maturity	September 30, 2022	December 31, 2021
			(U.S. $ in millions)	
Convertible senior debentures	0.25%	2026	23	23
Current maturities of long-term liabilities			2,746	1,403
Total short-term debt			$ 2,769	$ 1,426

Convertible senior debentures

The principal amount of Teva's 0.25% convertible senior debentures due 2026 was $23 million as of September 30, 2022 and December 31, 2021. 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.

b. Long-term debt:

	Weighted average interest rate as of September 30, 2022	Maturity	September 30, 2022	December 31, 2021
			(U.S. $ in millions)	
Senior notes EUR 1,500 million	1.13%	2024	614	708
Sustainability-linked senior notes EUR 1,500 million (1)(*)	4.38%	2030	1472	1,699
Senior notes EUR 1,300 million	1.25%	2023	578	670
Sustainability-linked senior notes EUR 1,100 million (2)(*)	3.75%	2027	1080	1,246
Senior notes EUR 1,000 million	6.00%	2025	983	1,134
Senior notes EUR 900 million	4.50%	2025	883	1,020
Senior notes EUR 750 million	1.63%	2028	733	844
Senior notes EUR 700 million (3)	3.25%	2022	—	307
Senior notes EUR 700 million	1.88%	2027	686	792
Senior notes USD 3,500 million	3.15%	2026	3,496	3,496
Senior notes USD 3,000 million	2.80%	2023	1,453	1,453
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
Sustainability-linked senior notes USD 1,000 million (2)(*)	4.75%	2027	1,000	1,000
Sustainability-linked senior notes USD 1,000 million (1)(*)	5.13%	2029	1,000	1,000
Senior notes USD 844 million	2.95%	2022	715	715
Senior notes USD 789 million	6.15%	2036	783	783
Senior notes CHF 350 million (4)	0.50%	2022	—	382
Senior notes CHF 350 million	1.00%	2025	360	383
Total senior notes			21,322	23,118
Other long-term debt			2	2
Less current maturities			(2,746)	(1,403)
Less debt issuance costs			(81)	(100)
Total senior notes and loans			$ 18,497	$ 21,617

(1) If Teva fails to achieve certain sustainability performance targets, the interest rate shall increase by 0.125%-0.375% per annum, from and including May 9, 2026.

(2) If Teva fails to achieve certain sustainability performance targets, a one-time premium payment of 0.15%-0.45% out of the principal amount will be paid at maturity or upon earlier redemption, if such redemption is on or after May 9, 2026.

(3) In April 2022, Teva repaid $296 million of its 3.25% senior notes at maturity.

(4) In July 2022, Teva repaid $365 million of its 0.50% senior notes at maturity.

(*) Interest rate adjustments and a potential one-time premium payment related to the sustainability-linked bonds are treated as bifurcated embedded derivatives. See note 8c.

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. The long-term debt outlined in the above table is generally redeemable at any time at varying redemption prices plus accrued and unpaid interest.

Teva's debt as of September 30, 2022 was effectively denominated in the following currencies: 65% in U.S. dollar, 33% in euro and 2% 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 $1.8 billion unsecured syndicated sustainability-linked revolving credit facility entered into in April 2022 ("RCF").

In April 2022, Teva entered into an unsecured syndicated sustainability-linked revolving credit facility of $1.8 billion with a maturity date of April 2026, with two one-year extension options. The RCF contains certain covenants, including certain limitations on incurring liens and indebtedness and maintenance of certain financial ratios, including a maximum leverage ratio, which becomes more restrictive over time. In addition, the RCF is linked to two sustainability performance targets, (i) the Company's S&P ESG Score and (ii) number of new regulatory submissions in low and middle-income countries. The RCF margin may increase or decrease depending on the Company's sustainability performance.

Under the terms of the RCF, the leverage ratio shall not exceed 4.50x in the third quarter of 2022, 4.25x in the fourth quarter of 2022, 4.00x in the first, second and third quarters of 2023, 3.75x in the fourth quarter of 2023 and 3.50x in 2024 and onwards.

The RCF can be used for general corporate purposes, including repaying existing debt. As of September 30, 2022 and as of the date of this Quarterly Report on Form 10-Q, no amounts were outstanding under the RCF. Based on current and forecasted results, the Company expects that it will not exceed the financial covenant thresholds set forth in the RCF within one year from the date 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, 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 and sustainability-linked senior notes is outstanding, could lead to an event of default under the Company's senior notes and sustainability-linked 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 the financial statements are issued.

NOTE 8 – Derivative instruments and hedging activities:

a. Foreign exchange risk management:

In the first nine months of 2022, 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.

The Company enters into forward exchange contracts and 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: euro, Swiss franc, Japanese yen, British pound, Canadian dollar, Polish zloty, new Israeli shekel, Indian rupee and other 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 has in the past entered into cross-currency swaps and forward-contracts in order to hedge such an exposure.

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

b. Interest risk management:

The Company raises capital through various debt instruments, including senior notes, sustainability-linked senior notes, bank loans, convertible debentures and syndicated revolving credit facility that bear a fixed or variable interest rate. In some cases, the Company has swapped from a fixed to a variable 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. Bifurcated embedded derivatives:

Upon issuance of sustainability-linked senior notes, Teva recognized embedded derivatives related to interest rate adjustments and a potential one-time premium payment upon failure to achieve certain sustainability performance targets, such as access to medicines in low-to-middle-income countries and absolute greenhouse gas emissions reduction, which were bifurcated and are accounted for separately as derivative financial instruments. As of September 30, 2022, the fair value of these derivative instruments is negligible.

d. Derivative instruments outstanding:

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

	Fair value	
	Not designated as hedging instruments	
Reported under	September 30, 2022	December 31, 2021
	(U.S. $ in millions)	
Asset derivatives:		
Other current assets:		
Option and forward contracts	$ 94	$ 30
Liability derivatives:		
Other current liabilities:		
Option and forward contracts	(53)	(23)

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

	Financial expenses, net		Net revenues	
	Three months ended,		Three months ended,	
Reported under	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	$ 252	$ 241	$ (3,595)	$ (3,887)
Option and forward contracts (1)	(6)	(9)	—	—
Option and forward contracts economic hedge (2)	—	—	(34)	(16)

	Financial expenses, net		Net revenues	
	Nine months ended,		Nine months ended,	
Reported under	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
	(U.S. $ in millions)			
Line items in which effects of hedges are recorded	$ 721	$ 805	$ (11,041)	$ (11,778)
Option and forward contracts (1)	(48)	(51)	—	—
Option and forward contracts economic hedge (2)	—	—	(69)	(29)

(1) 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.

(2) Teva entered into option and forward contracts designed to limit the exposure of foreign exchange fluctuations on projected revenues and expenses recorded in euro, Swiss franc, Japanese yen, British pound, Canadian dollar, Polish zloty and some other currencies to protect its projected operating results for 2022 and 2023. 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 the first nine months of 2022, the positive impact from these derivatives recognized under revenues was $69 million. In the first nine months of 2021, the positive impact from these derivatives recognized under revenues was $29 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.

e. 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 September 30, 2022 and 2021, respectively, and losses of $22 million and $24 million were recognized under financial expenses, net for each of the nine months ended September 30, 2022 and 2021, 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.

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 September 30, 2022 and 2021, respectively, and gains of $3 million and $2 million were recognized under financial expenses, net for the nine months ended September 30, 2022 and 2021, respectively.

NOTE 9 – Legal settlements and loss contingencies:

In the third quarter of 2022, Teva recorded expenses of $195 million in legal settlements and loss contingencies, compared to $3 million in the third quarter of 2021. The expenses in the third quarter of 2022 were mainly related to an update of the estimated settlement provision recorded in connection with the remaining opioid cases, as well as an estimated provision recorded for the claims brought by attorneys general representing states and territories throughout the United States in the generic drug antitrust litigation. See note 10.

In the first nine months of 2022, Teva recorded an expense of $2,048 million in legal settlements and loss contingencies, compared to an expense of $113 million in the first nine months of 2021. The expense in the first nine months of 2022 was mainly related to an update of the estimated settlement provision recorded in connection with the remaining opioid cases. The expense in the first nine months of 2021 was mainly due to the provision recorded for the carvedilol patent litigation.

As of September 30, 2022 and December 31, 2021, Teva's provision for legal settlements and loss contingencies recorded under accrued expenses and other taxes and long-term liabilities was $4,077 million and $2,710 million, respectively. In connection with Teva's provision for legal settlements and loss contingencies as of December 31, 2021, related to the Ontario Teachers Securities Litigation, Teva also recognized an insurance receivable.

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 data.

Intellectual Property Litigation

From time to time, Teva seeks to develop generic and biosimilar versions of patent-protected pharmaceuticals and biopharmaceuticals 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. For many biosimilar products that are covered by patents, Teva participates in the "patent dance" procedures of the Biologics Price Competition and Innovation Act (BPCIA), which allow for the challenge to originator patents prior to obtaining biosimilar product approval. 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 or biosimilar version of the product 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.

Teva could also be sued for patent infringement outside of the context of the Hatch-Waxman Act or BPCIA. For example, Teva could be sued for patent infringement after commencing sales of a product. This type of litigation can involve any of Teva's pharmaceutical products, not just its generic and biosimilar products.

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 the District Court for the District of Delaware 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 August 5, 2021, the Court of Appeals for the Federal Circuit issued a two-to-one decision reinstating the $235.5 million verdict and finding Teva liable for patent infringement. On February 11, 2022, the Court of Appeals for the Federal Circuit denied rehearing. Teva appealed this decision to the U.S. Supreme Court on July 11, 2022. In response to Teva's *certiorari* petition, on October 3, 2022, the U.S. Supreme Court issued an order seeking the views of the U.S. Solicitor General as to whether to review this case. At the same time, the case has been remanded to the district court for further proceedings on 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.

In October 2016, Adapt and Emergent Biosciences Inc. ("EBSI") sued Teva in the District Court for the District of New Jersey, asserting infringement of its patents expiring in 2035, as a result of Teva's filing of its Abbreviated New Drug Application ("ANDA") seeking to market a generic version of Narcan® nasal spray. In June 2020, the court issued a decision finding all of EBSI's patents expiring in 2035, to be invalid. On December 22, 2021, Teva launched its generic version of Narcan® nasal spray. On February 10, 2022, the Court of Appeals for the Federal Circuit affirmed the lower court decision finding that EBSI's patents are invalid. On May 5, 2022, the Court of Appeals for the Federal Circuit denied EBSI's petition for rehearing. EBSI did not seek the U.S. Supreme Court's review of this decision within the time allowed, so this case is now closed.

Product Liability Litigation

Teva's business inherently exposes it to potential product liability claims. Teva maintains a program of insurance, which may include commercial insurance, self-insurance (including direct risk retention), or a combination of both types of insurance, 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 and plaintiffs have filed amended complaints. The judge in the valsartan MDL has indicated that the first trial, likely commencing in 2023, will consider third-party payor economic loss claims against Teva and two other defendants. In the ranitidine MDL, the generics manufacturers' motions to dismiss have been granted, although certain plaintiffs have appeals pending. Teva, as well as other generic manufacturers, is also named in several state court actions asserting allegations similar to those in the ranitidine MDL and the valsartan and losartan MDL. The state court valsartan and losartan actions are pending in New Jersey and Delaware and are currently stayed. The state court ranitidine cases naming Teva are pending in California, Illinois, Pennsylvania and New York, with coordinated proceedings in California, Illinois and Pennsylvania. 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. Defendants' motion to dismiss the plaintiffs' amended metformin complaint from June 2021, was granted without prejudice with respect to the consumer economic loss plaintiffs and granted in part and denied in part with respect to the end payor plaintiffs. Plaintiffs were granted leave to file a second amended complaint, which defendants have moved to dismiss. Those motions are currently pending. Similar lawsuits are pending in Canada and Germany.

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 been named as defendants in cases that allege antitrust violations arising from such settlement agreements. The plaintiffs in these cases are usually direct and indirect purchasers of pharmaceutical products, some of whom assert claims on behalf of classes of all direct and indirect purchasers, and they typically allege that (i) Teva received something of value from the innovator in exchange for an agreement to delay generic entry, and (ii) significant savings could have been realized if there had been no settlement agreement and generic competition had commenced earlier. These plaintiffs 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 often 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., 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 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 euro 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.

In December 2011, three groups of plaintiffs sued Wyeth and Teva for alleged violations of the antitrust laws in connection with their November 2005 settlement of patent litigation involving extended release venlafaxine (generic Effexor XR®). 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 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. On April 9, 2021, the district court, which had previously granted an initial motion for class certification by the direct purchaser plaintiffs but was reversed on that ruling by the Third Circuit in April 2020, denied the direct purchaser plaintiffs' renewed motion for class certification. Plaintiffs thereafter sought leave to file a supplemental expert report in an effort to show that they could still meet the class certification standard, which was denied in full on January 21, 2022, and on April 21, 2022, the court entered a schedule for additional briefing on the remaining class certification issues. Plaintiffs filed a further renewed motion for class certification on May 20, 2022, which defendants opposed, and that motion remains pending. 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 was subsequently denied with prejudice by the district court and is now on appeal before the Court of Appeals for the Third Circuit. In October 2016, the District Attorney for Orange County, California, filed a similar complaint in California state court, alleging violations of state law and seeking restitution and civil penalties. 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.

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.

Putative classes of direct-purchaser and end-payer plaintiffs have filed antitrust lawsuits (which have since been coordinated in federal court in Delaware) against Amgen and Teva alleging that the January 2, 2019 settlement agreement between Amgen and Teva, resolving patent litigation over cinacalcet (generic Sensipar®), violated the antitrust laws. On November 30, 2020, the district court denied Teva's motion to dismiss in part, and on February 16, 2021, plaintiffs filed amended complaints. On March 30, 2021, Teva again moved to dismiss those claims based on plaintiffs' failure to allege both that the settlement violated the antitrust laws and that the settlement caused any actual injury to plaintiffs. On March 11, 2022, the district court denied Teva's motion to dismiss in part. Teva has requested that the district court certify its rulings for review by the United States Court of Appeals for the Third Circuit, and is awaiting the court's decision. 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.

In August 2019, certain direct-purchaser plaintiffs filed claims in federal court in Philadelphia naming Teva and its affiliates as defendants alleging that certain patent litigation settlement agreements relating to AndroGel® 1% (testosterone gel) violate the antitrust laws, specifically the September 2006 patent litigation settlement between Watson Pharmaceuticals, Inc. ("Watson"), from which Teva later acquired certain assets and liabilities, and Solvay Pharmaceuticals, Inc. ("Solvay"), and a 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 and related litigations in Georgia that have since been settled was included in the financial statements.

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 moved to dismiss. On January 24, 2022, the court dismissed plaintiffs' amended complaints without prejudice. The plaintiffs filed amended complaints on February 22, 2022, which defendants (including Teva, Actavis and Watson) moved to dismiss on April 19, 2022, and the court has scheduled oral argument for November 3, 2022. Annual sales of Bystolic® in the United States were approximately $700 million at the time of Watson's 2013 settlement with Forest.

In February 2021, the State of New Mexico filed a lawsuit against Teva and certain other defendants related to various medicines used to treat HIV. Between September and December 2021, several private plaintiffs including retailers and health insurance providers filed similar claims in federal court in the Northern District of California and in the District of Minnesota. As they relate to Teva, the lawsuits challenge settlement agreements Teva entered into with Gilead in 2013 and 2014 to resolve patent litigation relating to Teva's generic versions of Viread®, Truvada®, and Atripla®. Plaintiffs

allege that the settlements contain improper reverse payments that delayed the availability of Teva's generic products, in violation of the federal antitrust laws and state law. Several recently filed cases are in the process of being coordinated with the existing litigation in the Northern District of California. On February 16, 2022, Teva moved to dismiss the claims by certain private plaintiffs but that motion was denied. However, Teva has successfully moved to limit the potential damages period as to certain private plaintiffs. Discovery in those cases is now closed. Plaintiffs in these cases have abandoned any claim for damages relating to the Viread® settlement. Defendants have submitted summary judgment motions, and briefing is ongoing. Trial is currently scheduled to commence in March 2023. On August 5, 2021, Teva moved to dismiss the complaint brought by the State of New Mexico, and on December 20, 2021, the trial court denied Teva's motion. The trial court certified the decision as appropriate for interlocutory appeal, but on April 8, 2022, the appellate court in New Mexico declined to accept the appeal. Teva has appealed the decision to the New Mexico Supreme Court, and that appeal remains pending. Annual sales in the United States at the time of the settlement of Viread®, Truvada® and Atripla® were approximately $582 million, $2.4 billion, and $2.9 billion, respectively. Annual sales in the United States at the time Teva launched its generic version of Viread® in 2017, Truvada® in 2020 and Atripla® in 2020 were approximately $728 million, $2.1 billion and $444 million, respectively.

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. On October 10, 2022, the European Commission issued a Statement of Objections, which sets forth its preliminary allegations that Teva had engaged in anti-competitive practices. Teva now has the opportunity to formally respond to the European Commission's allegations. Annual sales of COPAXONE in the European Economic Area for 2021 were approximately $373 million.

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. On October 6, 2021, Accord UK and Auden Mckenzie appealed the CMA's decision. A provision for the estimated exposure for Teva related to the fines and/or damages has been recorded in the financial statements.

In August 2021, a plaintiff filed a putative class action suit in the United States District Court for the Eastern District of Pennsylvania against Takeda and several generic manufacturers, including Watson and Teva, alleging violations of the antitrust laws in connection with their settlement of patent litigation involving colchicine tablets (generic Colcrys®), entered into in January 2016. Plaintiff claims that the settlement was part of a horizontal conspiracy among Takeda and the generic manufacturers to unlawfully restrict output of colchicine by delaying generic entry. Defendants moved to dismiss the complaint for failure to state a claim. On December 28, 2021, the Court granted the defendants' motion to dismiss, finding that plaintiff's allegations were implausible, but granted plaintiff leave to amend, and on January 18, 2022, plaintiff filed its amended complaint, making substantively the same antitrust allegations as before, but with certain new allegations regarding the nature of the alleged conspiracy. On March 30, 2022, the Court granted in part and denied in part defendants' motion to dismiss, dismissing the newly pled bilateral conspiracy claims but allowing the revised overarching conspiracy claim to proceed against all defendants. On April 8, 2022, Teva and Watson, along with their codefendant Amneal, moved the court to reconsider its partial motion-to-dismiss denial or, in the alternative, to certify that denial for immediate appellate review. However, that motion was denied on April 25, 2022. The case is in discovery, and plaintiff's motion for class certification was fully briefed on September 28, 2022 and remains pending. Annual sales of Colcrys® in the United States were approximately $187 million at the time of the settlement.

Government Investigations and Litigation Relating to Pricing and Marketing

Teva is involved in government investigations and litigation arising from the marketing and promotion of its pharmaceutical products in the United States.

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 three separate conspiracies 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, 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. On September 9, 2021, the states' attorneys general amended their third complaint to, among other things, add California as a plaintiff. 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 certain complaints filed by private plaintiffs, to proceed first in the litigation as bellwether complaints. On February 9, 2021, Teva's motion to reconsider that ruling was granted, and on May 7, 2021, the Court chose the attorneys' general third complaint filed on June 10, 2020 and subsequently amended to serve as a bellwether complaint in the Pennsylvania MDL, along with certain complaints filed by private plaintiffs. On December 9, 2021, the Court entered an order setting the schedule for the proceedings in the bellwether cases. The order did not include trial dates, but provides for the parties to complete briefing on motions for summary judgement in early 2024. On June 7, 2022, the Court dismissed the attorneys' general claims for monetary relief under federal law, concluding that the federal statute under which the attorneys general brought suit authorizes injunctive relief only. However, the attorneys general have pending claims for monetary relief under state law. Teva has settled with the states of Mississippi (in June 2021), Louisiana (in March 2022), Georgia (in September 2022) and Arkansas (in October 2022). Teva paid each state an amount proportional

to its share of the national population (approximately $1,000,000 for each 1% share of the national population), and the states have dismissed their claims against Actavis and Teva USA, as well as certain former employees of Actavis and Teva USA, pursuant to these settlements. On March 30, 2022, the State of Alabama voluntarily dismissed all of its claims in the litigation, including its claims against Actavis and Teva USA, without prejudice. The most recent settlements with Georgia and Arkansas follow the pattern reached in earlier settlements. Specifically, as mentioned above, Teva agreed to pay each state an amount proportional to its share of the national population. This, in addition to the status of ongoing negotiations with several other U.S. state attorneys general to settle on comparable terms, caused management to consider settlement of the claims filed by the remaining attorneys general to be probable, and management recorded an estimated provision in the third quarter of 2022, in accordance with Accounting Standards Codification 450 "Accounting for Contingencies."

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, May 6, 2020 and October 8, 2021, certain individual plaintiffs commenced civil actions 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 complaints have been filed in the actions and each of the three of the cases have been placed in deferred status. Certain counties in New York and Texas have also 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. 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 September 10, 2021, the Court granted Teva's motion to dismiss the unjust enrichment claim and denied the remainder of the motion. On October 15, 2021, Teva filed an answer to the complaint. Trial for this matter is currently scheduled for September 2023. 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 and discovery is ongoing.

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 September 28, 2021, plaintiffs filed an amended complaint. On November 17, 2021, Teva moved to dismiss the suit, on the grounds that plaintiffs' claims are barred by the applicable statutes of limitations and the direct purchaser rule, suffer from jurisdictional defects, and fail to plausibly allege fraud or other elements of their claims. That motion is fully briefed and a decision remains pending.

On June 29, 2021, Mylan Pharmaceuticals ("Mylan") sued Teva in the District Court for the District of New Jersey. On March 11, 2022 and March 15, 2022, FWK Holdings, LLC, KPH Healthcare Servs., Inc. d/b/a Kinney Drugs, Inc., Meijer Inc., Meijer Distribution, Inc., Labor-Management Healthcare Fund, the Mayor and City Council of Baltimore, and the New York State Teamsters Council Health and Hospital Fund sued Teva in the District Court for the District of New

Jersey on behalf of themselves and other similarly situated direct and indirect purchasers of COPAXONE. On August 22, 2022, Blue Cross Blue Shield of Vermont and the Vermont Health Plan sued Teva in the District Court for the District of Vermont on behalf of themselves and other similarly situated indirect purchasers of COPAXONE. The complaints assert claims for alleged violations of the Lanham Act, state and federal unfair competition and monopolization laws, tortious interference, trade libel, and a violation of the Racketeer Influenced and Corrupt Organizations Act. 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, restitution, treble damages, attorneys' fees and costs, and injunctive relief. Teva has moved to dismiss the complaints filed by Mylan and the class plaintiffs in the District of New Jersey on the grounds, among others, that none of its challenged conduct violates the law. Those motions are fully briefed and a decision remains pending. Teva has moved to transfer the remaining complaint in Vermont to the District of New Jersey and expects to move to dismiss that complaint on similar grounds.

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 non-personal injury complaints and approximately 100 personal injury 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 against Teva and other defendants focused on the marketing of branded opioids. On December 14, 2021, the court issued its final judgment in favor of the defendants on all claims. Plaintiffs filed a notice of appeal of this judgment in February 2022. On June 29, 2021, a jury trial in New York (*In re Opioid Litigation*, Index No. 400000/2017) commenced against Teva and other defendants, focused on the marketing and distribution of opioids. The case was bifurcated between liability and damages. On December 30, 2021, the jury returned a liability verdict in favor of plaintiffs (the County of Suffolk, the County of Nassau and the State of New York) on the plaintiffs' public nuisance claim. Teva and the plaintiffs filed post-trial motions with respect to the liability portion of the case. In November 2022, Teva reached an agreement with the Attorney General of New York that settles the state's and its subdivisions' opioid-related claims.

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 agreed to 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.

On July 21, 2021, it was announced that four other defendants (not including Teva) reached nationwide settlements, subject to certain conditions, which include payment of up to approximately $26 billion spread over up to 18 years. Teva has continued to work toward a nationwide settlement with the working group of States' Attorneys General (the "Working Group"), the Multi-District Litigation Plaintiffs' Executive Committee ("PEC") and counsel for Native American tribes ("Tribes"). In July 2022, the parties reached an agreement in principle on the financial terms of a final nationwide settlement similar in structure to the nationwide settlements of other defendants. During the third quarter of 2022, Teva, the Working Group and PEC made substantial progress toward finalizing the non-financial terms of the proposed nationwide settlement agreement, and Teva and Allergan resolved their dispute with respect to Teva's indemnification obligations. Under the financial terms of the proposed nationwide settlement agreement, Teva will pay up to $4.25 billion (including the already settled cases) plus approximately $100 million for the Tribes, spread over 13 years. This total includes the supply of up to $1.2 billion of Teva's generic version of Narcan® (naloxone hydrochloride nasal spray), valued at wholesale acquisition cost, over 10 years or cash at 20% of the wholesale acquisition cost ($240 million) in lieu of product. The nationwide settlement agreement is contingent upon (i) final documentation of the proposed nationwide settlement agreement; (ii) reaching sufficient participation by states and subdivisions; and (iii) Allergan reaching a nationwide opioids settlement. No other trials currently are scheduled against Teva in 2022 in any opioids matter. If the nationwide settlement agreement is not finalized, additional trials are expected to proceed in several states in 2023.

On September 28, 2021, Teva reached an agreement with the Attorney General of Louisiana that settles the state's opioid-related claims. The agreement was contingent that all political subdivisions of Louisiana will formally release Teva as part of the settlement, which Teva was advised has occurred by the Attorney General of Louisiana. Under the terms of the settlement, Teva will pay Louisiana $15 million over an 18-year period and will provide buprenorphine naloxone (sublingual tablets) valued at $3 million (wholesale acquisition cost).

On February 4, 2022, Teva reached an agreement with the Attorney General of the State of Texas that settles Texas' and its subdivisions' opioid-related claims. On March 10, 2022, Texas confirmed that at least 96% of the population of subdivisions formally released Teva as part of the settlement. Under the terms of the settlement, Teva will pay Texas $150 million over a 15-year period and will provide its generic version of Narcan® (naloxone hydrochloride nasal spray), valued at $75 million (wholesale acquisition cost) over 10 years.

On March 21, 2022, Teva reached an agreement with the Attorney General of Rhode Island that settles Rhode Island's and its subdivisions' opioid-related claims. Under the terms of the settlement, Teva will pay Rhode Island $21 million over 13 years, in addition to attorneys' fees and costs, and will provide its generic version of Narcan® (naloxone hydrochloride nasal spray) and a significant amount of buprenorphine naloxone sublingual tablets known by the brand name Suboxone®, together valued at $78.5 million (wholesale acquisition cost) over 10 years.

On March 30, 2022, Teva reached an agreement with the Attorney General of Florida that settles Florida's and its subdivisions' opioid-related claims. Under the terms of the settlement, Teva will pay Florida $177 million over 15-years, in addition to attorneys' fees and costs, and will provide its generic version of Narcan® (naloxone hydrochloride nasal spray) valued at $84 million (wholesale acquisition cost) over 10 years.

On May 24, 2022, Teva reached an agreement in principle with the Attorney General of West Virginia that settles West Virginia's and its subdivisions' opioid-related claims. Under the terms of the settlement, Teva will pay West Virginia $75 million over 15-years, in addition to attorneys' fees and costs, and will provide its generic version of Narcan® (naloxone hydrochloride nasal spray) valued at $27 million (wholesale acquisition cost) over 10 years.

On July 12, 2022, Teva reached an agreement in principle with the City and County of San Francisco and the People of the State of California that settles opioid-related claims asserted on behalf of the City and County of San Francisco. Teva will provide San Francisco $20.3 million over 13 years, in addition to attorneys' fees and costs, and will provide its generic version of Narcan® (naloxone hydrochloride nasal spray), valued at $20 million (wholesale acquisition cost), over 10 years.

In light of the agreement in principle on the nationwide settlement between Teva, and the States' Attorneys General, their subdivisions and the Tribes, the agreement with the Attorney General of New York, Teva's indemnification obligations arising from Teva's acquisition of the Actavis Generics business for opioid-related claims, prior settlements with Texas, Florida, Louisiana, Rhode Island, West Virginia and San Francisco, as well as an estimate for a number of items including, but not limited to, costs associated with administering injunctive terms, and most favored nations clauses associated with prior settlements, the Company has reconsidered the potential settlement outcome and revised its provision. The revised provision is a reasonable estimate of the ultimate costs in the likely event that the nationwide settlement is finalized under its current proposed terms and conditions, after discounting payments to states to their net present value. However, if the nationwide settlement is not finalized for the entirety of the remaining 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.

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 merits hearing date is currently set. Currently, Teva cannot predict how the 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 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 January 2022, twenty-three 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. 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. Those motions are still pending. 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. On January 18, 2022, Teva entered into a settlement in the Ontario Teachers Securities Litigation for $420 million, which received final approval from the court on June 2, 2022. Pursuant to an agreement between the Company and its insurance carriers, the insurance carriers provided the vast majority of the total settlement amount, with a small portion contributed by Teva. Additionally, as part of the settlement, Teva admitted no liability and denied all allegations of wrongdoing. A number of "opt-out" complaints still remain outstanding, and 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.

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. On August 10, 2021, the lead plaintiff filed a corrected amended class action complaint, purportedly on behalf of persons who purchased or otherwise acquired Teva securities between October 29, 2015 and August 18, 2020. The corrected amended complaint alleges that Teva and certain of its current and 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 allegedly 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. The corrected amended complaint seeks unspecified damages and legal fees. On March 25, 2022, the court granted in part and denied in part Teva's and the individual defendants' motion to dismiss the corrected amended complaint, (i) holding that the plaintiffs' complaint failed to plead that certain public statements regarding Teva's compliance with the law were misleading, (ii) holding that two alleged partial corrective disclosures did not establish loss causation and cannot serve as the basis for plaintiff's claimed loss, (iii) dismissing all claims against one of the individual defendants, and (iv) otherwise denying the motion to dismiss. On August 2, 2022, the court stayed all proceedings other than class certification proceedings pending the resolution of the above-referenced August 2020 False Claims Act complaint filed by the DOJ. On September 13, 2022, the plaintiff moved for class certification, which remains pending. 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 seeking monetary damages against certain past and present directors and officers have been filed in Israeli Courts alleging negligence and recklessness. Motions for document disclosure prior to initiating derivative actions were filed with respect to several U.S. and EU settlement agreements, opioids, allegations related to the DOJ's complaint regarding COPAXONE patient assistance program in the U.S., and with respect to the COPAXONE European Commission's inspection. A motion for document disclosure prior to initiating derivative action with respect to the U.S. generic drug antitrust litigation matters was settled in October 2022.

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 disputed certain of the findings and the amount of the penalty and filed an appeal before the Supreme Court of India. On August 5, 2021, the Supreme Court of India admitted the appeal for hearing and granted an interim unconditional stay on the National Green Tribunal's order. The Company does not believe that the eventual outcome of such matter will have a material effect on its business.

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). On December 28, 2018, following defendants' motion to dismiss the complaint, the court granted the motion in part and dismissed all of plaintiffs' claims, except for their claim against Cephalon for breach of contract. In November 2021, plaintiffs moved to amend their complaint to, among other things, reassert claims against the Company and Teva USA. However, on July 12, 2022, plaintiffs filed a new amended complaint that includes claims against Teva USA but not the Company, in exchange for Teva USA's agreement to guarantee any judgment entered against Cephalon in the litigation. A bench trial for this matter was held in September 2022, and a ruling is expected in 2023, following post-trial briefing and closing arguments.

NOTE 11 – Income taxes:

In the third quarter of 2022, Teva recognized a tax expense of $107 million, on pre-tax income of $166 million. In the third quarter of 2021, Teva recognized a tax expense of $76 million, on pre-tax income of $382 million.

In the second quarter of 2022, one of Teva's U.S. subsidiaries was determined to be insolvent for tax purposes (i.e., its liabilities exceeded the fair market value of its assets), mainly in light of its accumulated operational losses. Consequently, Teva will recognize on its 2022 tax return, a worthless stock deduction of approximately $4.2 billion, with related tax benefit of approximately $850 million.

Teva's tax rate for the third quarter of 2022 was mainly affected by legal settlements, interest expense disallowances and adjustments to valuation allowances on deferred tax assets.

In the first nine months of 2022, Teva recognized a tax benefit of $792 million, on pre-tax loss of $1,964 million. In the first nine months of 2021, Teva recognized a tax expense of $235 million, on pre-tax income of $833 million.

Teva's tax rate for the first nine months of 2022 was mainly affected by the realization of losses related to its investment in one of its U.S. subsidiaries mentioned above, as well as impairments, legal settlements, interest expense disallowances and adjustments to valuation allowances on deferred tax assets.

The statutory Israeli corporate tax rate is 23% in 2022. 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, interest expense disallowances, 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. A trial for this case is currently scheduled to begin in November 2022. A final and binding decision against Teva in this case may lead to an impairment of $128 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.

In October 2021, the Central District Court in Israel held in favor of the Israeli tax authorities with respect to 2008-2011 decrees. The case with respect to 2012-2016 remains pending with similar legal claims. The October 2021 Central District Court decision found that Teva has a tax liability to the Israeli government for 2008-2011 of approximately $350 million, of which a portion is being paid in cash during 2022 and 2023, and the remaining portion is being offset by carried forward losses that Teva would otherwise be entitled to. Teva appealed the decision to the Israeli Supreme Court and expects the appeal hearings to begin in early 2023.

The Company believes it has adequately provided for all of its uncertain tax positions, including those items currently under dispute, however, adverse results could be material.

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
	(U.S. $ in millions)		(U.S. $ in millions)	
Impairments of long-lived tangible assets (1)	$ 4	$ 26	$ 34	$ 106
Contingent consideration	6	9	100	(7)
Restructuring	25	28	117	96
Other	1	(1)	31	32
Total	$ 36	$ 62	$ 282	$ 227

(1) Including impairments related to exit and disposal activities.

Impairments

Impairments of tangible assets for the three months ended September 30, 2022 and 2021 were $4 million and $26 million, respectively.

Impairments of tangible assets for the nine months ended September 30, 2022 and 2021 were $34 million and $106 million, respectively. The impairment for the nine months ended September 30, 2022 was mainly related to certain assets in North America. The impairment for the nine months ended September 30, 2021 was mainly related to certain assets in Europe and North America.

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 September 30, 2022, Teva recorded an expense of $6 million for contingent consideration, compared to an income of $9 million in the three months ended September 30, 2021.

In the nine months ended September 30, 2022, Teva recorded an expense of $100 million for contingent consideration, compared to an income of $7 million in the nine months ended September 30, 2021. The expense in the first nine months of 2022 was mainly related to changes in the estimated future royalty payments to Allergan in connection with lenalidomide (generic equivalent of Revlimid®), which was part of the Actavis Generics acquisition.

Restructuring

In the three months ended September 30, 2022, Teva recorded $25 million of restructuring expenses, compared to $28 million in the three months ended September 30, 2021. The expenses for the three months ended September 30, 2022 and September 30, 2021 were primarily related to network consolidation activities and residual expenses of the restructuring plan announced in 2017.

In the nine months ended September 30, 2022, Teva recorded $117 million of restructuring expenses, compared to $96 million in the nine months ended September 30, 2021. The expenses for the nine months ended September 30, 2022 and September 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 restructuring costs:

	Three months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
Restructuring		
Employee termination	$ 32	$ 24
Other	(7)	4
Total	$ 25	$ 28

	Nine months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
Restructuring		
Employee termination	$ 95	$ 84
Other	22	12
Total	$ 117	$ 96

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, 2022	$ (131)	$ (7)	$(138)
Provision	(95)	(22)	(117)
Utilization and other*	114	22	136
Balance as of September 30, 2022	$ (112)	$ (7)	$(119)

	Employee termination costs	Other	Total
	(U.S. $ in millions)		
Balance as of January 1, 2021	$ (115)	$ (7)	$(122)
Provision	(84)	(12)	(96)
Utilization and other*	78	12	90
Balance as of September 30, 2021	$ (121)	$ (7)	$(128)

* Includes adjustments for foreign currency translation.

Significant regulatory and other events

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 water supply remediation is expected to be completed during the fourth quarter of 2022, and in the meantime the site is operating under an interim water solution without any material impact expected on compliance and supply capacity. The impact to Teva's financial results for the three and nine months ended September 30, 2022 was immaterial.

In June 2021, the Company temporarily paused manufacturing at its Irvine, California facility in the United States, and suspended release of product from the facility pending completion of an open manufacturing investigation. In July 2021, the FDA initiated an establishment inspection at the facility. On August 18, 2021, the Company issued field alert reports to the FDA for products manufactured at the Irvine facility and put Irvine manufactured products in Teva's distribution center on hold. On August 20, 2021, the FDA completed its inspection and issued a Form FDA-483 to the Irvine facility with ten observations and, on December 17, 2021, the FDA notified the Company that the inspection classification of this site is "official action indicated" ("OAI"). Teva began working diligently to address the FDA's concerns in a manner consistent with current good manufacturing practice ("CGMP") requirements, and was in discussions with the FDA Drug Shortage Staff (DSS) and FDA Office of Manufacturing Quality (OMQ) to recommence distribution, release and manufacture of certain medically necessary products from the site under defined controls and protocols.

On March 22, 2022, the Company announced its decision to permanently cease all manufacturing activities and to close the site, and to transfer certain products to other facilities. Teva will remain in contact with FDA regarding the status of the Irvine, California site to ensure that the Company continues to comply with all relevant CGMP requirements, particularly those involved with product transfers to other sites within the Teva network.

If Teva is unable to address FDA inspection issues satisfactorily, it could be subject to additional regulatory actions. Teva has considered these developments and, during the nine months ended September 30, 2022, recorded $90 million costs in its financial statements related to this matter. Teva will continue to assess potential financial implications, including loss of revenues, impairments, inventory write offs, customer penalties, 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 income (loss) attributable to Teva's ordinary shareholders by the weighted average number of ordinary shares outstanding, including fully vested restricted share units ("RSUs") and performance share units ("PSUs") during the period, net of treasury shares.

In computing diluted earnings per share for the three months ended September 30, 2022 and 2021, 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 and PSUs 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 loss per share for the nine months ended September 30, 2022, no account was taken of the potential dilution that could occur upon the exercise of options and non-vested RSUs and PSUs granted under employee stock compensation plans, and convertible senior debentures, since they had an anti-dilutive effect on loss per share.

In computing diluted earnings per share for the nine months ended September 30, 2021, 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 and PSUs 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.

The weighted average diluted shares outstanding used for the fully diluted share calculations for the three months ended September 30, 2022, and 2021, were 1,119 million and 1,109 million shares, respectively.

The weighted average diluted shares outstanding used for the fully diluted share calculations for the nine months ended September 30, 2022, and 2021, were each 1,109 million shares.

Basic and diluted earnings per share were $0.05 for the three months ended September 30, 2022, compared to basic and diluted earnings per share of $0.26 for the three months ended September 30, 2021. Basic and diluted loss per share was $1.02 for the nine months ended September 30, 2022, compared to basic and diluted earnings per share of $0.52 for the nine months ended September 30, 2021.

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, 2021, net of taxes	$ (2,274)	$ (324)	$ (85)	$(2,683)
Other comprehensive income (loss) before reclassifications	(438)	—	—	(438)
Amounts reclassified to the statements of income	—	21	—	21
Net other comprehensive income (loss) before tax	(438)	21	—	(417)
Corresponding income tax	(53)	—	—	(53)
Net other comprehensive income (loss) after tax*	(491)	21	—	(470)
Balance as of September 30, 2022, net of taxes	$ (2,765)	$ (303)	$ (85)	$(3,153)

* Amounts do not include a $193 million loss from foreign currency translation adjustments attributable to non-controlling interests.

	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	(270)	—	—	(270)
Amounts reclassified to the statements of income	—	27	2	29
Net other comprehensive income (loss) before tax	(270)	27	2	(241)
Corresponding income tax	26	(6)	—	20
Net other comprehensive income (loss) after tax*	(244)	21	2	(221)
Balance as of September 30, 2021, net of taxes	$ (2,163)	$ (342)	$ (115)	$(2,620)

* Amounts do not include an $81 million loss 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, the United Kingdom 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.

a. Segment information:

	Three months ended September 30, 2022		
	North America	Europe	International Markets
	(U.S. $ in millions)		
Revenues	$ 1,809	$1,069	$ 475
Gross profit	942	634	252
R&D expenses	111	44	15
S&M expenses	232	169	97
G&A expenses	122	61	30
Other income	§	§	(2)
Segment profit	$ 477	$ 360	$ 112

§ Represents an amount less than $0.5 million.

	Three months ended September 30, 2021		
	North America	Europe	International Markets
		(U.S. $ in millions)	
Revenues	$ 1,875	$1,220	$ 530
Gross profit	967	714	296
R&D expenses	146	55	16
S&M expenses	250	204	102
G&A expenses	121	64	29
Other income	(7)	(2)	(2)
Segment profit	$ 458	$ 394	$ 152

	Nine months ended September 30, 2022		
	North America	Europe	International Markets
		(U.S. $ in millions)	
Revenues	$ 5,450	$3,396	$ 1,422
Gross profit	2,841	2,031	780
R&D expenses	401	157	54
S&M expenses	733	561	293
G&A expenses	361	183	89
Other income	(12)	(1)	(43)
Segment profit	$ 1,359	$1,130	$ 386

	Nine months ended September 30, 2021		
	North America	Europe	International Markets
		(U.S. $ in millions)	
Revenues	$ 5,807	$3,618	$ 1,505
Gross profit	3,081	2,063	826
R&D expenses	467	184	51
S&M expenses	734	628	303
G&A expenses	338	180	79
Other income	(14)	(3)	(5)
Segment profit	$ 1,556	$1,074	$ 398

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 nine months ended September 30, 2022 and 2021:

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
	(U.S. $ in millions)		(U.S. $ in millions)	
North America profit	$ 477	$ 458	$ 1,359	$1,556
Europe profit	360	394	1,130	1,074
International Markets profit	112	152	386	398
Total reportable segments profit	949	1,004	2,875	3,028
Profit of other activities	29	38	135	125
Total segments profit	977	1,042	3,010	3,153
Amounts not allocated to segments:				
Amortization	165	199	576	613
Other assets impairments, restructuring and other items	36	62	282	227
Goodwill impairment	—	—	745	—
Intangible assets impairments	24	21	223	295
Legal settlements and loss contingencies	195	3	2,048	113
Other unallocated amounts	139	134	379	266
Consolidated operating income (loss)	419	623	(1,244)	1,638
Financial expenses, net	252	241	721	805
Consolidated income (loss) before income taxes	$ 166	$ 382	$(1,964)	$ 833

b. Segment revenues by major products and activities:

The following tables present revenues by major products and activities for the three and nine months ended September 30, 2022 and 2021:

North America	Three months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
Generic products	$ 806	$ 859
AJOVY	57	46
AUSTEDO	260	201
BENDEKA®/TREANDA®	77	95
COPAXONE	105	133
Anda	371	363
Other	133	178
Total	$ 1,809	$ 1,875

North America	Nine months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
Generic products	$ 2,731	$ 2,864
AJOVY	142	123
AUSTEDO	618	520
BENDEKA/TREANDA	241	292
COPAXONE	285	448
Anda	1,021	968
Other	411	592
Total	$ 5,450	$ 5,807

Europe	Three months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
Generic products	$ 803	$ 895
AJOVY	30	23
COPAXONE	63	95
Respiratory products	62	85
Other	111	122
Total	$ 1,069	$ 1,220

Europe	Nine months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
Generic products	$2,552	$2,637
AJOVY	90	58
COPAXONE	207	296
Respiratory products	198	263
Other	349	364
Total	$3,396	$3,618

International markets	Three months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
Generic products	$ 393	$ 412
AJOVY	6	39
COPAXONE	9	10
Other	67	69
Total	$ 475	$ 530

International markets	Nine months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
Generic products	$1,175	$1,211
AJOVY	22	46
COPAXONE	29	29
Other	195	219
Total	$1,422	$1,505

NOTE 16 – Fair value measurement:

Financial items carried at fair value on a recurring basis as of September 30, 2022 and December 31, 2021 are classified in the tables below in one of the three categories of fair value levels:

	September 30, 2022			
	Level 1	Level 2	Level 3	Total
	(U.S. $ in millions)			
Cash and cash equivalents:				
Money markets	$ 897	$ —	$ —	$ 897
Cash, deposits and other	1,328	—	—	1,328
Investment in securities:				
Equity securities	9	—	—	9
Other	5	—	1	6
Restricted cash	33	—	—	33
Derivatives:				
Asset derivatives—options and forward contracts	—	94	—	94
Liability derivatives:				
Options and forward contracts	—	(53)	—	(53)
Bifurcated embedded derivatives	—	—	§	—
Contingent consideration*	—	—	(113)	(113)
Total	$2,272	$ 41	$ (112)	$2,201

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
	(U.S. $ in millions)			
Cash and cash equivalents:				
Money markets	$ 220	$ —	$ —	$ 220
Cash, deposits and other	1,945	—	—	1,945
Investment in securities:				
Equity securities	18	—	—	18
Other	6	—	1	7
Restricted cash	33	—	—	33
Derivatives:				
Asset derivatives—options and forward contracts	—	30	—	30
Liability derivatives:				
Options and forward contracts	—	(23)	—	(23)
Bifurcated embedded derivatives	—	—	§	—
Contingent consideration*	—	—	(176)	(176)
Total	$ 2,222	$ 7	$ (175)	$2,054

§ Represents an amount less than $0.5 million.
* 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

of 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 8.5% to 11.2%. The weighted average discount rate, calculated based on the relative fair value of Teva's contingent consideration liabilities, was 8.9%. 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.

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

	Nine months ended September 30, 2022	Nine months ended September 30, 2021
	(U.S. $ in millions)	
Fair value at the beginning of the period	$ (175)	(258)
Redemption of debt securities	—	(9)
Bifurcated embedded derivatives	§	—
Adjustments to provisions for contingent consideration:		
Actavis Generics transaction	(98)	21
Eagle transaction	(2)	(14)
Settlement of contingent consideration:		
Actavis Generics transaction	106	—
Eagle transaction	68	74
Additional contingent consideration resulting from Novetide acquisition*	(11)	—
Fair value at the end of the period	$ (112)	$ (186)

§ Represents an amount less than $0.5 million.

* In January 2022, Teva acquired 100% ownership of Novetide Ltd. ("Novetide"), which was previously accounted for as "investment in associated companies". This transaction was accounted for as a business combination. Total consideration for the transaction included cash and certain contingent royalty payments through 2034. As part of the transaction, Teva recognized a gain under "Share in (profits) losses of associated companies, net", reflecting the difference between the book value of its investment in Novetide and its fair value as of the date Teva completed its acquisition.

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*	
	September 30, 2022	December 31, 2021
	(U.S. $ in millions)	
Senior notes and sustainability-linked senior notes included under senior notes and loans	$ 15,552	$ 21,477
Senior notes and convertible senior debentures included under short-term debt	2,710	1,426
Total	$ 18,262	$ 22,903

* 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.

Macroeconomic Environment

In recent months, the global economy has been impacted by fluctuating foreign exchange rates. Approximately 47% of our revenues are denominated in currencies other than the U.S. dollar. The strengthening of the U.S. dollar versus other currencies in which we operate, negatively impacts our revenues, results of operations, profits and cash flows. We also manufacture largely outside of the United States, which may to varying degrees result in lower expenses. Additionally, high levels of inflation have recently resulted in significant economic volatility and monetary tightening by central banks. The global economy has also been impacted by the ongoing conflict between Russia and Ukraine, which has spurred rising energy costs and caused disruptions to the global supply chain. Supply chain disruptions and rising energy costs could result in delays in our production and distribution processes, R&D initiatives and our ability to timely respond to consumer demand. See also discussion under "—International Markets segment" below.

We have implemented certain measures in response to such macroeconomic pressures and are continually considering various initiatives, including price adjustments, to allow us to mitigate and offset the impact of these macro-economic factors. However, although inflationary and other macroeconomic pressures may ease, the higher costs we have experienced during the recent period have already impacted our operations and will likely continue to have an effect on our financial results.

Highlights

Significant highlights in the third quarter of 2022 included:

- Revenues in the third quarter of 2022 were $3,595 million, a decrease of 8% in U.S. dollars, or 2% in local currency terms, compared to the third quarter of 2021. This decrease in local currency terms was mainly due to lower revenues from generic products in our North America segment, COPAXONE in our North America and Europe segments, and BENDEKA and TREANDA in our North America segment, partially offset by higher revenues from AUSTEDO in our North America segment and generic products in our Europe segment.
- Our North America segment generated revenues of $1,809 million and profit of $477 million in the third quarter of 2022. Revenues decreased by 4% compared to the third quarter of 2021. Profit increased by 4% compared to the third quarter of 2021.
- Our Europe segment generated revenues of $1,069 million and profit of $360 million in the third quarter of 2022. Revenues decreased by 12% in U.S. dollars, but increased by 1% in local currency terms compared to the third quarter of 2021. Profit decreased by 8% compared to the third quarter of 2021.

- Our International Markets segment generated revenues of $475 million and profit of $112 million in the third quarter of 2022. Revenues decreased by 10% in U.S. dollars, or 3% in local currency terms, compared to the third quarter of 2021. Profit decreased by 27% compared to the third quarter of 2021.
- Our revenues from other activities in the third quarter of 2022 were $241 million, a decrease of 8% in U.S. dollars, or 3% in local currency terms, compared to the third quarter of 2021.
- Exchange rate movements during the third quarter of 2022, net of hedging effects, negatively impacted overall revenues by $215 million and operating income by $53 million, compared to the third quarter of 2021.
- Impairments of identifiable intangible assets were $24 million in the third quarter of 2022, compared to $21 million in the third quarter of 2021. See note 5 to our consolidated financial statements.
- We recorded expenses of $36 million for other asset impairments, restructuring and other items in the third quarter of 2022, compared to expenses of $62 million in the third quarter of 2021. See note 12 to our consolidated financial statements.
- Legal settlements and loss contingencies expenses were $195 million in the third quarter of 2022, compared to $3 million in the third quarter of 2021. See note 9 to our consolidated financial statements.
- Operating income was $419 million in the third quarter of 2022, compared to an operating income of $623 million in the third quarter of 2021.
- Financial expenses were $252 million in the third quarter of 2022, compared to $241 million in the third quarter of 2021.
- In the third quarter of 2022, we recognized a tax expense of $107 million, on pre-tax income of $166 million. In the third quarter of 2021, we recognized a tax expense of $76 million, on pre-tax income of $382 million. See note 11 to our consolidated financial statements.
- As of September 30, 2022, our debt was $21,266 million, compared to $23,043 million as of December 31, 2021. This decrease was mainly due to $1,139 million from exchange rate fluctuations and $661 million senior notes repaid at maturity.
- Cash flow generated from operating activities during the third quarter of 2022 was $543 million, compared to $529 million in the third quarter of 2021. The increase in the third quarter of 2022 resulted mainly from changes in the deferred purchase price under our securitization agreement, partially offset by changes in working capital items, primarily a lower reduction in our inventory levels compared to the third quarter of 2021.
- During the third quarter of 2022, we generated free cash flow of $685 million, which we define as comprising: $543 million in cash flow generated from operating activities, $262 million in beneficial interest collected in exchange for securitized accounts receivables and $2 million in proceeds from divestitures of businesses and other assets, partially offset by $122 million in cash used for capital investment. During the third quarter of 2021, we generated free cash flow of $795 million. The decrease in the third quarter of 2022 resulted mainly from changes in working capital items, primarily a lower reduction in our inventory levels compared to the third quarter of 2021.

Results of Operations

Comparison of Three Months Ended September 30, 2022 to Three Months Ended September 30, 2021

Segment Information

North America Segment

The following table presents revenues, expenses and profit for our North America segment for the three months ended September 30, 2022 and 2021:

	Three months ended September 30,			
	2022		2021	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 1,809	100%	$ 1,875	100%
Gross profit	942	52.1%	967	51.6%
R&D expenses	111	6.1%	146	7.8%
S&M expenses	232	12.8%	250	13.3%
G&A expenses	122	6.8%	121	6.4%
Other income	§	§	(7)	§
Segment profit*	$ 477	26.3%	$ 458	24.4%

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

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

North America Revenues

Our North America segment includes the United States and Canada. Revenues from our North America segment in the third quarter of 2022 were $1,809 million, a decrease of $66 million, or 4%, compared to the third quarter of 2021, mainly due to a decrease in revenues from generic products, COPAXONE and BENDEKA and TREANDA, partially offset by higher revenues from AUSTEDO.

On October 1, 2022, we discontinued marketing ProAir® HFA, while focusing our marketing efforts on albuterol sulfate inhalation aerosol (our ProAir authorized generic) and ProAir Digihaler® (albuterol sulfate 117 mcg). ProAir HFA and ProAir Digihaler results are included in “Other” in the revenues table below and were not material during the third quarter of 2022.

Revenues by Major Products and Activities

The following table presents revenues for our North America segment by major products and activities for the three months ended September 30, 2022 and 2021:

	Three months ended September 30,		Percentage Change
	2022	2021	2022-2021
	(U.S. $ in millions)		
Generic products	$ 806	$ 859	(6%)
AJOVY	57	46	23%
AUSTEDO	260	201	30%
BENDEKA/TREANDA	77	95	(20%)
COPAXONE	105	133	(21%)
Anda	371	363	2%
Other	133	178	(25%)
Total	$1,809	$1,875	(4%)

Generic products revenues in our North America segment (including biosimilars) in the third quarter of 2022 were $806 million, a decrease of 6% compared to the third quarter of 2021, mainly due to increased competition.

Among the most significant generic products we sold in North America in the third quarter of 2022 were epinephrine injectable solution (the generic equivalent of EpiPen® and EpiPen Jr.®), Truxima® (the biosimilar to Rituxan®), and albuterol sulfate inhalation aerosol (our ProAir authorized generic).

In the third quarter of 2022, our total prescriptions were approximately 303 million (based on trailing twelve months), representing 8.2% of total U.S. generic prescriptions according to IQVIA data.

AJOVY revenues in our North America segment in the third quarter of 2022 increased by 23% to $57 million, compared to the third quarter of 2021, mainly due to growth in volume. In the third quarter of 2022, AJOVY's exit market share in the United States in terms of total number of prescriptions was 25% compared to 21% in the third quarter of 2021.

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 between 2035 and 2039. 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 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 inter partes review ("IPR") petitions to the Patent Trial and Appeal Board ("PTAB"), challenging the validity of the nine patents asserted against it in the litigation. The litigation in the district court was stayed pending resolution of the IPR petitions. On February 18, 2020, the PTAB issued decisions on the first six IPRs, finding the six composition of matter patents invalid as being obvious. On March 31, 2020, the PTAB issued a decision upholding the three method of treatment patents. On August 16, 2021 the Court of Appeals for the Federal Circuit affirmed all of the PTAB's decisions. On October 3, 2022, the Massachusetts District Court issued an opinion resolving several motions for summary judgement brought by both Teva and Lilly. The Court denied Lilly's motions to invalidate all three of Teva's method of treatment patents, granted Lilly's motion of non-infringement on two of the twenty asserted claims, and denied Teva's motions to estop Lilly from making certain arguments at trial and to dismiss Lilly's allegations that Teva's patents are not enforceable. Trial for this case opened on October 18, 2022, and is expected to be completed by November 10, 2022.

We also filed another suit against Lilly on June 8, 2021, asserting two patents recently granted to Teva, related to the treatment of refractory migraine. On March 15, 2022, the U.S. District Court for the District of Massachusetts denied Lilly's motion to dismiss and on March 23, 2022, Lilly submitted IPR petitions challenging the patentability of the two refractory migraine patents, followed by another IPR submitted on April 11, 2022 challenging the patentability of a patent related to the two refractory migraine patents. On September 28, 2022, the U.S. Patent and Trademark Office issued decisions to institute a full trial on the validity of two of the three refractory patents, and instituted a full trial on the third patent on October 14, 2022. 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 third quarter of 2022 increased by 30%, to $260 million, compared to $201 million in the third quarter of 2021, 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 eight Orange Book patents expiring between 2031 and 2038 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 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. The seventh patent was issued in November 2021, and listed in the Orange Book in December 2021. In addition,

Apotex filed a petition for IPR by the PTAB of the patent covering the deutetrabenazine compound that expires in 2031. On March 9, 2022, the U.S. Patent and Trademark Office denied Apotex's petition and declined to institute a review of the deutetrabenazine patent. On April 29, 2022 and June 8, 2022, we reached agreements with Lupin and Aurobindo, respectively, to resolve the abovementioned disputes over Lupin's and Aurobindo's ANDAs for a generic deutetrabenazine product. Under the terms of the settlement agreements, the litigation between the parties in the U.S. District Court for the District of New Jersey have been ended, and Lupin and Aurobindo will have a license to sell their generic products beginning April 2033, or earlier under certain circumstances. There are no further patent litigations pending regarding AUSTEDO.

BENDEKA and **TREANDA** combined revenues in our North America segment in the third quarter of 2022 decreased by 20% to $77 million, compared to the third quarter of 2021, mainly due to the availability of alternative therapies and intense competition in anticipation of the orphan drug exclusivity expiration in December 2022, as discussed below.

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 16 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 U.S. 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 appealed the district court decision. Teva settled with one of the three ANDA filers, and on August 13, 2021, the Federal Circuit issued a Rule 36 affirmance of the district court decision with respect to the other two filers. On December 14, 2021, Apotex filed a Petition for a Writ of Certiorari with the U.S. Supreme Court, which was denied. Litigation against the fifth ANDA filer was dismissed after the withdrawal of its patent challenge, and the case against a sixth ANDA filer was also settled. Suits against two filers of 505(b)(2) NDAs referencing BENDEKA are pending.

Additionally, in July 2018, Teva and Eagle filed suit against Hospira, Inc. ("Hospira") related to its 505(b)(2) NDA referencing BENDEKA in the U.S. District Court for the District of Delaware. On December 16, 2019, the district court dismissed the case against Hospira on all but one of the asserted patents, which expires in 2031. On April 18, 2022, Teva and Eagle settled this matter, allowing Hospira to launch its product on January 17, 2028 or earlier under certain circumstances. A trial against two additional 505(b)(2) NDA filers, Doctor Reddy's and Accord, is set to begin in April 2023.

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.

COPAXONE revenues in our North America segment in the third quarter of 2022 decreased by 21% to $105 million, compared to the third quarter of 2021, mainly due to generic competition in the United States and a decrease in glatiramer acetate market share due to availability of alternative therapies.

The market for MS treatments continues to develop, particularly with the approval of generic versions of COPAXONE. 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® and Kesimpta®.

Anda revenues in our North America segment in the third quarter of 2022 increased by 2% to $371 million, compared to $363 million in the third quarter of 2021, mainly due to higher demand. Anda, our distribution business in the United States, distributes generic, specialty and OTC pharmaceutical products from various third party manufacturers to independent retail pharmacies, pharmacy retail chains, hospitals and physician offices in the United States. Anda is able to compete in the secondary distribution market by maintaining high inventory levels for a broad offering of products, competitive pricing and offering next day delivery throughout the United States.

Product Launches and Pipeline

In the third quarter of 2022, 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))*
Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg and 300 mcg	Synthroid® tablets	September	$ 2,035
Tacrolimus Ointment	Protopic® Ointment	September	$ 79.9
Pantoprazole Sodium for Injection	Protonix® I.V. for Injection	September	$ 76.5
Mycophenolate Mofetil Tablets 500mg	CellCept® Tablets	September	$ 67.8
Nitrofurantoin Capsules, USP (Monohydrate/Macrocrystals) 100mg	Macrobid®	September	$ 54.5
Icosapent Ethyl Capsules 500mg	Vascepa® Capsules	September	$ 21.1

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

Our generic products pipeline in the United States includes, as of September 30, 2022, 173 product applications awaiting FDA approval, including 69 tentative approvals. This total reflects all pending ANDAs, supplements for product line extensions and tentatively approved applications and includes some instances where more than one application was submitted for the same reference product. Excluding overlaps, the branded products underlying these pending applications had U.S. sales for the twelve months ended June 30, 2022 of approximately $108 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 72 of these products, or 99 products including final approvals where launch is pending a settlement agreement or court decision. Collectively, these first to file opportunities represent over $79 billion in U.S. brand sales for the twelve months ended June 30, 2022, according to IQVIA.

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

In the third quarter of 2022, we received tentative approvals for generic equivalents of the products listed in the table below, excluding overlapping applications. A "tentative approval" indicates that the FDA has substantially completed its review of an application and final approval is expected once the relevant patent expires, a court decision is reached, a 30-month regulatory stay lapses or a 180-day exclusivity period awarded to another manufacturer either expires or is forfeited.

Generic Name	Brand Name	Total Annual U.S. Branded Sales at Time of Launch (U.S. $ in millions (IQVIA))*
Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg	Sprycel®	$ 1,569
Dapagliflozin/ Metformin Tablets	Xigduo XR®	$ 560
Paclitaxel Protein-Bound Particles for Injectable Suspension, 100 mg/vial **	N/A	No Data

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

** Teva's Paclitaxel is a 505(b)(2) product, was filed as an NDA and is not bioequivalent to a brand product.

For information regarding our specialty and biosimilar products pipeline, see "—Teva Consolidated Results—Research and Development (R&D) Expenses" below.

North America Gross Profit

Gross profit from our North America segment in the third quarter of 2022 was $942 million, a decrease of 3%, compared to $967 million in the third quarter of 2021.

Gross profit margin for our North America segment in the third quarter of 2022 increased to 52.1%, compared to 51.6% in the third quarter of 2021. This increase was mainly due to a favorable change in the mix of products.

North America R&D Expenses

R&D expenses relating to our North America segment in the third quarter of 2022 were $111 million, a decrease of 24%, compared to $146 million in the third quarter of 2021.

For a description of our R&D expenses in the third quarter of 2022, see "—Teva Consolidated Results—Research and Development (R&D) Expenses" below.

North America S&M Expenses

S&M expenses relating to our North America segment in the third quarter of 2022 were $232 million, a decrease of 7%, compared to $250 million in the third quarter of 2021, mainly due to cost efficiencies.

North America G&A Expenses

G&A expenses relating to our North America segment in the third quarter of 2022 were $122 million, an increase of 1% compared to $121 million in the third quarter of 2021.

North America Profit

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

Profit from our North America segment in the third quarter of 2022 was $477 million, an increase of 4% compared to $458 million in the third quarter of 2021, mainly due to a favorable change in the mix of products, cost efficiencies and lower R&D expenses, as discussed above.

Europe Segment

The following table presents revenues, expenses and profit for our Europe segment for the three months ended September 30, 2022 and 2021:

	Three months ended September 30,			
	2022		2021	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 1,069	100%	$ 1,220	100%
Gross profit	634	59.3%	714	58.6%
R&D expenses	44	4.1%	55	4.5%
S&M expenses	169	15.8%	204	16.7%
G&A expenses	61	5.7%	64	5.2%
Other income	§	§	(2)	§
Segment profit*	$ 360	33.7%	$ 394	32.3%

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

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

Europe Revenues

Our Europe segment includes the European Union, the United Kingdom and certain other European countries. Revenues from our Europe segment in the third quarter of 2022 were $1,069 million, a decrease of 12%, or $151 million, compared to the third quarter of 2021. In local currency terms, revenues increased by 1%, mainly due to higher demand for generic products, together with higher revenues from generic product launches.

In the third quarter of 2022, revenues were negatively impacted by exchange rate fluctuations of $162 million, net of hedging effects, compared to the third quarter of 2021. Revenues in the third quarter of 2022 included $24 million from a positive hedging impact, which is included in "Other" in the table below. See note 8d to our consolidated financial statements.

Revenues by Major Products and Activities

The following table presents revenues for our Europe segment by major products and activities for the three months ended September 30, 2022 and 2021:

	Three months ended September 30,		Percentage Change
	2022	2021	2022-2021
	(U.S. $ in millions)		
Generic products	$ 803	$ 895	(10%)
AJOVY	30	23	31%
COPAXONE	63	95	(34%)
Respiratory products	62	85	(27%)
Other	111	122	(9%)
Total	$ 1,069	$ 1,220	(12%)

Generic products revenues (including OTC and biosimilar products) in our Europe segment in the third quarter of 2022, decreased by 10% to $803 million, compared to the third quarter of 2021. In local currency terms, revenues increased by 5%, mainly due to higher demand for generic and OTC products, together with higher revenues from generic product launches.

On August 29, 2022 the European Commission granted a marketing authorization for Ranivisio® (ranibizumab), a biosimilar to Lucentis®, across all five indications in adults for which Lucentis® is authorized, including age-related macular degeneration (AMD) and four other ophthalmology indications.

AJOVY revenues in our Europe segment in the third quarter of 2022 increased to $30 million, compared to $23 million in the third quarter of 2021, mainly due to growth in European countries in which AJOVY had previously been launched, as well as launches and reimbursements in additional 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 third quarter of 2022 decreased by 34% to $63 million, compared to the third quarter of 2021. In local currency terms, revenues decreased by 23%, due to price reductions and a decline in volume resulting from competing glatiramer acetate products.

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 were found invalid at the European Patent Office in December 2021. 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 third quarter of 2022 decreased by 27% to $62 million compared to the third quarter of 2021. In local currency terms, revenues decreased by 15%, mainly due to net price reductions and lower volumes.

Product Launches and Pipeline

As of September 30, 2022, our generic products pipeline in Europe included 588 generic approvals relating to 72 compounds in 155 formulations, with no European Medicines Agency ("EMA") approvals received. In addition, approximately 1,199 marketing authorization applications are pending approval in 37 European countries, relating to 110 compounds in 220 formulations. Two applications are pending with the EMA with one application relating to two strengths in 30 markets and one application relating to three strengths in 30 markets.

For information regarding our specialty and biosimilar products pipeline, see "—Teva Consolidated Results—Research and Development (R&D) Expenses" below.

Europe Gross Profit

Gross profit from our Europe segment in the third quarter of 2022 was $634 million, a decrease of 11% compared to $714 million in the third quarter of 2021, mainly due to exchange rate fluctuations.

Gross profit margin for our Europe segment in the third quarter of 2022 increased to 59.3%, compared to 58.6% in the third quarter of 2021. This increase was mainly due to higher revenues from the positive impact of hedging activities discussed above, as well as lower cost of goods sold, mainly due to a better mix of products and decrease in write-offs.

Europe R&D Expenses

R&D expenses relating to our Europe segment in the third quarter of 2022 were $44 million, a decrease of 21% compared to $55 million in the third quarter of 2021.

For a description of our R&D expenses in the third quarter of 2022, see "—Teva Consolidated Results—Research and Development (R&D) Expenses" below.

Europe S&M Expenses

S&M expenses relating to our Europe segment in the third quarter of 2022 were $169 million, a decrease of 17% compared to $204 million in the third quarter of 2021. This decrease was mainly due to exchange rate fluctuations and cost efficiencies in the third quarter of 2022.

Europe G&A Expenses

G&A expenses relating to our Europe segment in the third quarter of 2022 were $61 million, a decrease of 4% compared to $64 million in the third quarter of 2021.

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 third quarter of 2022 was $360 million, a decrease of 8%, compared to $394 million in the third quarter of 2021. This decrease was mainly due to exchange rate fluctuations.

International Markets Segment

The following table presents revenues, expenses and profit for our International Markets segment for the three months ended September 30, 2022 and 2021:

	Three months ended September 30,			
	2022		2021	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 475	100%	$ 530	100%
Gross profit	252	53.0%	296	55.9%
R&D expenses	15	3.2%	16	3.0%
S&M expenses	97	20.5%	102	19.2%
G&A expenses	30	6.2%	29	5.4%
Other income	(2)	§	(2)	§
Segment profit*	$ 112	23.5%	$ 152	28.8%

* 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. 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.

In February 2022, Russia launched an invasion of Ukraine. As of the date of this Quarterly Report on Form 10-Q, sustained conflict and disruption in the region is ongoing. Russia and Ukraine markets are included in our International Markets segment results. We have no manufacturing or R&D facilities in these markets. During the three and nine months ended September 30, 2022, the impact of this conflict on our International Markets segment's results of operations and financial condition was immaterial. Consistent with our foreign exchange risk management hedging programs, we entered into hedges to hedge our exposure to currency exchange rate fluctuations with respect to our balance sheet assets, revenues and expenses. However, as of the end of the third quarter of 2022, we were unable to renew certain of our expiring hedging positions due to the liquidity situation in the market for Russian rubles. Prior to and since the escalation of the conflict, we have been taking measures to reduce our operational cash balances in Russia and Ukraine. We have been monitoring the solvency of our customers in Russia and Ukraine and have taken measures, where practicable, to mitigate our exposure to risks related to the conflict in the region. However, the duration, severity and global implications (including potential inflation and devaluation consequences) of the conflict cannot be predicted at this time and could have an effect on our business, including on our exchange rate exposure, supply chain, operational costs and commercial presence in these markets.

Revenues from our International Markets segment in the third quarter of 2022 were $475 million, a decrease of 10% in U.S. dollars, or 3% in local currency terms, compared to the third quarter of 2021. Revenues in the third quarter of 2021 included a milestone payment of $35 million received from Otsuka related to the launch of AJOVY in Japan.

In the third quarter of 2022, revenues were negatively impacted by exchange rate fluctuations of $38 million, net of hedging effects, compared to the third quarter of 2021. Revenues in the third quarter of 2022 included a positive hedging impact of $4 million, which is included in "Other" in the table below. See note 8d 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 three months ended September 30, 2022 and 2021:

	Three months ended September 30,		Percentage Change
	2022	2021	2022-2021
	(U.S. $ in millions)		
Generic products	$ 393	$ 412	(5%)
AJOVY	6	39	(85%)
COPAXONE	9	10	(4%)
Other	67	69	(2%)
Total	$ 475	$ 530	(10%)

Generic products revenues in our International Markets segment in the third quarter of 2022, which include OTC products, decreased by 5% in U.S. dollars to $393 million. In local currency terms, revenues increased by 3% compared to the third quarter of 2021. This increase was mainly due to higher revenues in certain markets, as well as price increases largely as a result of rising costs due to inflationary pressure, partially offset by lower sales in Japan due to regulatory price reductions and generic competition to off-patented products in Japan.

AJOVY was launched in certain markets in our International Markets segment, including in Japan in August 2021. We are moving forward with plans to launch AJOVY in other markets. AJOVY revenues in our International Markets segment in the third quarter of 2022 were $6 million, compared to $39 million in the third quarter of 2021. Revenues in the third quarter of 2021 included a milestone payment of $35 million received from Otsuka related to the launch of AJOVY in Japan.

COPAXONE revenues in our International Markets segment in the third quarter of 2022 were $9 million compared to $10 million in the third quarter of 2021.

AUSTEDO was launched in early 2021 in China for the treatment of chorea associated with Huntington's disease and for the treatment of tardive dyskinesia, and was also launched in Israel during 2021. During the third quarter of 2022, AUSTEDO was launched in Brazil. We continue with additional submissions in various other markets.

International Markets Gross Profit

Gross profit from our International Markets segment in the third quarter of 2022 was $252 million, a decrease of 15% compared to $296 million in the third quarter of 2021.

Gross profit margin for our International Markets segment in the third quarter of 2022 decreased to 53.0%, compared to 55.9% in the third quarter of 2021. This decrease was mainly due to the impact of a milestone payment of $35 million related to AJOVY in the third quarter of 2021 as mentioned above, as well as regulatory price reductions and generic competition to off-patented products in Japan in the third quarter of 2022, partially offset by price increases largely as a result of rising costs due to inflationary pressure.

International Markets R&D Expenses

R&D expenses relating to our International Markets segment in the third quarter of 2022 were $15 million, a decrease of 3% compared to $16 million in the third quarter of 2021.

For a description of our R&D expenses in the third quarter of 2022, see "—Teva Consolidated Results—Research and Development (R&D) Expenses" below.

International Markets S&M Expenses

S&M expenses relating to our International Markets segment in the third quarter of 2022 were $97 million, a decrease of 4% compared to $102 million in the third quarter of 2021.

International Markets G&A Expenses

G&A expenses relating to our International Markets segment in the third quarter of 2022 were $30 million, an increase of 3% compared to $29 million in the third quarter of 2021.

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 third quarter of 2022 was $112 million, a decrease of 27%, compared to $152 million in the third quarter of 2021. This decrease was mainly due to lower 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 third quarter of 2022 were $241 million, a decrease of 8% compared to the third quarter of 2021. In local currency terms, revenues decreased by 3%.

API sales to third parties in the third quarter of 2022 were $149 million, a decrease of 7% in both U.S. dollars and local currency terms compared to the third quarter of 2021.

Teva Consolidated Results

Revenues

Revenues in the third quarter of 2022 were $3,595 million, a decrease of 8% compared to the third quarter of 2021. In local currency terms, revenues decreased by 2%, mainly due to a decrease in revenues from generic products in our North America segment, COPAXONE in our North America and Europe segments, and BENDEKA and TREANDA in our North America segment, partially offset by higher revenues from AUSTEDO in our North America segment and generic products in our Europe segment. See "—North America Revenues," "—Europe Revenues," "—International Markets Revenues" and "—Other Activities" above.

Exchange rate movements during the third quarter of 2022, net of hedging effects, negatively impacted revenues by $215 million, compared to the third quarter of 2021. See note 8d to our consolidated financial statements.

Gross Profit

Gross profit in the third quarter of 2022 was $1,669 million, a decrease of 7% compared to the third quarter of 2021.

Gross profit margin was 46.4% in the third quarter of 2022, compared to 46.2% in the third quarter of 2021. This increase was mainly driven by higher revenues from AUSTEDO, a favorable mix of generic products in our Europe segment, and higher revenues from the positive impact of hedging activities, partially offset mainly by higher operational costs due to macroeconomic headwinds and lower revenues from 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 third quarter of 2022 were $175 million, a decrease of 21% compared to $222 million in the third quarter of 2021.

In the third quarter of 2022, our R&D expenses related primarily to specialty product candidates in neuroscience (such as migraine, movement disorders/ neurodegeneration and neuropsychiatry, including post-approval commitments), immunology (such as respiratory medicines) and selected other areas, as well as generic products and biosimilars.

Our lower R&D expenses in the third quarter of 2022, compared to the third quarter of 2021, were mainly due to a decrease in neuroscience (in the pain and migraine and headache therapeutic areas) and immunology (in the respiratory therapeutic area) as well as various generics projects, and an adjustment in payments pursuant to a contract with one of our R&D partners in the third quarter of 2022, partially offset by higher R&D expenses related to our biosimilar products pipeline.

R&D expenses as a percentage of revenues were 4.9% in the third quarter of 2022, compared to 5.7% in the third quarter of 2021.

Specialty Products Pipeline

Below is a description of key products in our specialty pipeline as of October 31, 2022:

	Phase 2	Phase 3	Pre-Submission	Under Regulatory Review
Neuroscience		***Deutetrabenazine*** Dyskinesia in Cerebral Palsy (September 2019) ***TEV-44749 LAI*** Schizophrenia (September 2022)		***Risperidone LAI*** Schizophrenia [(1)]
Immunology	***TEV-48574*** Inflammatory Bowel Disease			
Other			***Digihaler®*** (budesonide and formoterol fumarate dihydrate) (EU) ***Digihaler®*** (beclomethasone dipropionate HFA)(U.S.)	

(1) Developed under a license agreement with MedinCell. In August 2021, the FDA accepted the NDA for risperidone LAI, based on phase 3 data from two pivotal studies. In April 2022, the FDA issued a Complete Response Letter ("CRL") regarding the NDA for risperidone LAI. We resubmitted the NDA in October 2022 and await the FDA's response.

Discontinued Project

In October 2022, development of fasinumab for the treatment of osteoarthritic pain was discontinued.

Biosimilar Products Pipeline

We have additional biosimilar products in development internally and with our partners that are in various stages of clinical trials and regulatory review worldwide, including phase 3 clinical trials for biosimilars to Prolia® (denosumab), Xolair® (omalizumab) and Eylea® (afilbercept), a biosimilar to Lucentis® (ranibizumab) that was submitted in Canada, Stelera® (ustekinumab) that is currently in pre-submission in the U.S., as well as a biosimilar to Humira® (adalimumab) that is currently under U.S. regulatory review.

Selling and Marketing (S&M) Expenses

S&M expenses in the third quarter of 2022 were $539 million, a decrease of 10% compared to the third quarter of 2021. This decrease was mainly a result of the factors discussed above under "—North America segment—S&M Expenses" and "—Europe Segment—S&M Expenses."

S&M expenses as a percentage of revenues were 15.0% in the third quarter of 2022, compared to 15.4% in the third quarter of 2021.

General and Administrative (G&A) Expenses

G&A expenses in the third quarter of 2022 were $283 million, a decrease of 3% compared to the third quarter of 2021.

G&A expenses as a percentage of revenues were 7.9% in the third quarter of 2022, compared to 7.5% in the third quarter of 2021.

Intangible Asset Impairments

We recorded expenses of $24 million for identifiable intangible asset impairments in the third quarter of 2022, compared to expenses of $21 million in the third quarter of 2021. See note 5 to our consolidated financial statements.

Goodwill Impairment

No goodwill impairments were recorded in the third quarters of 2022 and 2021.

Other Asset Impairments, Restructuring and Other Items

We recorded expenses of $36 million for other asset impairments, restructuring and other items in the third quarter of 2022, compared to expenses of $62 million in the third quarter of 2021. 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 third quarter of 2022, we recorded expenses of $195 million in legal settlements and loss contingencies, compared to an expense of $3 million in the third quarter of 2021. See note 9 to our consolidated financial statements.

Other Income

Other income in the third quarter of 2022 was $2 million, compared to $25 million in the third quarter of 2021.

Operating Income (Loss)

Operating income was $419 million in the third quarter of 2022, compared to an operating income of $623 million in the third quarter of 2021. The decrease in operating income in the third quarter of 2022 compared to the third quarter of 2021 was mainly due to legal settlements and loss contingencies as well as lower gross profit, partially offset by lower S&M and R&D expenses, as discussed above.

Operating income as a percentage of revenues was 11.6% in the third quarter of 2022, compared to operating income as a percentage of revenues of 16.0% in the third quarter of 2021.

Financial Expenses, Net

Financial expenses were $252 million in the third quarter of 2022, compared to $241 million in the third quarter of 2021. Financial expenses in the third quarter of 2022 were mainly comprised of interest expenses of $230 million. Financial expenses in the third quarter of 2021 were mainly comprised of interest expenses of $232 million.

The following table presents a reconciliation of our segment profits to our consolidated operating income (loss) and to consolidated income (loss) before income taxes for the three months ended September 30, 2022 and 2021:

	Three months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
North America profit	$ 477	$ 458
Europe profit	360	394
International Markets profit	112	152
Total reportable segments profit	949	1,004
Profit of other activities	29	38
Total segments profit	977	1,042
Amounts not allocated to segments:		
Amortization	165	199
Other assets impairments, restructuring and other items	36	62
Goodwill impairment	—	—
Intangible assets impairments	24	21
Legal settlements and loss contingencies	195	3
Other unallocated amounts	139	134
Consolidated operating income (loss)	419	623
Financial expenses, net	252	241
Consolidated income (loss) before income taxes	$ 166	$ 382

Income taxes

In the third quarter of 2022, we recognized a tax expense of $107 million, on pre-tax income of $166 million. In the third quarter of 2021, we recognized a tax expense of $76 million, on pre-tax income of $382 million. See note 11 to our consolidated financial statements.

Share in (Profits) Losses of Associated Companies, Net

Share in losses of associated companies, net in the third quarter of 2022 was $1 million, compared to share in losses of $5 million in the third quarter of 2021.

Net Income (Loss) Attributable to Teva

Net income was $56 million in the third quarter of 2022, compared to net income of $292 million in the third quarter of 2021. The decrease in net income in the third quarter of 2022 was mainly due to lower operating income and higher income taxes, all as discussed above.

Diluted Shares Outstanding and Earnings (Loss) per Share

The weighted average diluted shares outstanding used for the fully diluted share calculations for the three months ended September 30, 2022 and 2021 were 1,119 million and 1,109 million shares, respectively.

Diluted earnings per share were $0.05 in the third quarter of 2022, compared to diluted earnings per share of $0.26 in the third quarter of 2021. See note 13 to our consolidated financial statements.

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 PSUs and the conversion of our convertible senior debentures, in each case, at period end.

As of September 30, 2022 and 2021, the fully diluted share count for purposes of calculating our market capitalization was approximately 1,144 million and 1,128 million, respectively.

Impact of Currency Fluctuations on Results of Operations

In the third quarter of 2022, 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, Canadian dollar, Russian ruble, Japanese yen, Swiss franc and new Israeli shekel) impact our results.

During the third quarter of 2022, 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): Turkish lira by 52%, Argentinian peso by 28%, Hungarian forint by 25%, Ukrainian hryvna by 23%, Japanese yen by 20%, Swedish krona by 18%, Polish zloty by 18%, Chilean peso by 17%, British pound by 15% and the euro by 15%. The Russian ruble increased in value against the U.S. dollar by 23%.

As a result, exchange rate movements during the third quarter of 2022, net of hedging effects, negatively impacted overall revenues by $215 million and operating income by $53 million, compared to the third quarter of 2021.

In the third quarter of 2022, a positive hedging impact of $34 million was recognized under revenues, and a negative impact of $1 million was recognized under cost of sales. In the third quarter of 2021, a positive hedging impact of $16 million was recognized under revenues and a minimal negative impact 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 8d 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.

Commencing in the second quarter of 2022, the cumulative inflation in Turkey exceeded 100% or more over a three-year period. Although this triggered highly inflationary accounting treatment, it did not have a material impact on our results of operations.

Comparison of Nine Months Ended September 30, 2022 to Nine Months Ended September 30, 2021

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 nine months ended September 30, 2022 and 2021. Where there are different factors affecting the nine 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 nine months ended September 30, 2022 and 2021:

	Nine months ended September 30,			
	2022		2021	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 5,450	100%	$ 5,807	100%
Gross profit	2,841	52.1%	3,081	53.1%
R&D expenses	401	7.4%	467	8.1%
S&M expenses	733	13.4%	734	12.6%
G&A expenses	361	6.6%	338	5.8%
Other income	(12)	§	(14)	§
Segment profit*	$ 1,359	24.9%	$ 1,556	26.8%

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

§ Represents an amount less than 0.5%.

North America Revenues

Our North America segment includes the United States and Canada. Revenues from our North America segment in the first nine months of 2022 were $5,450 million, a decrease of 6% compared to $5,807 million in the first nine months of 2021.

Revenues by Major Products and Activities

The following table presents revenues for our North America segment by major products and activities for the nine months ended September 30, 2022 and 2021:

	Nine months ended September 30,		Percentage Change 2022-2021
	2022	2021	
	(U.S. $ in millions)		
Generic products	$ 2,731	$ 2,864	(5%)
AJOVY	142	123	16%
AUSTEDO	618	520	19%
BENDEKA/TREANDA	241	292	(17%)
COPAXONE	285	448	(36%)
Anda	1,021	968	5%
Other	411	592	(31%)
Total	$ 5,450	$ 5,807	(6%)

North America Gross Profit

Gross profit from our North America segment in the first nine months of 2022 was $2,841 million, a decrease of 8%, compared to $3,081 million in the first nine months of 2021.

Gross profit margin for our North America segment in the first nine months of 2022 decreased to 52.1% compared to 53.1% in the first nine months of 2021. This decrease was mainly due to a change in mix of products.

North America R&D Expenses

R&D expenses relating to our North America segment in the first nine months of 2022 were $401 million, a decrease of 14%, compared to $467 million in the first nine months of 2021.

North America S&M Expenses

S&M expenses relating to our North America segment in the first nine months of 2022 were $733 million, flat compared to the first nine months of 2021.

North America G&A Expenses

G&A expenses relating to our North America segment in the first nine months of 2022 were $361 million, an increase of 7%, compared to $338 million in the first nine months of 2021.

North America Profit

Profit from our North America segment in the first nine months of 2022 was $1,359 million, a decrease of 13%, compared to $1,556 million in the first nine months of 2021. This decrease was mainly due to lower revenues and an unfavorable change in the mix of products, as mentioned above.

Europe Segment

The following table presents revenues, expenses and profit for our Europe segment for the nine months ended September 30, 2022 and 2021:

	Nine months ended September 30,			
	2022		2021	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 3,396	100%	$ 3,618	100%
Gross profit	2,031	59.8%	2,063	57.0%
R&D expenses	157	4.6%	184	5.1%
S&M expenses	561	16.5%	628	17.3%
G&A expenses	183	5.4%	180	5.0%
Other (income) expense	(1)	§	(3)	§
Segment profit*	$ 1,130	33.3%	$ 1,074	29.7%

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

§ Represents an amount less than 0.5%.

Europe Revenues

Our Europe segment includes the European Union, the United Kingdom, and certain other European countries. Revenues from our Europe segment in the first nine months of 2022 were $3,396 million, a decrease of 6% or $222 million, compared to the first nine months of 2021. In local currency terms, revenues increased by 6%, compared to the first nine months of 2021.

In the first nine months of 2022, revenues were negatively impacted by exchange rate fluctuations of $357 million, net of hedging effects, compared to the first nine months of 2021. Revenues in the first nine months of 2022 included $63 million from a positive hedging impact, which are included in "Other" in the table below. See note 8d to our consolidated financial statements.

Revenues by Major Products and Activities

The following table presents revenues for our Europe segment by major products and activities for the nine months ended September 30, 2022 and 2021:

	Nine months ended September 30,		Percentage Change 2022-2021
	2022	2021	
	(U.S. $ in millions)		
Generic products	$ 2,552	$ 2,637	(3%)
AJOVY	90	58	55%
COPAXONE	207	296	(30%)
Respiratory products	198	263	(25%)
Other	349	364	(4%)
Total	$ 3,396	$ 3,618	(6%)

Europe Gross Profit

Gross profit from our Europe segment in the first nine months of 2022 was $2,031 million, a decrease of 2% compared to $2,063 million in the first nine months of 2021.

Gross profit margin for our Europe segment in the first nine months of 2022 increased to 59.8% compared to 57.0% in the first nine months of 2021.

Europe R&D Expenses

R&D expenses relating to our Europe segment in the first nine months of 2022 were $157 million, a decrease of 14% compared to $184 million in the first nine months of 2021.

Europe S&M Expenses

S&M expenses relating to our Europe segment in the first nine months of 2022 were $561 million, a decrease of 11% compared to $628 million in the first nine months of 2021.

Europe G&A Expenses

G&A expenses relating to our Europe segment in the first nine months of 2022 were $183 million, an increase of 2% compared to $180 million in the first nine months of 2021.

Europe Profit

Profit from our Europe segment in the first nine months of 2022 was $1,130 million, an increase of 5% compared to first nine months of 2021. This increase was primarily due to lower R&D and S&M expenses. Profit from our Europe segment in the first nine months of 2022 was impacted by exchange rate fluctuations.

International Markets Segment

The following table presents revenues, expenses and profit for our International Markets segment for the nine months ended September 30, 2022 and 2021:

	2022		2021	
	(U.S. $ in millions / % of Segment Revenues)			
Revenues	$ 1,422	100%	$ 1,505	100%
Gross profit	780	54.9%	826	54.9%
R&D expenses	54	3.8%	51	3.4%
S&M expenses	293	20.6%	303	20.1%
G&A expenses	89	6.3%	79	5.3%
Other (income) expense	(43)	(3.0%)	(5)	§
Segment profit*	$ 386	27.2%	$ 398	26.4%

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

§ Represents an amount less than 0.5%.

International Markets Revenues

Our International Markets segment includes all countries other than those in our North America and Europe segments. Revenues from our International Markets segment in the first nine months of 2022 were $1,422 million, a decrease of $83 million, or 6%, compared to the first nine months of 2021. In local currency terms, revenues increased by 2%. This increase was mainly due to higher revenues in certain markets, as well as price increases largely as a result of rising costs due to inflationary pressure, partially offset by a milestone payment of $35 million related to AJOVY in the third quarter of 2021 as mentioned above, regulatory price reductions and generic competition to off-patented products in Japan, and the sale of the majority of the generic and operational assets of our business venture in Japan in the first quarter of 2021.

In the first nine months of 2022, revenues were negatively impacted by exchange rate fluctuations of $120 million net of hedging effects, compared to the first nine months of 2021. Revenues in the first nine months of 2022 included a minimal negative hedging impact, which is included in "Other" in the table below. See note 8d 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 nine months ended September 30, 2022 and 2021:

	Nine months ended September 30,		Percentage Change 2022-2021
	2022	2021	
	(U.S. $ in millions)		
Generic products	$ 1,175	$ 1,211	(3%)
AJOVY	22	46	(51%)
COPAXONE	29	29	1%
Other	195	219	(11%)
Total	$ 1,422	$ 1,505	(6%)

International Markets Gross Profit

Gross profit from our International Markets segment in the first nine months of 2022 was $780 million, compared to $826 million in the first nine months of 2021.

Gross profit margin for our International Markets segment in the first nine months of 2022 was 54.9%, flat compared to the first nine months of 2021.

International Markets R&D Expenses

R&D expenses relating to our International Markets segment in the first nine months of 2022 were $54 million, an increase of 7% compared to $51 million in the first nine months of 2021.

International Markets S&M Expenses

S&M expenses relating to our International Markets segment in the first nine months of 2022 were $293 million, a decrease of 3% compared to $303 million in the first nine months of 2021.

International Markets G&A Expenses

G&A expenses relating to our International Markets segment in the first nine months of 2022 were $89 million, an increase of 12% compared to $79 million in the first nine months of 2021.

International Markets Other Income

Other income in the first nine months of 2022 was $43 million, compared to $5 million in the first nine months of 2021. Other income in the first nine months of 2022 was mainly the result of settlement proceeds.

International Markets Profit

Profit from our International Markets segment in the first nine months of 2022 was $386 million, a decrease of 3%, compared to $398 million in the first nine months of 2021.

Other Activities

Our revenues from other activities in the first nine months of 2022 decreased by 9% to $773 million, compared to the first nine months of 2021. In local currency terms, revenues decreased by 5%.

API sales to third parties in the first nine months of 2022 were $507 million, a decrease of 6% in both U.S. dollars and local currency terms, compared to the first nine months of 2021.

Teva Consolidated Results

Revenues

Revenues in the first nine months of 2022 were $11,041 million, a decrease of 6%, or 2% in local currency terms, compared to the first nine months of 2021.

Exchange rate movements during the first nine months of 2022, net of hedging effects, negatively impacted revenues by $510 million, compared to the first nine months of 2021. See note 8d to our consolidated financial statements.

Gross Profit

Gross profit in the first nine months of 2022 was $5,203 million, a decrease of 6% compared to the first nine months of 2021.

Gross profit margin was 47.1% in the first nine months of 2022, flat compared to the first nine months of 2021.

Research and Development (R&D) Expenses

R&D expenses in the first nine months of 2022 were $628 million, a decrease of 13% compared to the first nine months of 2021.

R&D expenses as a percentage of revenues were 5.7% in the first nine months of 2022, compared to 6.1% in the first nine months of 2021.

Selling and Marketing (S&M) Expenses

S&M expenses in the first nine months of 2022 were $1,716 million, a decrease of 5% compared to the first nine months of 2021.

S&M expenses as a percentage of revenues were 15.5% in the first nine months of 2022, compared to 15.3% in the first nine months of 2021.

General and Administrative (G&A) Expenses

G&A expenses in the first nine months of 2022 were $892 million, an increase of 8% compared to the first nine months of 2021. The increase in G&A expenses in the first nine months of 2022 was related to proceeds received from Teva's insurance carriers pursuant to a settlement reached on a derivative proceeding related to the acquisition of Actavis Generics in the second quarter of 2021, as well as higher litigation fees in the second quarter of 2022.

G&A expenses as a percentage of revenues were 8.1% in the first nine months of 2022, compared to 7.0% in the first nine months of 2021.

Intangible Asset Impairments

We recorded expenses of $223 million for identifiable intangible asset impairments, in the first nine months of 2022, compared to expenses of $295 million in the first nine months of 2021. See note 5 to our consolidated financial statements.

Goodwill Impairment

We recorded a goodwill impairment charge of $745 million in the first nine months of 2022, of which $479 million is related to our International Markets reporting unit and $266 million is related to Teva's API reporting unit. See note 6 to our consolidated financial statements.

Other Asset Impairments, Restructuring and Other Items

We recorded expenses of $282 million for other asset impairments, restructuring and other items in the first nine months of 2022, compared to expenses of $227 million in the first nine months of 2021. See note 12 to our consolidated financial statements.

Legal Settlements and Loss Contingencies

In the first nine months of 2022, we recorded expenses of $2,048 million in legal settlements and loss contingencies, compared to expenses of $113 million in the first nine months of 2021. See note 9 to our consolidated financial statements.

Other Income

Other income in the first nine months of 2022 was $88 million, compared to $73 million in the first nine months of 2021. Other income in the first nine months of 2022 was mainly the result of settlement proceeds in our International Markets segment as well as a capital gain related to the sale of an R&D site. Other income in the first nine months of 2021 was mainly due to capital gains related to the sale of certain OTC assets.

Operating Income (Loss)

Operating loss was $1,244 million in the first nine months of 2022, compared to operating income of $1,638 million in the first nine months of 2021.

Operating loss as a percentage of revenues was 11.3% in the first nine months of 2022, compared to operating income as a percentage of revenues of 13.9% in the first nine months of 2021.

Financial Expenses, Net

Financial expenses were $721 million in the first nine months of 2022, compared to $805 million in the first nine months of 2021. Financial expenses in the first nine months of 2022 were mainly comprised of interest expenses of $693 million. Financial expenses in the first nine months of 2021 were mainly comprised of interest expenses of $711 million and loss on revaluations of marketable securities of $104 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 nine months ended September 30, 2022 and 2021:

	Nine months ended September 30,	
	2022	2021
	(U.S. $ in millions)	
North America profit	$ 1,359	$1,556
Europe profit	1,130	1,074
International Markets profit	386	398
Total reportable segments profit	2,875	3,028
Profit of other activities	135	125
Total segments profit	3,010	3,153
Amounts not allocated to segments:		
Amortization	576	613
Other assets impairments, restructuring and other items	282	227
Goodwill impairment	745	—
Intangible asset impairments	223	295
Legal settlements and loss contingencies	2,048	113
Other unallocated amounts	379	266
Consolidated operating income (loss)	(1,244)	1,638
Financial expenses, net	721	805
Consolidated income (loss) before income taxes	$(1,964)	$ 833

Income taxes

In the first nine months of 2022, we recognized a tax benefit of $792 million, on pre-tax loss of $1,964 million. In the first nine months of 2021, we recognized a tax expense of $235 million, on pre-tax income of $833 million. See note 11 to our consolidated financial statements.

Share in (Profits) Losses of Associated Companies, Net

Share in profits of associated companies, net in the first nine months of 2022 was $20 million, compared to share in profits of $9 million in the first nine months of 2021. Share in profits of associated companies, net in the first nine months of 2022 was mainly related to the difference between the book value of our investment in Novetide and its fair value as of the date we completed its acquisition in January 2022.

Net Income (Loss) Attributable to Teva

Net loss was $1,132 million in the first nine months of 2022, compared to net income of $576 million in the first nine months of 2021.

Diluted Shares Outstanding and Earnings (Loss) per Share

The weighted average diluted shares outstanding used for the fully diluted share calculation for the nine months ended September 30, 2022 and 2021 were 1,109 million shares.

Diluted loss per share was $1.02 in the first nine months of 2022, compared to diluted earnings per share of $0.52 in the first nine months of 2021. See note 13 to our consolidated financial statements.

Impact of Currency Fluctuations on Results of Operations

In the first nine months of 2022, 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, Canadian dollar, Russian ruble, Japanese yen, Swiss franc and new Israeli shekel) impact our results.

During the first nine months of 2022, the following main currencies relevant to our operations decreased in value against the U.S. dollar: Turkish lira by 48%, Argentinian peso by 22%, Hungarian forint by 17%, Japanese yen by 15%, Swedish krona by 14%, Chilean peso by 14%, Polish zloty by 13%, Ukrainian hryvna by 11%, euro by 11% and British pound by 9% (all compared on a nine-month average basis). The following main currencies relevant to our operations increased in value against the U.S. dollar: Russian ruble by 7% and Brazilian real by 4%.

As a result, exchange rate movements during the first nine months of 2022 negatively impacted overall revenues by $510 million and our operating income by $115 million, in comparison to the first nine months of 2021.

In the first nine months of 2022, a positive hedging impact of $69 million was recognized under revenues, and a negative hedging impact of $5 million was recognized under cost of sales. In the first nine months of 2021, a positive hedging impact of $29 million was recognized under revenues and a negative hedging 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 8d to our consolidated financial statements.

Liquidity and Capital Resources

Total balance sheet assets were $44,252 million as of September 30, 2022, compared to $47,666 million as of December 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 $448 million as of September 30, 2022, compared to $787 million as of December 31, 2021. This decrease was mainly due to a decrease in accounts receivables, net of SR&A and an increase in accrued expenses mainly due to an update to the estimated settlement provision recorded in connection with the remaining opioid cases, partially offset by a decrease in employee-related obligations due to performance incentive payments to employees.

Employee-related obligations, as of September 30, 2022 were $496 million, compared to $563 million as of December 31, 2021. The decrease in the first nine months of 2022 was mainly due to performance incentive payments to employees for 2021, partially offset by an accrual for performance incentive payments to employees for 2022.

Cash investment in property, plant and equipment in the third quarter of 2022 was $122 million, compared to $146 million in the third quarter of 2021. Depreciation in the third quarter of 2022 was $156 million, compared to $132 million in the third quarter of 2021.

Cash and cash equivalents and short-term and long-term investments as of September 30, 2022 were $2,241 million, compared to $2,191 million as of December 31, 2021.

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.

Teva's principal sources of short-term liquidity are its cash on hand, existing cash investments, liquid securities and available credit facilities, primarily its $1.8 billion unsecured syndicated sustainability-linked revolving credit facility, entered into in April 2022 ("RCF"). See note 7 to our consolidated financial statements.

Debt Balance and Movements

As of September 30, 2022, our debt was $21,266 million, compared to $23,043 million as of December 31, 2021. This decrease was mainly due to $1,139 million from exchange rate fluctuations and $661 million senior notes repaid at maturity.

Our debt as of September 30, 2022 was effectively denominated in the following currencies: 65% in U.S. dollars, 33% in euros and 2% in Swiss francs.

The portion of total debt classified as short-term as of September 30, 2022 was 13%, compared to 6% as of December 31, 2021.

Our financial leverage which is the ratio between our debt and the sum of our debt and equity, was 69% as of September 30, 2022, compared to 67% as of December 31, 2021.

Our average debt maturity was approximately 5.9 years as of September 30, 2022, compared to 6.4 years as of December 31, 2021.

Total Equity

Total equity was $9,519 million as of September 30, 2022, compared to $11,244 million as of December 31, 2021. This decrease was mainly due to a net loss of $1,152 million and a negative impact of $684 million from exchange rate fluctuations.

Exchange rate fluctuations affected our balance sheet, as approximately 68% of our net assets as of September 30, 2022 (including both non-monetary and monetary assets) were in currencies other than the U.S. dollar. When compared to December 31, 2021, changes in currency rates had a negative impact of $684 million on our equity as of September 30, 2022. The following main currencies decreased in value against the U.S. dollar: Turkish lira by 41%, Japanese yen by 26%, Polish zloty by 22%, British pound by 21%, Croatian kuna by 15%, Bulgarian lev by 15%, euro by 15%, Chilean peso by 13% and Indian rupee by 10%. The Russian ruble increased in value against the U.S. dollar by 23%. All comparisons are on a year to date basis.

Cash Flow

We seek to continually improve the efficiency of our working capital management. From time to time, as part of our cash and commercial relationship 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 may have an impact on our annual operating cash flow measurement, as well as on our quarterly results.

Cash flow generated from operating activities during the third quarter of 2022 was $543 million, compared to $529 million in the third quarter of 2021. The increase in the third quarter of 2022 resulted mainly from changes in the deferred purchase price under our securitization agreement, partially offset by changes in working capital items, primarily a lower reduction in our inventory levels compared to the third quarter of 2021.

During the third quarter of 2022, we generated free cash flow of $685 million, which we define as comprising $543 million in cash flow generated from operating activities, $262 million in beneficial interest collected in exchange for securitized accounts receivables and $2 million in proceeds from divestitures of businesses and other assets, partially offset by $122 million in cash used for capital investment. During the third quarter of 2021, we generated free cash flow of $795 million, comprising $529 million in cash flow generated from operating activities, $397 million in beneficial interest collected in exchange for securitized accounts receivables and $15 million in proceeds from divestitures of businesses and other assets, partially offset by $146 million in cash used for capital investment. The decrease in the third quarter of 2022, resulted mainly from changes in working capital items, primarily a lower reduction in our inventory levels compared to the third quarter of 2021.

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 October 2021, Teva announced a license agreement with MODAG GmbH (“Modag”) that will provide Teva an exclusive global license to develop, manufacture and commercialize Modag’s lead compound (TEV-56286) and a related compound (TEV-56287). TEV-56286 was initially developed for the treatment of Multiple System Atrophy (“MSA”) and Parkinson’s disease, and has the potential to be applied to other treatments for neurodegenerative disorders, such as Alzheimer’s disease. A phase 1b clinical trial is currently being completed for TEV-56286. In the fourth quarter of 2021, Teva made an upfront payment of $10 million to Modag that was recorded as an R&D expense. Modag may be eligible for future development milestone payments, totaling an aggregate amount of up to $70 million, as well as future commercial milestones and royalties.

In August 2020, Teva entered into an agreement with biopharmaceutical company Alvotech for the exclusive commercialization in the U.S. of five biosimilar product candidates. The initial pipeline for this collaboration contains biosimilar candidates addressing multiple therapeutic areas, including a proposed biosimilar to Humira®. Under the terms of the 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, which were recorded as R&D expenses. Additional development and commercial milestone payments of up to $400 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. Alvotech was previously involved in litigation involving certain IP and trade secrets claims filed by Abbvie in relation to Alvotech’s proposed biosimilar to Humira®, all of which were settled on

March 8, 2022. Pursuant to that settlement, Alvotech and Teva may sell Alvotech's proposed biosimilar to Humira® in the United States beginning on July 1, 2023, provided that U.S. regulatory approval is obtained by that date. In September 2022, Alvotech announced they received a Complete Response Letter ("CRL") from the FDA with respect to Alvotech's proposed biosimilar to Humira®.

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. In October 2022, development of fasinumab for the treatment of osteoarthritic pain was discontinued.

In November 2013, Teva entered into an agreement with MedinCell for the development and commercialization of multiple long-acting injectable ("LAI") products. The lead product candidate selected was risperidone LAI (TV-46000) suspension for subcutaneous use for the treatment of schizophrenia. In August 2021, the FDA accepted the new drug application ("NDA") for risperidone LAI, based on phase 3 data from two pivotal studies. Teva leads the clinical development and regulatory process and is responsible for commercialization of this product candidate. MedinCell may be eligible for development milestones, and future commercial milestones of up to $112 million in respect of risperidone LAI. Teva will also pay MedinCell royalties on net sales. In April 2022, the FDA issued a CRL regarding the NDA for risperidone LAI. Teva resubmitted the NDA in October 2022 and awaits the FDA's response.

The second selected product candidate is TEV-44749, a LAI for the treatment of schizophrenia. In the third quarter of 2022, Teva decided to progress development of the product to phase 3, as a result of which a $3 million milestone payment was paid to MedinCell. MedinCell may become eligible for further milestones and royalties on sales of TEV-44749.

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

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

2022 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, 2021.

Non-GAAP Net Income and Non-GAAP EPS Data

We present non-GAAP net income and non-GAAP earnings per share ("EPS") as management believes that such data provide useful information to investors because they are used by management and our Board of Directors, in conjunction with other performance metrics, to evaluate our operational performance, to prepare and evaluate our work plans and annual budgets and ultimately to evaluate the performance of management, including annual compensation. While other qualitative factors and judgment also affect annual compensation, the principal quantitative element in the determination of such compensation are performance targets tied to the work plan, which are based on these non-GAAP measures.

Non-GAAP financial measures have no standardized meaning and accordingly have limitations in their usefulness to investors. 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 net income and non-GAAP EPS in addition to, and not as replacements for, or superior to, measures of financial performance prepared in accordance with GAAP.

In preparing our non-GAAP net income and non-GAAP EPS data, we exclude items that either have a non-recurring impact on our financial performance or which, in the judgment of our management, are items that, either as a result of their nature or size, could, were they not excluded, potentially cause investors to extrapolate future performance from an improper base that is not reflective of our underlying business performance. Certain of these items are also excluded because of the difficulty in predicting their timing and scope. The items excluded from our non-GAAP net income and non-GAAP EPS include:

- amortization of purchased intangible assets;
- legal settlements and material litigation fees 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 and inventory step-up;
- expenses related to our equity compensation;
- significant one-time financing costs, amortization of issuance costs and terminated derivative instruments, and marketable securities investment valuation gains/losses;
- unusual tax items;
- other awards or settlement amounts, either paid or received;
- other exceptional items that we believe are sufficiently large that their exclusion is important to facilitate an understanding of trends in our financial results, such as impacts due to changes in accounting, significant costs for remediation of plants, or other unusual events; and
- corresponding tax effects of the foregoing items.

Commencing the first quarter of 2022, we no longer exclude IPR&D acquired in development arrangements from our non-GAAP financial measures. No IPR&D acquired in development arrangements was recorded in our comparable non-GAAP financial measures for the third quarter of 2021. In our comparable non-GAAP financial measures for the nine months ended September 30, 2021, we excluded $5 million IPR&D acquired in development. We are not recasting the non-GAAP presentation for the nine months ended September 30, 2021 since the adjustment is not significant. We made this change to our presentation of non-GAAP financial measures to improve the comparability of our non-GAAP presentation to those of other companies in the pharmaceutical industry that made a similar change to their presentations beginning in the first quarter of 2022.

The following tables present our non-GAAP net income and non-GAAP EPS for the three and nine months ended September 30, 2022 and 2021, as well as reconciliations of each measure to their nearest GAAP equivalents:

($ in millions except per share amounts)	Three months ended September 30, 2022	2021	Nine months ended September 30, 2022	2021
Net income (loss) attributable to Teva	($) 56	292	($)(1,132)	576
Increase (decrease) for excluded items:				
Amortization of purchased intangible assets	165	199	576	613
Legal settlements and loss contingencies	195	3	2,048	113
Goodwill impairment	—	—	745	—
Impairment of long-lived assets	28	47	257	401
Other R&D expenses	—	—	—	5
Restructuring costs	25	28	117	96
Costs related to regulatory actions taken in facilities	2	5	6	17
Equity compensation	26	26	88	86
Contingent consideration	6	9	100	(7)
Gain on sale of business	—	(7)	(31)	(44)
Accelerated depreciation	45	4	78	13
Financial expenses	14	6	48	104
Share in profits (losses) of associated companies – net	—	—	(22)	(1)
Items attributable to non-controlling interests	(4)	(4)	(54)	(10)
Other non-GAAP items*	67	105	268	220
Corresponding tax effects and unusual tax items	33	(62)	(1,072)	(182)
Non-GAAP net income attributable to Teva	($) 658	651	($) 2,021	2,001
Diluted earnings (loss) per share attributable to Teva	($) 0.05	0.26	($) (1.02)	0.52
EPS difference**	0.54	0.32	2.83	1.29
Diluted Non-GAAP EPS attributable to Teva**	($) 0.59	0.59	($) 1.81	1.81

* 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, primarily related to the rationalization of our plants and other unusual events.

** EPS difference and diluted non-GAAP EPS are calculated by dividing our non-GAAP net income attributable to Teva by our non-GAAP diluted weighted average number of shares. The non-GAAP diluted weighted average number of shares for the three months ended September 30, 2022, and 2021, were 1,119 million and 1,109 million shares, respectively. The non-GAAP diluted weighted average number of shares for the nine months ended September 30, 2022, and 2021, were 1,114 million and 1,109 million shares, respectively.

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, 2021, 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, 2021.

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, 2021.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

After evaluating the effectiveness of our disclosure controls and procedures as of September 30, 2022, 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 September 30, 2022, 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, 2021.

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

Unregistered Sales of Equity Securities

There were no sales of unregistered equity securities during the three months ended September 30, 2022.

Repurchase of Shares

We did not repurchase any of our shares during the three months ended September 30, 2022 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.

ITEM 6. EXHIBITS

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

* Filed herewith.

SIGNATURES

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

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

Date: November 3, 2022

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

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Kåre Schultz, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2022

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, 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: November 3, 2022

/s/ Eli Kalif
Eli Kalif
Executive Vice President, Chief Financial Officer

Exhibit 32

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Teva Pharmaceutical Industries Limited (the "Company") on Form 10-Q for the period ended September 30, 2022 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: November 3, 2022

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

/s/ Eli Kalif
Eli Kalif
Executive Vice President, Chief Financial Officer