

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 10-K

February 19, 2019

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2018**

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

**For the transition period from            to**

**Commission file number 001-16174**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**(Exact name of registrant as specified in its charter)**

**Israel**  
**(State or other jurisdiction of**

**Not Applicable**  
**(I.R.S. Employer**

**incorporation or organization)**

**Identification No.)**

**5 Basel Street, Petach Tikva, ISRAEL, 4951033**

**(Address of principal executive offices and Zip Code)**

**+972 (3) 914-8171**

**(Registrant's telephone number, including area code)**

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

**American Depositary Shares, each representing one Ordinary  
Share**

**New York Stock Exchange**

**(Title of each class)**

**(Name of each exchange on which registered)**

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

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☐

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 Exchange Act). Yes No

The aggregate market value of the voting common equity held by non-affiliates of the registrant, computed by reference to the closing price at which the American Depositary Shares were last sold on the New York Stock Exchange, as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2018), was approximately \$20.7 billion. Teva Pharmaceutical Industries Limited has no non-voting common equity. For purpose of this calculation only, this amount excludes ordinary shares and American Depositary Shares held by directors and executive officers and by each person who owns or may be deemed to own 10% or more of the registrant's common equity at June 30, 2018.

As of December 31, 2018, the registrant had 1,089,388,686 ordinary shares outstanding.

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### **INTRODUCTION AND USE OF CERTAIN TERMS**

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

### **FORWARD-LOOKING STATEMENTS**

In addition to historical information, this Annual Report on Form 10-K, and the reports and documents incorporated by reference in this Annual Report on Form 10-K, 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 in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include risks relating to:

our ability to successfully compete in the marketplace, including: that we are substantially dependent on our generic products; competition for our specialty products, especially COPAXONE®, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives; the uncertainty of commercial success of AJOVY® or AUSTEDO®; competition from companies with greater resources and capabilities; efforts of pharmaceutical companies to limit the use of generics, including through legislation and regulations; consolidation of our customer base and commercial alliances among our customers; the increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products; price erosion relating to our products, both from competing products and increased regulation; delays in launches of new products and our ability to achieve expected results from investments in our product pipeline; our ability to take advantage of high-value opportunities; the difficulty and expense of obtaining licenses to proprietary technologies; and the effectiveness of our patents and other measures to protect our intellectual property rights;

our substantial indebtedness, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, may result in a further downgrade of our credit ratings; and our inability to raise debt or borrow funds in amounts or on terms that are favorable to us;

our business and operations in general, including: failure to effectively execute our restructuring plan announced in December 2017; uncertainties related to, and failure to achieve, the potential benefits and success of our senior management team and organizational structure; harm to our pipeline of future products due to the ongoing review of our R&D programs; our ability to develop and commercialize additional pharmaceutical products; potential additional adverse consequences following our resolution with the U.S. government of our FCPA investigation; compliance with sanctions and other trade control laws; manufacturing or quality control problems, which may damage our reputation for quality production and require costly remediation; interruptions in our supply chain; disruptions of our or third

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party information technology systems or breaches of our data security; the failure to recruit or retain key personnel; variations in intellectual property laws that may adversely affect our ability to manufacture our products; challenges associated with conducting business globally, including adverse effects of political or economic instability, major hostilities or terrorism; significant sales to a limited number of customers in our U.S. market; our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; and our prospects and opportunities for growth if we sell assets;

compliance, regulatory and litigation matters, including: costs and delays resulting from the extensive governmental regulation to which we are subject; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; increased legal and regulatory action in connection with public concern over the abuse of opioid medications in the U.S.; governmental investigations into S&M practices; potential liability for patent infringement; product liability claims; increased government scrutiny of our patent settlement agreements; failure to comply with complex Medicare and Medicaid reporting and payment obligations; and environmental risks;

other financial and economic risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; potential impairments of our intangible assets; potential significant increases in tax liabilities; and the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business;

and other factors discussed in this Annual Report on Form 10-K, 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**

### **ITEM 1. BUSINESS**

#### **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 over-the-counter ( 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 active pharmaceutical ingredients ( API ) to third parties and certain contract manufacturing services.



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In December 2017, we announced a comprehensive restructuring plan intended to significantly reduce our cost base, unify and simplify our organization and improve business performance, profitability, cash flow generation and productivity. This plan is intended to reduce our total cost base by \$3 billion by the end of 2019.

For information regarding our major customers, see note 20 to our consolidated financial statements.

For information regarding certain business transactions completed during 2018, see Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Transactions.

Below is an overview of our three business segments.

### ***North America***

Our North America segment includes the United States and Canada.

We are the leading generic drug company in the United States. We market over 500 generic prescription and OTC products in more than 2,000 dosage strengths and packaging sizes, including oral solid dosage forms, injectable products, inhaled products, liquids, ointments and creams. Most of our generic sales in the United States are made to retail drug chains, mail order distributors and wholesalers.

Our wholesale and retail selling efforts are supported by participation in key pharmaceutical conferences as well as focused advertising in professional journals and on leading pharmacy websites. We continue to strengthen consumer awareness of the benefits of generic medicines through partnerships and digital marketing programs.

During 2018, our generics business in the United States continued to be negatively impacted by certain developments, including: (i) pricing pressure as a result of customer consolidation into larger buying groups capable of extracting greater price reductions, (ii) an accelerated FDA approval process for generic versions of off-patent medicines, resulting in increased competition for these products, and (iii) delays in the launch of some of our new generic products. We have also experienced supply discontinuities due to regulatory actions and approval delays, which also had an impact on our ability to timely meet demand in certain instances.

Our specialty portfolio in North America has an established presence in central nervous system ( CNS ) medicines with our leading product COPAXONE®, which is among the leading products for the treatment of multiple sclerosis ( MS ) in North America. In addition, we continue to strengthen our specialty portfolio with the recent launch of AJOVY® for the treatment of migraine and the continued growth of our neurodegenerative and movement disorder treatment medicine AUSTEDO®. We are committed to maintaining a leading presence in the respiratory market by delivering a range of medicines for the treatment of asthma and chronic obstructive pulmonary disease ( COPD ). We also maintain a meaningful presence in oncology medicines.

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.

### ***Europe***

Our Europe segment includes the European Union and certain other European countries.

We are the leading generic pharmaceutical company in Europe. We are among the top three companies in more than 20 markets across Europe. No single market in Europe represents more than 25% of our total

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European generic revenues, and therefore we are not dependent on any single market that could be affected by pricing reforms or changes in public policy. In Europe, we also out-license certain generic pharmaceutical products to third parties.

Despite their diversity and highly fragmented nature, the European markets share many characteristics that allow us to leverage our pan-European presence and broad portfolio. Global customers are crucial partners in our generic business and are expanding across Europe, although customer consolidation is lower than in the United States. We are one of a few generic pharmaceutical companies with a pan-European footprint. Most competitors focus on a select few markets or business lines.

Our OTC portfolio in Europe includes global brands such as SUDOCREM® as well as local and regional brands like FLUX® in the Nordic countries.

Our specialty portfolio in Europe focuses on three main areas: CNS and pain, respiratory and oncology. Our leading product is COPAXONE, which is among the leading products for the treatment of MS in the European Union.

## ***International Markets***

Our International Markets segment includes all countries in which we operate other than those in our North America and Europe segments. These markets comprise more than 35 countries, covering a substantial portion of the global pharmaceutical market.

Our key international markets are Japan, Russia and Israel. In Japan, we operate our business through a business venture with Takeda Pharmaceutical Companies Limited ( Takeda ), in which we own a 51% stake and Takeda owns the remaining 49%. The countries in our International Markets segment range from highly regulated, pure generic markets, such as Israel, to hybrid markets, such as Japan, to branded generics oriented markets, such as Russia and certain Commonwealth of Independent States (CIS), Latin American and Asia Pacific markets.

Each market's strategy is built upon differentiation and filling the unmet needs of that market. Our integrated sales force enables us to extract synergies across our branded generic, OTC and specialty medicines product offerings and across various channels (e.g., retail, institutional).

Our specialty portfolio in International Markets focuses on three main areas: CNS and pain, respiratory and oncology.

## **Our Product Portfolio and Business Offering**

Our product and service portfolio includes generic medicines, specialty medicines, OTC products, a distribution business, API and contract manufacturing. Each region manages the entire range of products and services offered in its region and our global marketing and portfolio function optimizes our pipeline and product lifecycle across therapeutic areas. In most markets in which we operate, we use an integrated and comprehensive marketing model, offering a portfolio of generic, specialty and OTC products.

## ***Generic Medicines***

Generic medicines are the chemical and therapeutic equivalents of originator medicines and are typically more affordable in comparison to the originator's products. Generics are required to meet similar governmental requirements as their brand-name equivalents, such as those relating to manufacturing processes and health authorities' inspections, and must receive regulatory approval prior to their sale in any given country. Generic medicines may be manufactured

and marketed if relevant patents on their brand-name equivalents (and any additional government-mandated market exclusivity periods) have expired or have been challenged or otherwise circumvented.

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We develop, manufacture and sell generic medicines in a variety of dosage forms, including tablets, capsules, injectables, inhalants, liquids, ointments and creams. We offer a broad range of basic chemical entities, as well as specialized product families, such as sterile products, hormones, high-potency drugs and cytotoxic substances, in both parenteral and solid dosage forms.

Our generic business has a wide-reaching commercial presence. We are the market leader in the United States and have a top three leadership position in over 30 countries, including some of our key European markets. We have a robust product portfolio, comprehensive R&D capabilities and product pipeline and a global operational network, which enables us to execute key generic launches to further expand our product pipeline and diversify our revenue stream. We use these capabilities to mitigate price erosion in our generics business.

When considering whether to develop a generic medicine, we take into account a number of factors, including our overall strategy, regional and local patient and customer needs, R&D and manufacturing capabilities, regulatory considerations, commercial factors and the intellectual property landscape. We will challenge patents when appropriate if we believe they are either invalid or would not be infringed by our generic version. We may seek alliances to acquire rights to products we do not have in our portfolio, to share development costs or litigation risks, or to resolve patent and regulatory barriers to entry.

As part of our comprehensive restructuring plan, we have substantially optimized our generics portfolio globally, particularly in the United States, through product discontinuation and price adjustments, with a focus on increasing profitability. This will enable us to accelerate the restructuring and optimization of our manufacturing and supply network, including the closure or divestment of a significant number of manufacturing plants in the United States, Europe and International Markets.

In markets such as the United States, the United Kingdom, Canada, the Netherlands and Israel, generic medicines may be substituted by the pharmacist for their brand name equivalent or prescribed by International Nonproprietary Name (INN). In these so-called pure generic markets, physicians and patients have little control over the choice of generic manufacturer, and consequently generic medicines are not actively marketed or promoted to physicians or consumers. Instead, the relationship between the manufacturer and pharmacy chains and distributors, health funds and other health insurers is critical. Many of these markets have automatic substitution models when generics are available as alternatives to brands. In Russia, Turkey, Ukraine, Kazakhstan, certain Asia Pacific, Latin American and European countries, generic medicines are generally sold under brand names alongside the originator brand. These markets are referred to as branded generic markets and are generally out of pocket markets in which consumers can pay for a particular branded generic medicine (as opposed to government or privately funded medical health insurance), often at the recommendation of their physician. Branded generic products are actively promoted and a sales force is necessary to create and maintain brand awareness. Other markets, such as Germany, Japan, France, Italy and Spain, are hybrid markets with elements of both approaches.

Our position in the generics market is supported by our global R&D function, as well as our API R&D and manufacturing activities, which provide significant vertical integration for our products.

For information about our product launches and pipeline of generic medicines in North America and Europe, see Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Segment Information North America Segment and Item 7 Management's Discussions and Analysis of Financial Condition and Results of Operations Segment Information Europe Segment.

## ***Specialty Medicines***

Our specialty medicines business, which is focused on delivering innovative solutions to patients and providers via medicines, devices and services in key regions and markets around the world, includes our core therapeutic areas of CNS (with a strong emphasis on MS, neurodegenerative disorders, movement disorders and

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pain care including migraine) and respiratory medicines (with a focus on asthma and COPD). We also have specialty products in oncology and selected other areas.

We deploy medical and sales and marketing professionals within each therapeutic area who seek to address the needs of patients and healthcare professionals. We tailor our patient support, payer relations and medical affairs activities to the distinct characteristics of each therapeutic area and medicine.

The U.S. market is the most significant market in our specialty business. In Europe and International Markets, we leverage existing synergies between our specialty business and our generics and OTC businesses. Our specialty presence in International Markets is mainly built on our CNS franchise, with gradual development in other therapeutic areas closely related to our branded generics portfolios in those countries.

We have built specialized Patient Support Programs to help patients adhere to their treatments, improve patient outcomes and, in certain markets, to ensure timely delivery of medicines and assist in securing reimbursement. These programs reflect the importance we place on supporting patients and ensuring better medical outcomes for them. As part of our restructuring plan, we outsourced certain of these services to external vendors. Patient Support Programs are currently operated in many countries around the world in multiple therapeutic areas. We believe that it is important to provide a range of services and solutions tailored to meet the needs of patients according to their specific condition and local market requirements. We believe this capability provides an important competitive advantage in the specialty medicines market.

Below is a description of our key products:

### ***CNS and Pain***

Our **CNS and pain** portfolio includes COPAXONE for the treatment of relapsing forms of MS, AJOVY for the treatment of migraine (launched in the United States in September 2018) and AUSTEDO for the treatment of tardive dyskinesia and chorea associated with Huntington disease (launched in the United States in 2017).

### **COPAXONE**

**COPAXONE** (glatiramer acetate injection) is one of the leading MS therapies in the United States (according to IQVIA data as of January 4, 2019). COPAXONE is indicated for the treatment of patients with relapsing forms of MS ( RMS ), including the reduction of the frequency of relapses in relapsing-remitting multiple sclerosis ( RRMS ), including in patients who have experienced a first clinical episode and have MRI features consistent with MS.

COPAXONE is believed to have a unique mechanism of action that works with the immune system, unlike many therapies that are believed to rely on general immune suppression or cell sequestration to exert their effect. COPAXONE provides a proven mix of efficacy, safety and tolerability.

The FDA approved generic versions of COPAXONE 40 mg/mL in October 2017 and February 2018 and a second generic version of COPAXONE 20 mg/mL in October 2017 in the United States. Hybrid versions of COPAXONE 20 mg/mL and 40 mg/mL were also approved in the European Union.

On October 12, 2018, the U.S. Court of Appeals for the Federal Circuit ( CAFC ) handed down its ruling in the consolidated appeal of decisions from the U.S. District Court and Patent Trial and Appeal Board, relating to patents covering COPAXONE 40 mg/ml. The CAFC found all claims at issue to be invalid, and we are currently evaluating our options for further appeals. COPAXONE 40 mg/mL is protected by one European patent expiring in 2030. This patent is being challenged in Italy and Norway and has been opposed at the European Patent Office. The U.K. High Court found this patent invalid and our application for permission to appeal this decision was rejected.

The market for MS treatments continues to develop, particularly with the recent approvals of generic versions of COPAXONE discussed above, as well as additional generic versions expected to be



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approved in the future. Oral treatments for MS, such as Tecfidera®, Gilenya® and Aubagio®, continue to present significant and increasing competition. COPAXONE also continues to face competition from existing injectable products, as well as from monoclonal antibodies.

### **AJOVY (anti CGRP)**

**AJOVY** is a fully humanized monoclonal antibody that binds to calcitonin gene-related peptide ( CGRP ). On September 14, 2018, the FDA approved AJOVY (fremanezumab-vfrm) injection for the preventive treatment of migraine in adults. We launched the product in the United States immediately upon approval.

In February 2019, the European Medicines Agency ( EMA ) recommended granting a Marketing Authorization Application for AJOVY in the European Union in a centralized process. We expect regulatory action in the first half of 2019.

On May 12, 2017, we entered into a license and collaboration agreement with Otsuka Pharmaceutical Co., Ltd. ( Otsuka ) providing Otsuka with an exclusive license to conduct phase 2 and 3 clinical trials for AJOVY in Japan and, once approved, to commercialize the product in Japan.

AJOVY is also in clinical development to evaluate safety and efficacy in the treatment of episodic cluster headache as well as post traumatic headache.

AJOVY is protected by patents expiring in 2026 in Europe and in 2027 in the United States, with possibility for extension in various markets. An additional patent relating to the use of AJOVY in the treatment of migraine is issued in the United States and will expire in 2035. This patent is also pending in other countries. AJOVY will also be protected by regulatory exclusivity of 12 years from marketing approval in the United States and 10 years from marketing approval in Europe.

We have filed a lawsuit in the United States District Court for the District of Massachusetts alleging that Eli Lilly & Co. s ( Lilly ) marketing and sale of its galcanezumab product for the treatment of migraine infringes nine Teva patents. Lilly has also submitted IPR (inter partes review) petitions to the Patent Trial and Appeal Board, challenging the validity of the nine patents asserted against them in the litigation. In addition, we have entered into separate agreements with Alder Biopharmaceuticals and Lilly, resolving the European Patent Office oppositions they have filed against our AJOVY patents. The settlement agreement with Lilly also resolved Lilly s action to revoke the patent protecting AJOVY in the U.K.

### **AUSTEDO**

**AUSTEDO** (deutetrabenazine) is a deuterated form of a small molecule inhibitor of vesicular monoamine 2 transporter, or VMAT2, that is designed to regulate the levels of a specific neurotransmitter, dopamine, in the brain. The FDA granted Deutetrabenazine New Chemical Entity Exclusivity until April 2022 and Orphan Drug exclusivity for the treatment of chorea associated with Huntington disease until April 2024.

AUSTEDO was approved by the FDA and launched in April 2017 in the United States for the treatment of chorea associated with Huntington disease. In August 2017, the FDA approved AUSTEDO for the treatment of tardive dyskinesia ( TD ) in adults in the United States and we launched AUSTEDO for the treatment of TD in September 2017. TD is a debilitating, often irreversible movement disorder caused by certain medications used to treat mental health or gastrointestinal conditions.

In September 2017, we entered into a partnership agreement with Nuvelution Pharma, Inc ( Nuvelution ) for the development of AUSTEDO for the treatment of Tourette syndrome in pediatric patients in the United States.

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AUSTEDO is protected in the United States by five Orange Book patents expiring between 2031 and 2033 and in Europe by two patents expiring in 2029.

### ***Oncology***

Our **oncology** portfolio includes BENDEKA® / TREANDA®, GRANIX® and TRISENOX® in the United States and LONQUEX®, TEVAGRASTIM®/RATIOGRASTIM® and TRISENOX® outside the United States.

### **BENDEKA and TREANDA**

**BENDEKA** (bendamustine hydrochloride) injection and TREANDA (bendamustine hydrochloride) for injection are approved in the United States for the treatment of patients with chronic lymphocytic leukemia ( CLL ) and patients with indolent B-cell non-Hodgkin's lymphoma ( NHL ) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. BENDEKA, which was launched in the United States in January 2016, is a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride that we licensed from Eagle Pharmaceuticals, Inc. ( Eagle ) to complement our bendamustine franchise, which also includes TREANDA. BENDEKA is now the most-used bendamustine product in the United States. The lyophilized formulation of TREANDA continues to be available, but its use has substantially declined in favor of BENDEKA. In December 2018, TREANDA was approved in China.

Eagle launched a ready-to-dilute bendamustine hydrochloride in June 2018, which competes directly with Bendeka. Other competitors to BENDEKA include combination therapies such as R-CHOP (a combination of cyclophosphamide, vincristine, doxorubicin and prednisone in combination with rituximab) and CVP-R (a combination of cyclophosphamide, vincristine and prednisolone in combination with rituximab) for the treatment of NHL, as well as a combination of fludarabine, doxorubicin and rituximab for the treatment of CLL and newer targeted oral therapies, ibrutinib and idelalisib.

There are 15 patents listed in the U.S. Orange Book for BENDEKA with expiry dates between 2026 and 2033. Teva and Eagle received notices of Abbreviated New Drug Application ( ANDA ) filings by Slayback Pharmaceuticals, Fresenius Kabi, Apotex and Mylan for generic versions of BENDEKA, which all contained Paragraph IV challenges against one or more of the patents listed in the U.S. Orange Book for BENDEKA. In response, Teva and Eagle filed patent infringement lawsuits against Slayback, Fresenius and Apotex in August 2017 and against Mylan in December 2017. All lawsuits were filed in the U.S. District Court for the District of Delaware. The respective 30 month stays expire starting in January 2020. Additionally, in June 2018, Teva and Eagle received a notification from Hospira that it filed a 505(b)(2) new drug application ( NDA ) referencing BENDEKA. In response, Teva and Eagle filed a lawsuit in the U.S. District Court for the District of Delaware. Hospira's 30 month stay expires in December 2020.

We have U.S. Orange Book patents for TREANDA expiring between 2026 and 2031. To date, one company has filed an NDA for a liquid version of bendamustine and 21 others have filed ANDAs for a generic version of the lyophilized form of TREANDA. Trial against five of the 21 ANDA filers began in December 2015. In June 2017, the court issued a final judgement affirming the validity of certain claims of the patents. We have reached final settlements with 19 of the 21 ANDA filers, which provide for the launch of generic versions

prior to patent expiration. The two ANDA filers with whom we have not reached final settlements filed an appeal of the final judgment.

In July 2018, Eagle prevailed in its suit in the U.S. district court against the FDA to obtain seven years of orphan drug exclusivity in the United States for BENDEKA. The FDA has appealed the district court's decision, but barring a reversal by the appellate court, drug applications referencing BENDEKA will not be approved by the FDA until the orphan drug exclusivity expires in December 2022.

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### **Truxima®**

**Truxima** (rituximab-abbs) is a monoclonal antibody biosimilar to Rituxan® (rituximab). It was approved by the FDA in November 2018 for the treatment of adult patients in three indications: (i) relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma (NHL) as a single agent, (ii) previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy, and (iii) non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.

Truxima is the first rituximab biosimilar to be approved in the United States.

We entered into an exclusive partnership with Celltrion, Inc. (Celltrion) in October 2016 to commercialize Truxima in the United States and Canada.

We have reached an agreement with Genentech, Inc. (Genentech) to settle the U.S. patent litigation regarding Truxima, including entry terms.

### **Herzuma®**

**Herzuma** (trastuzumab-pkrb) is a HER2/neu receptor antagonist biosimilar to Herceptin®1 (trastuzumab). Herzuma was approved by the FDA in December 2018 for the following indications: (i) adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer, as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel or as part of a treatment regimen with docetaxel and carboplatin, and (ii) in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, or as a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.

We entered into an exclusive partnership with Celltrion in October 2016 to commercialize Herzuma in the United States and Canada.

We have reached an agreement with Genentech to settle the U.S. patent litigation regarding Truxima, including entry terms.

### ***Respiratory***

Our **respiratory** portfolio includes ProAir®, QVAR®, DuoResp Spiromax®, AirDuo RespiClick®/ ArmonAir RespiClick® and CINQAIR®/CINQAERO®.

We are committed to maintaining a leading presence in the respiratory market by delivering a range of medicines for the treatment of asthma and COPD. Our portfolio is centered on optimizing respiratory treatment for patients and healthcare providers through the development and commercialization of innovative delivery systems and therapies that help address unmet needs.

Our respiratory pipeline is based on drug molecules delivered in our proprietary dry powder formulations and breath-actuated device technologies and targeted biologics. With this portfolio, we are targeting high value markets in the respiratory area such as inhaled short-acting beta agonists, inhaled corticosteroids, fixed-dose corticosteroid and beta2 agonist combinations, long-acting muscarinic antagonist products and biologics.

The key areas of focus for our respiratory R&D include development of differentiated respiratory therapies for patients using innovative delivery systems to deliver chemical and biological therapies. Our device strategy is intended to result in device consistency, allowing physicians to choose the device that best matches a patient's needs both in terms of ease of use and effectiveness of delivery of the prescribed molecule.

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Our innovative delivery systems include:

A breath-actuated inhaler ( BAI ) recently approved in the United States for use with QVAR as QVAR ReditHaler®; and

**ProAir** Spiromax (EU) or RespiClick (U.S.), a novel inhalation-driven multi-dose dry powder inhaler ( MDPI ).

The ProAir line of products includes ProAir hydrofluoroalkane ( HFA ), ProAir RespiClick® and ProAir Digihaler , which are sold only in the United States.

**ProAir HFA** (albuterol sulfate) is an inhalation aerosol with dose counter and is indicated for patients four years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm. ProAir HFA is the leading quick relief inhaler in the United States. It is protected by various patents expiring through 2031. In June 2014, we settled a patent challenge to ProAir HFA with Perrigo Pharmaceuticals ( Perrigo ) permitting Perrigo to launch its generic product in limited quantities once it receives FDA approval and without quantity limitations after June 2018. In November 2017, we settled another patent challenge to ProAir HFA with Lupin Pharmaceuticals, Inc., et al. ( Lupin ) permitting Lupin to launch its generic product as of September 23, 2019, or earlier under certain circumstances. To date, no generic competition has been launched. In January 2019, we launched our own ProAir authorized generic.

**ProAir Digihaler** (albuterol sulfate 117 mcg) inhalation powder is the first and only digital inhaler with built-in sensors which connects to a companion mobile application and provides inhaler use information to people with asthma and COPD. ProAir Digihaler was approved by the FDA on December 21, 2018 for the treatment or prevention of bronchospasm in patients aged four years and older with reversible obstructive airway disease and for prevention of exercise-induced bronchospasm (EIB) in patients aged four years and older. ProAir Digihaler contains built-in sensors that detect when the inhaler is used and measure inspiratory flow. This inhaler-use data is then sent to the companion mobile app using Bluetooth® Wireless Technology so patients can review their data over time and, if desired, share it with their healthcare professionals. ProAir Digihaler will be available in the United States in 2019 through a small number of early experience programs, which will be conducted in partnership with healthcare systems and in limited geographies, in order to gather real-world experience. A national launch is planned for 2020.

**ProAir RespiClick** (albuterol sulfate) inhalation powder is a breath-actuated, multi-dose, dry-powder, short-acting beta-agonist inhaler for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients four years of age and older. ProAir RespiClick was approved by the FDA for use in adults and adolescents aged 12 years and older in March 2015 and its label was expanded for use by children 4 to 11 years of age in April 2016. ProAir RespiClick remains the only breath-actuated, multi-dose, dry powder, short-acting beta-agonist inhaler

available in the United States. ProAir RespiClick is protected by various U.S. Orange Book patents expiring between 2021 and 2032.

Three major brands compete with ProAir HFA and ProAir RespiClick in the United States in the short-acting beta agonist market: Ventolin<sup>®</sup> HFA (albuterol), Proventil<sup>®</sup> HFA (albuterol) and Xopenex<sup>®</sup> HFA (levalbuterol). In addition, an authorized generic version Ventolin<sup>®</sup> HFA (albuterol) was approved in January 2019.

## **QVAR**

**QVAR** (beclomethasone dipropionate HFA) is indicated as a maintenance treatment for asthma as a prophylactic therapy in patients five years of age or older. QVAR is also indicated for asthma patients



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who require systemic corticosteroid administration, where adding QVAR may reduce or eliminate the need for systemic corticosteroids. QVAR has the highest preferred and total formulary coverage in the inhaled corticosteroid class in the United States. We market QVAR, which is manufactured by 3M Pharmaceuticals, in the United States and in major European markets. QVAR is protected by various U.S. Orange Book patents expiring between 2020 and 2031.

Four major brands compete with QVAR in the mono inhaled corticosteroid segment: Flixotide/Flovent® (fluticasone), Pulmicort Flexhaler® (budesonide), Asmanex® (mometasone) and Alvesco® (ciclesonide).

**QVAR ReditHaler** (beclomethasone dipropionate HFA) inhalation aerosol, a breath actuated inhaler, was approved by the FDA in August 2017 for the maintenance treatment of asthma as a prophylactic therapy in patients four years of age and older. This product became commercially available to patients by prescription in both 40 mcg and 80 mcg strengths in February 2018. The ReditHaler device is the next generation of our QVAR product and contains the same small particle aerosol formulation as the existing QVAR in a breath-actuated device.

The actuator with dose counter used with ProAir HFA and QVAR is protected by patents and applications expiring through 2031.

QVAR ReditHaler is protected by U.S. and European device patents and applications expiring in 2031.

## **CINQAIR/CINQAERO**

**CINQAIR/CINQAERO** (reslizumab) injection, a humanized interleukin-5 antagonist monoclonal antibody for add-on maintenance treatment of adult patients with severe asthma and with an eosinophilic phenotype, received FDA, EMA and Health Canada approval in 2016. This biologic treatment became commercially available to patients in the United States in April 2016, in certain European countries in November 2016 and in Canada in 2017. Additional regulatory filings have been submitted in other markets.

CINQAIR was protected by patents in the United States that expired in 2017. We have requested extension of one of the patents until 2021. CINQAIR has biological exclusivity in the United States until 2028 and is entitled to regulatory exclusivity in Europe until 2026. A subcutaneous version is in development (see below).

Major brands competing with CINQAIR/CINQAERO in the United States, Europe and Canada in the interleukin-5 market are Nucala® (mepolizumab) and Fasenra® (benralizumab).

## **AirDuo RespiClick / ArmonAir RespiClick**

**AirDuo RespiClick** (fluticasone propionate and salmeterol inhalation powder) is a combination of an inhaled corticosteroid and a long acting beta-agonist bronchodilator, approved in the United States for the treatment of asthma in patients aged 12 years and older who are uncontrolled on an inhaled corticosteroid ( ICS ) or whose disease severity clearly warrants the use of an ICS/long-acting beta2-adrenergic agonist ( LABA ) combination.

In April 2017, we launched AirDuo RespiClick and its authorized generic simultaneously in an effort to meet the needs of patients, providers and payers in the United States seeking greater access to lower-cost asthma inhaler technology, while also allowing us to compete in the highly competitive asthma combination controller market. The authorized generic is known as fluticasone propionate and salmeterol inhalation powder (multidose dry powder inhaler).

AirDuo RespiClick and its authorized generic have the same active ingredients as Advair® but are delivered via Teva's breath-activated, MDPI, RespiClick, which is used with other approved medicines in our respiratory product portfolio.

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This important launch marked not only the first available generic ICS/LABA product in the United States, but also the continued expansion of our RespiClick family of products, which now includes breath-actuated inhaler options for both maintenance treatment and rescue medication.

**ArmonAir RespiClick** (fluticasone propionate MDPI U.S.) is a formulation of long acting ICS using our MDPI device, indicated for maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older, with an enhanced lung delivery designed to allow lower doses to achieve the same clinical outcomes as Flovent<sup>®</sup> Diskus.

Both ArmonAir RespiClick and AirDuo RespiClick were approved by the FDA in January 2017 and are protected by U.S. and European device patents and applications expiring through 2034.

**BRALTUS<sup>®</sup>**

**BRALTUS** (tiotropium bromide), a long-acting muscarinic antagonist, indicated for adult patients with COPD, delivered via the Zonda<sup>®</sup> inhaler, was launched in Europe in August 2016.

Below is a description of key products in our specialty pipeline:

<b>Product</b>	<b>Potential Indication(s)</b>	<b>Route of Administration</b>	<b>Development Phase (date entered phase 3)</b>	<b>Comments</b>
<b>CNS, Neurology and Neuropsychiatry</b>				
<b>AUSTEDO</b> (deutetrabenazine)	Tourette syndrome	Oral	3 (December 2017)	Teva and Nuvelution entered into a partnership agreement on September 19, 2017 to develop AUSTEDO for the treatment of tics associated with Tourette syndrome in pediatric patients in the United States. Nuvelution will fund and manage phase 3 clinical development, leading all operational aspects of the program. Teva will lead the regulatory process and be responsible for commercialization.
		Oral	3 (January 2019)	

TV-46000 (risperidone LAI)	Dyskinesia in cerebral palsy Schizophrenia	LAI	3 (April 2018)
<b><u>Migraine and Pain</u></b>			
AJOVY (anti CGRP)	Episodic	Subcutaneous	3 (November 2016)
	cluster headache		
	Post traumatic headache	Subcutaneous	2

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<b>Product</b>	<b>Potential Indication(s)</b>	<b>Route of Administration</b>	<b>Development Phase (date entered phase 3)</b>	<b>Comments</b>
Fasinumab	Osteoarthritis pain	Subcutaneous	3 (March 2016)	Developed in collaboration with Regeneron Pharmaceuticals, Inc. ( Regeneron ).
<i>A fully human monoclonal antibody that targets NGF, a protein that plays a central role in the regulation of pain signaling. There is evidence that NGF levels are elevated in patients with chronic pain conditions.</i>				In August 2018 Regeneron and Teva announced positive topline phase 3 results in patients with chronic pain from osteoarthritis of the knee or hip with the remaining low dose 1mg every month (1mg4W) and 1mg every two months (1mg8W).
				Fasinumab is protected by patents expiring in 2028 and will also be protected by regulatory exclusivity of 12 years from marketing approval in the United States and 10 years from marketing approval in Europe.
	Chronic lower back pain	Subcutaneous	3 (December 2017)	
<b><u>Respiratory</u></b>				
CINQAIR/CINQAERO	Severe asthma with eosinophilia	Subcutaneous	3 (August 2015)	In January 2018, we announced that the phase 3 study did not meet its primary endpoint. We are reviewing the full data to determine

ProAir e-RespiClick	Bronchospasm and exercise induced bronchitis	Oral inhalation	Submitted to FDA (September 2017)  Resubmitted to FDA (August 2018)	next steps.  Following feedback from the FDA, changes in application were implemented resulting in a re-submission of the supplemental NDA to the FDA on August 30, 2018.
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<b>Product</b>	<b>Potential Indication(s)</b>	<b>Route of Administration</b>	<b>Development Phase (date entered phase 3)</b>	<b>Comments</b>
<b><u>Oncology</u></b>				
Truxima (formerly CT-P10)	(biosimilar to Rituxan® US)		Approved by FDA (November 2018)	See Truxima above.
Herzuma (formerly CT-P06)	(biosimilar to Herceptin® US)		Approved by FDA (December 2018)	See Herzuma above.
During 2018, development of the following projects was either discontinued or transferred:				

Laquinimod development for RRMS, progressive forms of MS and Huntington disease was discontinued and we returned the development and commercialization rights to Active Biotech AB in September 2018.

Pridopidine discontinued due to pipeline prioritization.

TV-45070 discontinued. The partnership with Xenon Pharmaceuticals Inc. was terminated by mutual agreement.

**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.

We produce approximately 300 APIs for our own use and for sale to third parties in many therapeutic areas. APIs used in pharmaceutical products are subject to regulatory oversight by national health authorities. We utilize a variety of production technologies, including chemical synthesis, semi-synthetic fermentation, enzymatic synthesis, high potency manufacturing, plant extract technology and peptide synthesis. Our advanced technology and expertise in the field of solid state particle technology enable us to meet specifications for particle size distribution, bulk density, specific surface area and polymorphism, as well as other characteristics.

We sell medical devices and provide contract manufacturing services related to products divested in connection with the sale of certain business lines in the past, as well as other miscellaneous items. Our other activities are not included in our North America, Europe and International Markets segments described above.

**Research and Development**

Our R&D activities span the breadth of our business, including generic medicines (finished goods and API), specialty pharmaceuticals, biopharmaceuticals and OTC medicines.

All of our R&D activities are concentrated under one global group with overall responsibility for generics, specialty and biologics, enabling better focus and efficiency. We recently closed and sold a significant number of R&D facilities across all geographies, delivering efficiencies and substantial cost savings. During the past year, we conducted a thorough review of all R&D programs across the entire company, in generics and specialty, prioritizing

core projects and terminating others, while maintaining a substantial pipeline.

A strong focus for Teva is the development of new generic medicines. We develop generic products for the United States, Europe and our International Markets segment. Our focus is on developing complex formulations with complex technologies, which have higher barriers to entry. Generic R&D activities, which are carried out in development centers located around the world, include product formulation, analytical method development, stability testing, management of bioequivalence, bio-analytical studies, other clinical studies and registration of



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generic drugs in all of the markets where we operate. We also operate several clinics where most of our bioequivalent studies are performed. We have more than 1,550 generic products in our pre-approved global pipeline, which includes products in all stages of the approval process: pre-submission, post-submission and after tentative approval.

In addition, our generic R&D supports our OTC business in developing OTC products, as well as in overseeing the work performed by contract developers.

Current R&D capabilities include solid oral dosage forms (such as tablets and capsules), inhalation, semi-solid and liquid formulations (such as ointments and creams), sterile formulations and other dosage forms, and delivery systems, such as matrix systems, special coating systems for sustained release products, orally disintegrating systems, sterile systems, such as vials, syringes and blow-fill-seal systems, and more recently, capability build-up in long-acting release injectable, transdermal patches, oral thin film, drug device combinations and nasal delivery systems. In addition, we are in the process of developing multiple AB-rated respiratory programs and devices for our long active injectable pipeline.

Our API R&D division focuses on the development of processes for the manufacturing of APIs, including intermediates, chemicals and fermentation products, for both our generic and proprietary drugs. Our facilities include two large development centers in India and Croatia, focusing on synthetic products, and three centers with specific expertise: a center in Hungary specializing in fermentation and semi-synthetic products, a center in Israel for oligonucleotides and a center in the Czech Republic for high-potency APIs. Our substantial investment in API R&D generates a steady flow of API products, supporting the timely introduction of generic products to market. The API R&D division also seeks methods to continuously reduce API production costs, enabling us to improve our cost structure.

Our specialty R&D product pipeline is focused on biologic products, biosimilar products and discovery of new biologic candidates. Specialty development activities include preclinical assessment (including toxicology, pharmacokinetics, pharmacodynamics and pharmacology studies), clinical development (including pharmacology and the design, execution and analysis of global safety and efficacy trials), as well as regulatory strategy to deliver registration of our pipeline products.

Our specialty R&D develops novel specialty products in our core therapeutic and disease focus areas. We have CNS projects in areas such as migraine, pain, movement disorders/neurodegeneration and neuropsychiatry. Our respiratory projects are focused on asthma and COPD and include both novel compounds and delivery systems designed to address unmet patient needs. We also pursue select pipeline projects (e.g., biosimilars) in other therapeutic and disease areas that leverage our global R&D and commercial areas of expertise.

While our focus is on internal growth that leverages our R&D capabilities, we have entered into, and expect to pursue, in-licensing, acquisition and partnership opportunities to supplement and expand our existing specialty pipeline (e.g., the transactions with Celltrion, Eagle and Regeneron). In parallel, we evaluate and expand the development scope of our existing R&D pipeline products as well as our existing products for submission in additional markets.

## **Operations**

We operate our business globally and believe that our global infrastructure provides us with the following capabilities and advantages:

global R&D facilities that enable us to have a broad global generic pipeline and product line, as well as a focused pipeline of specialty products;

pharmaceutical manufacturing facilities approved by the FDA, EMA and other regulatory authorities located around the world, which offer a broad range of production technologies and the ability to concentrate production in order to achieve high quality and economies of scale;

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API manufacturing capabilities that offer a stable, high-quality supply of key APIs, vertically integrated with our pharmaceutical operations; and

high-volume, technologically advanced distribution facilities that allow us to deliver new products to our customers quickly and efficiently, providing a cost-effective, safe and reliable supply.

These capabilities provide us with the means to respond on a global scale to a wide range of therapeutic and commercial requirements of patients, customers and healthcare providers.

### ***Pharmaceutical Production***

We operate 55 finished dosage and packaging pharmaceutical plants in 22 countries. These plants manufacture solid dosage forms, sterile injectables, liquids, semi-solids, inhalers, transdermal patches and medical devices. In 2018, we produced approximately 80 billion tablets and capsules and approximately 650 million sterile units. The FDA and EMA have approved 32 and 29 of our finished dosage manufacturing facilities, respectively.

Our primary manufacturing technologies, solid dosage forms, injectables and blow-fill-seal, are available in North America, Europe, Latin America and Israel. The manufacturing sites located in Israel, Germany, Hungary, Croatia, Bulgaria, India, Spain, Poland and the Czech Republic make up the majority of our production capacity.

We use several external contract manufacturers to achieve operational and cost benefits. We continue to strengthen our third party operations unit to strategically work with our supplier base in order to meet cost, supply security and quality targets on a sustainable base in alignment with our global procurement organization.

Our policy is to maintain multiple supply sources for our strategic products and APIs to appropriately mitigate risk in our supply chain to the extent possible. However, our ability to do so may be limited by regulatory and other requirements.

In 2018, we closed or divested a significant number of manufacturing plants in Latin America, Europe, Israel and other markets in connection with implementation of our comprehensive restructuring plan announced in December 2017.

### ***Raw Materials for Pharmaceutical Production***

In general, we purchase our raw materials and supplies required for the production of our products in the open market. For some products, we purchase such raw materials and supplies from one source (the only source available to us) or a single source (the only approved source among many available to us), thereby requiring us to obtain such raw materials and supplies from that particular source. We attempt, if possible, to mitigate our raw material supply risks through inventory management and alternative sourcing strategies.

We source a large portion of our APIs from our own manufacturing facilities. Additional APIs are purchased from suppliers located in Europe, Asia and the United States. We have implemented a supplier audit program to ensure that our suppliers meet our high standards and are able to fulfill the requirements of our global operations.

We currently have 18 API production facilities, producing approximately 300 APIs in various therapeutic areas. Our API intellectual property portfolio includes approximately 650 granted patents and pending applications worldwide.

We have expertise in a variety of production technologies, including chemical synthesis, semi-synthetic fermentation, enzymatic synthesis, high-potency manufacturing, plant extract technology, peptides synthesis, vitamin D derivatives synthesis and prostaglandins synthesis. Our advanced technology and expertise in the field of solid state particle technology enable us to meet specifications for particle size distribution, bulk density, specific surface area and polymorphism, as well as other characteristics.

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Our API facilities are required to comply with applicable current Good Manufacturing Practices ( cGMP ) requirements under U.S., European, Japanese and other applicable quality standards. Our API plants are regularly inspected by the FDA, European agencies and other authorities, as applicable.

## **Patents and Other Intellectual Property Rights**

We rely on a combination of patents, trademarks, copyrights, trade secrets and other proprietary know-how and regulatory exclusivities, as well as contractual protections, to establish and protect our intellectual property rights. We own or license numerous patents covering our products in the United States and other countries. We have also developed many brand names and own many trademarks covering our products. We consider the overall protection of our intellectual property rights to be of material value and act to protect these rights from infringement. We license or assign certain intellectual property rights to third parties in connection with certain business transactions.

## **Environment, Health and Safety**

We are committed to business practices that promote socially and environmentally responsible economic growth. During 2018, we continued to make significant progress on our multi-year plan towards our long-term environment, health and safety ( EHS ) goal referred to as Target Zero : zero incidents, zero injuries and zero releases. Among other things, in 2018, we:

continued the implementation of our global EHS management system, which promotes proactive compliance with applicable EHS requirements, establishes EHS standards throughout our global operations and helps drive continuous improvement in our EHS performance;

provided EHS regulatory monitoring tools in all countries where we have significant operations; and

proactively evaluated EHS compliance through self-evaluation and an internal audit program, addressing non-conformities through appropriate corrective and preventative action.

## **Quality**

We are committed not only to complying with quality requirements but to developing and leveraging quality as a competitive advantage. In 2018, we successfully completed numerous inspections by various regulatory agencies of our finished dosage pharmaceutical plants and our pharmacovigilance function, continued discussions with authorities about drug shortages and participated in several industry-wide task forces. We continue to focus on maintaining a solid and sustainable quality compliance foundation, as well as making quality a priority beyond compliance. We seek to ensure that quality remains part of our corporate culture and is reflected in all of our operations, resulting in reliable and high quality products.

In 2018, we successfully resolved issues raised in an FDA warning letter in 2016 for our API production facility in China, following corrective actions addressing both the specific concerns raised by investigators as well as the underlying causes of those concerns. We resumed shipments from this facility in May 2017.

In January 2018, Celltrion received an FDA warning letter for its facility in Incheon, South Korea, our sole API source for AJOVY. All issues were resolved successfully and, in September 2018, we received FDA approval and

launched AJOVY in the United States.

In July 2018, the FDA completed an inspection of our manufacturing plant in Davie, Florida in the United States, and issued a Form FDA-483 to the site. In October 2018, the FDA notified us that the inspection of the site is classified as official action indicated (OAI). On February 5, 2019, we received a warning letter from the FDA that contains four enumerated concerns related to production, quality control, and investigations at this site. We are working diligently to investigate the FDA's concerns in a manner consistent with current good

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manufacturing practice (CGMP) requirements, and to address those concerns as quickly and as thoroughly as possible. If we are unable to remediate the warning letter findings to the FDA's satisfaction, we may face additional consequences, including delays in FDA approval for future products from the site, financial implications due to loss of revenues, impairments, inventory write offs, customer penalties, idle capacity charges, costs of additional remediation and possible FDA enforcement action. We expect to generate approximately \$255 million in revenues from this site in 2019, assuming remediation or enforcement does not cause any unscheduled slowdown or stoppage at the facility.

In July 2018, we announced the voluntary recall of valsartan and certain combination valsartan medicines in various countries due to the detection of trace amounts of a previously unknown impurity called NDMA found in valsartan API supplied to us by Zhejiang Huahai Pharmaceutical. Since July 2018, we have been actively engaged with regulatory agencies around the world in reviewing our valsartan and other sartan products for NDMA and other related impurities and, where necessary, have initiated additional voluntary recalls. The impact of this recall on our 2018 financial statements was \$51 million, primarily related to inventory reserves. We expect to continue to experience loss of revenues and profits in connection with this matter. In addition, multiple lawsuits have been filed in connection with this matter. We may also incur customer penalties, impairments and litigation costs going forward.

## **Geographic Areas**

Our business is conducted in many countries around the world and a significant portion of our revenues is generated from operations outside the United States. We operate our business through three segments: North America, Europe and International Markets. Each region manages our entire product portfolio, including generics, specialty and OTC products. The products we manufacture and sell around the world include many of those described above under Our Product Portfolio and Business Offering.

Investments and activities in some countries outside the United States are subject to higher risks than comparable U.S. activities because the investment and commercial climate in such countries may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties. Changes in the relative value of international currencies may also materially affect our results of operations. For a discussion of these risks, see Item 1A Risk Factors.

## **Competition**

Sales of generic medicines have benefitted from increasing awareness and acceptance on the part of healthcare insurers and institutions, consumers, physicians and pharmacists around the world. Factors contributing to this increased awareness are the passage of legislation permitting or encouraging generic substitution and the publication by regulatory authorities of lists of equivalent pharmaceuticals, which provide physicians and pharmacists with generic alternatives. In addition, various government agencies and many private managed care or insurance programs encourage the substitution of brand-name pharmaceuticals with generic products as a cost-savings measure in the purchase of, or reimbursement for, prescription pharmaceuticals.

In the United States, we are subject to competition in the generic drug market from domestic and international generic drug manufacturers and brand-name pharmaceutical companies through lifecycle management initiatives, authorized generics, existing brand equivalents and manufacturers of therapeutically similar drugs. An increase in FDA approvals for generic products is increasing the competition on our base generic products. Price competition from additional generic versions of the same product typically results in margin pressures, which is causing some generics companies to refocus their portfolio.

The European market continues to be ever more competitive, especially in terms of pricing, higher quality standards, customer service and portfolio relevance. We are one of only a few companies with a pan-European footprint, while most of our European competitors focus on a limited number of selected markets or business lines. Our leadership position in Europe allows us to be a reliable partner to fulfill the needs of patients, physicians, pharmacies, customers and payers.



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In our International Markets, our global scale and broad portfolio give us a significant competitive advantage over local competitors, allowing us to optimize our offerings through a combination of high quality medicines and unique go-to-market approaches.

Furthermore, in significant markets such as France, Japan and Russia, governments have issued or are in process of issuing regulations designed to increase generic penetration. Specifically, in Japan, ongoing regulatory pricing reductions and generic competition to off-patented products have negatively affected our sales in Japan. These conditions result in intense competition in the generic market, with generic companies competing for advantage based on pricing, time to market, reputation and customer service.

Our specialty medicines business faces intense competition from both specialty and generic pharmaceutical companies. The specialty business may continue to be affected by price reforms and changes in the political landscape, following recent public debate in the United States. We believe that our primary competitive advantages include our commercial marketing teams, global R&D capabilities, the body of scientific evidence substantiating the safety and efficacy of our various medicines, our patient-centric solutions, physician and patient experience with our medicines and our medical capabilities, which are tailored to our product offerings, regional and local markets and the needs of our stakeholders.

## **Regulation**

### **United States**

#### ***Food and Drug Administration and the Drug Enforcement Administration***

All pharmaceutical manufacturers selling products in the United States are subject to extensive regulation by the United States federal government, principally by the FDA and the Drug Enforcement Administration ( DEA ), and, to a lesser extent, by state and local governments. The Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act ( CSA ) and other federal and state statutes and regulations govern or influence the development, manufacture, testing, safety, efficacy, labeling, approval, storage, distribution, recordkeeping, advertising, promotion, sale, import and export of our products. Our facilities are periodically inspected by the FDA, which has extensive enforcement powers over the activities of pharmaceutical manufacturers. Noncompliance with applicable requirements may result in fines, criminal penalties, civil injunction against shipment of products, recall and seizure of products, total or partial suspension of production, sale or import of products, refusal of the government to enter into supply contracts or to approve NDAs, ANDAs or biologics license applications ( BLAs ) and criminal prosecution by the Department of Justice. The FDA also has the authority to deny or revoke approvals of marketing applications and the power to halt the operations of non-complying manufacturers. Any failure to comply with applicable FDA policies and regulations could have a material adverse effect on our operations.

FDA approval is required before any new drug (including generic versions of previously approved drugs) may be marketed, including new strengths, dosage forms and formulations of previously approved drugs. Applications for FDA approval must contain information relating to bioequivalence (for generics), safety, toxicity and efficacy (for new drugs), product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. FDA procedures generally require that commercial manufacturing equipment be used to produce test batches for FDA approval. The FDA also requires validation of manufacturing processes so that a company may market new products. The FDA conducts pre-approval and post-approval reviews and plant inspections to implement these requirements.

The federal CSA and its implementing regulations establish a closed system of controlled substance distribution for legitimate handlers. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements upon legitimate handlers under the oversight of the DEA. The DEA categorizes controlled substances into one of five schedules Schedule I, II, III, IV, or V with varying qualifications for listing in each schedule. Facilities that manufacture, distribute, conduct

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chemical analysis, import or export any controlled substance must register annually with the DEA. The DEA inspects manufacturing facilities to review security, record keeping and reporting and handling prior to issuing a controlled substance registration and periodically thereafter. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action, such as civil penalties, refusal to renew necessary registrations or the initiation of proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

The Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act) established the procedures for obtaining FDA approval for generic forms of brand-name drugs. This act also provides market exclusivity provisions that can delay the approval of certain NDAs and ANDAs. One such provision allows a five-year period of data exclusivity for NDAs containing new chemical entities and a three-year period of market exclusivity for NDAs (including different dosage forms) containing new clinical trial(s) essential to the approval of the application. The Orphan Drug Act grants seven years of exclusive marketing rights to a specific drug for a specific orphan indication. The term orphan drug refers, generally, to a drug that treats a rare disease affecting fewer than 200,000 Americans. Market exclusivity provisions are distinct from patent protections and apply equally to patented and non-patented drug products. Another provision of the Hatch-Waxman Act extends certain patents for up to five years as compensation for the reduction of effective life of the patent which resulted from time spent in clinical trials and time spent by the FDA reviewing a drug application.

Under the Hatch-Waxman Act, any company submitting an ANDA or an NDA under Section 505(b)(2) of the Food, Drug, and Cosmetic Act (i.e., an NDA that, similar to an ANDA, relies, in whole or in part, on FDA's prior approval of another company's drug product; also known as a 505(b)(2) application) must make certain certifications with respect to the patent status of the drug for which it is seeking approval. In the event that such applicant plans to challenge the validity or enforceability of an existing listed patent or asserts that the proposed product does not infringe an existing listed patent, it files a Paragraph IV certification. In the case of ANDAs, the Hatch-Waxman Act provides for a potential 180-day period of generic exclusivity for the first company to submit an ANDA with a Paragraph IV certification. This filing triggers a regulatory process in which the FDA is required to delay the final approval of subsequently filed ANDAs containing Paragraph IV certifications until 180 days after the first commercial marketing. For both ANDAs and 505(b)(2) applications, when litigation is brought by the patent holder, in response to this Paragraph IV certification, the FDA generally may not approve the ANDA or 505(b)(2) application until the earlier of 30 months or a court decision finding the patent invalid, not infringed or unenforceable. Submission of an ANDA or a 505(b)(2) application with a Paragraph IV certification can result in protracted and expensive patent litigation.

Products manufactured outside the United States and marketed in the United States are subject to all of the above regulations, as well as to FDA, DEA and United States customs regulations at the port of entry. Products marketed outside the United States that are manufactured in the United States are additionally subject to various export statutes and regulations, as well as regulation by the country in which the products are to be sold.

Our products also include biopharmaceutical products that are comparable to brand-name biologics, but that are not approved as biosimilar versions of such brand-name products. While regulations are still being developed by the FDA relating to the Biologics Price Competition and Innovation Act of 2009, which created a statutory pathway for the approval of biosimilar versions of brand-name biological products and a process to resolve patent disputes, the FDA has issued guidance to provide a roadmap for development of biosimilar products.

In August 2017, the FDA user fee reauthorization legislation, known as the FDA Reauthorization Act of 2017 (FDARA) was enacted in the United States. The agreements for pharmaceuticals, biosimilars and medical devices were negotiated with industry representatives over the course of 2016 to establish the amounts regulated companies would pay the FDA to support the product review process at the agency. Various fees must be paid by these

manufacturers at different times, such as annually and with the submission of different types of applications. In return for this additional funding, the FDA has entered into agreements with each of the affected industries (known as the user fee agreements ) that commit the agency to interacting with manufacturers and

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reviewing applications such as NDAs, ANDAs and BLAs in certain ways, and taking action on those applications at certain times. The agency is obligated to set specific timelines to communicate with companies, meet with company product sponsors during the review process and take action on their applications. On the generics side, FDARA established a new 180-day exclusivity for generic drugs that are no longer protected by exclusivity or patents, as well as new programs for enhanced and priority review of certain generic drug applications. On the branded side, this was the sixth agreement between the industry and the FDA. The user fee agreement for biosimilars was reauthorized for the second time as well.

### ***The Patient Protection and Affordable Care Act and Certain Government Programs***

The Patient Protection and Affordable Care Act ( ACA ) from 2010 represented the most significant health care reform in the United States in over thirty years. It was passed to require individuals to have health insurance and to control the rate of growth in healthcare spending through, among other things, stronger prevention and wellness measures, increased access to primary care, changes in healthcare delivery systems and the creation of health insurance exchanges. Enrollment in the health insurance exchanges began in October 2013. However, the individual mandate was subsequently repealed by Congress in the tax reform bill signed into law in December 2017. The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years and is likely to lead to increases in insurance premiums. In December 2018, a U.S. federal district court ruled that the ACA is unconstitutional, but such decision has been stayed and will not take effect while such decision is on appeal.

The ACA requires the pharmaceutical industry to share in the costs of reform, by, among other things, increasing Medicaid rebates and expanding Medicaid rebates to cover Medicaid managed care programs. The ACA also included funding of pharmaceutical costs for Medicare patients in excess of the prescription drug coverage limit and below the catastrophic coverage threshold. Under the ACA, pharmaceutical companies are obligated to fund 50% of the patient obligation for branded prescription pharmaceuticals in this gap, or donut hole. Additionally, an excise tax was levied against certain branded pharmaceutical products. The tax is specified by statute to be approximately \$3.5 billion in 2017, \$4.2 billion in 2018 and \$2.8 billion each year thereafter. The tax is to be apportioned to qualifying pharmaceutical companies based on an allocation of their governmental programs as a portion of total pharmaceutical government programs.

The Centers for Medicare & Medicaid Services ( CMS ) administer the Medicaid drug rebate program, in which pharmaceutical manufacturers pay quarterly rebates to each state Medicaid agency. Generally, for generic drugs marketed under ANDAs, manufacturers (including Teva) are required to rebate 13% of the average manufacturer price, and for products marketed under NDAs or BLAs, manufacturers are required to rebate the greater of 23.1% of the average manufacturer price or the difference between such price and the best price during a specified period. An additional rebate for products marketed under NDAs or BLAs is payable if the average manufacturer price increases at a rate higher than inflation and other methodologies apply to new formulations of existing drugs. This provision was extended at the end of 2015 to cover generic drugs marketed under ANDAs as well. The Association for Accessible Medicines, the generic drug manufacturers trade association, is working to undo this policy as penalty on the industry and will continue to lobby for its abolishment.

In addition, the ACA revised certain definitions used for purposes of calculating the rebates, including the definition of average manufacturer price. The Comprehensive Addiction and Recovery Act of 2016 contains language intended to exempt certain abuse-deterrent formulations of a drug from the definition of line extension for purposes of the program.

Various state Medicaid programs have implemented voluntary supplemental drug rebate programs that may provide states with additional manufacturer rebates in exchange for preferred status on a state's formulary or for patient populations that are not included in the traditional Medicaid drug benefit coverage.

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### **Europe**

#### ***General***

In Europe, marketing authorizations for pharmaceutical products may be obtained either through a centralized procedure involving the EMA, a mutual recognition procedure which requires submission of applications in other member states following approval by a so-called reference member state, a decentralized procedure that entails simultaneous submission of applications to chosen member states or occasionally through a local national procedure.

During 2018, we continued to register products in the European Union, primarily using the decentralized procedure (simultaneous submission of applications to chosen member states). We continue to use, on occasion, the mutual recognition and centralized procedures.

The European pharmaceutical industry is highly regulated and much of the legislative and regulatory framework is driven by the European Parliament and the European Commission. This has many benefits, including the potential to harmonize standards across the complex European market, but it also has the potential to create complexities affecting the entire European market.

In November 2017, the last part of the 2012 European Union regulation regarding pharmacovigilance was implemented, requiring centralized reporting in the European Union instead of individual country reporting. Under this regulation, all adverse events need to be reported regardless of severity.

#### ***European Union***

The medicines regulatory framework of the European Union requires that medicinal products, including generic versions of previously approved products and new strengths, dosage forms and formulations of previously approved products, receive a marketing authorization before they can be placed on the market in the European Union. Authorizations are granted after a favorable assessment of quality, safety and efficacy by the respective health authorities. In order to obtain authorization, application must be made to the EMA or to the competent authority of the member state concerned. Besides various formal requirements, the application must contain the results of pharmaceutical (physico-chemical, biological or microbiological) tests, pre-clinical (toxicological and pharmacological) tests and clinical trials. All of these tests must have been conducted in accordance with relevant European regulations and must allow the reviewer to evaluate the quality, safety and efficacy of the medicinal product.

In order to control expenditures on pharmaceuticals, most member states of the European Union regulate the pricing of such products and in some cases limit the range of different forms of a drug available for prescription by national health services. These controls can result in considerable price differences among member states.

In addition to patent protection, exclusivity provisions in the European Union may prevent companies from applying for marketing approval for a generic product for eight years (or ten years for orphan medicinal products) from the date of the first marketing authorization of the original product in the European Union. Further, the generic product will be barred from market entry (marketing exclusivity) for a further two years, with the possibility of extending the market exclusivity by one additional year under certain circumstances.

The term of certain pharmaceutical patents may be extended in the European Union by up to five years upon grant of Supplementary Patent Certificates ( SPC ). The purpose of this extension is to increase effective patent life (i.e., the period between grant of a marketing authorization and patent expiry) to 15 years.

Subject to the respective pediatric regulation, the holder of an SPC may obtain a further patent term extension of up to six months under certain conditions. This six-month period cannot be claimed if the license holder claims a one-year extension of the period of marketing exclusivity based on the grounds that a new pediatric indication brings a significant clinical benefit in comparison with other existing therapies.



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Orphan designated products, which receive, under certain conditions, a blanket period of ten years of market exclusivity, may receive an additional two years of exclusivity instead of an extension of the SPC if the requirements of the pediatric regulation are met.

The legislation also allows for R&D work during the patent term for the purpose of developing and submitting registration dossiers.

In 2016, the United Kingdom conducted a referendum and voted to leave the European Union, also known as Brexit. On March 29, 2017, the British government invoked Article 50 of the Treaty on the European Union and, as a result, the United Kingdom is scheduled to leave the European Union on March 29, 2019. The United Kingdom and European Union are currently in the process of defining their future relationship, but as pharmaceutical legislation in the United Kingdom is largely derived from European Union law and relies on mutual recognition of decision making, implementation of a number of practical steps is required before the United Kingdom exits the European Union. We are working on processes to ensure a smooth transition irrespective of the future relationship between the European Union and the United Kingdom.

## **International Markets**

In addition to regulations in the United States and Europe, we, and our partners, are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales, marketing and distribution of our products. Such regulations may be similar or, in some cases, more stringent than those applicable in the United States and Europe.

Whether or not we, or our partners, obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of such product in those countries. The requirements and processes governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In addition, we, and our partners, may be subject to foreign laws and regulations and other compliance requirements, including, without limitation, anti kickback laws, false claims laws and other fraud and abuse laws, as well as laws and regulations requiring transparency of pricing and marketing information and governing the privacy and security of health information.

If we, or our partners, fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

## **Miscellaneous Regulatory Matters**

We are subject to various national, regional and local laws of general applicability, such as laws regulating working conditions. We are also subject to country specific data protection laws and regulations applicable to the storage and processing of personal data around the world. In addition, we are subject to various national, regional and local environmental protection laws and regulations, including those governing the emission of material into the environment. We are also subject to various national, regional and local laws regulating how we interact with healthcare professionals and representatives of government that impact our promotional activities.

Data exclusivity provisions exist in many countries around the world and may be introduced in additional countries in the future, although their application is not uniform. In general, these exclusivity provisions prevent the approval and/or submission of generic drug applications to the health authorities for a fixed period of time following the first approval of the brand-name product in that country. As these exclusivity provisions operate independently of patent

exclusivity, they may prevent the submission of generic drug applications for some products even after the patent protection has expired.

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In October 2015, the European Commission adopted regulations providing detailed rules for the safety features appearing on the packaging of medicinal products for human use. This legislation, part of the Falsified Medicines Directive ( FMD ), is intended to prevent counterfeit medicines entering into the supply chain and will allow wholesale distributors and others who supply medicines to the public to verify the authenticity of the medicine at the level of the individual pack. The safety features comprise a unique identifier and a tamper-evident seal on the outer packaging, which are to be applied to certain categories of medicines. FMD is effective as of February 2019. Teva's packing sites for the European market comply with this new requirement.

In November 2017, the federal Drug Supply Chain Security Act became effective in the United States, mandating an industry-wide, national serialization system for pharmaceutical packaging with a ten-year phase-in process. By November 2018, all manufacturers and re-packagers were required to mark each prescription drug package with a unique serialized code. We believe that Teva's packing sites for the U.S. market comply with this new requirement. Other countries are following suit with variations of two main requirements: (i) to be able to associate the unit data with the uniquely-identified shipping package, or (ii) to report the data for tracking and tracing of products, reimbursements and other purposes. Certain countries, such as Russia, China, Korea, Turkey, Argentina, Brazil and India (for exported products), already have laws mandating serialization and we are working to comply with these requirements. Other countries, including India (domestic market), Indonesia, Malaysia, Taiwan and other Latin American countries are currently considering mandating similar requirements.

**Employees**

As of December 31, 2018, Teva's work force consisted of 42,535 full-time-equivalent employees. In certain countries, we are party to collective bargaining agreements with certain groups of employees.

The following table presents our work force by geographic area:

	<b>December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
United States	7,056	8,807	10,168
Europe	19,236	22,352	24,170
International Markets (excluding Israel)	11,351	14,387	15,759
Israel	4,893	6,245	6,863
<b>Total</b>	<b>42,535</b>	<b>51,792</b>	<b>56,960</b>

As part of our restructuring plan announced in December 2017, we are reducing approximately 25% of Teva's total work force by the end of 2019. The majority of these reductions occurred in 2018. Since the announcement of the restructuring plan, we reduced our global headcount by approximately 10,300 full-time-equivalent employees. Restructuring efforts are being conducted in accordance with applicable local requirements.

**Available Information**

Our main corporate website address is <http://www.tevapharm.com>. Copies of our Quarterly Reports on Form 10-Q, Annual Report on Form 10-K and Current Reports on Form 8-K filed or furnished to the U.S. Securities and Exchange Commission (the SEC), and any amendments to the foregoing, will be provided without charge to any shareholder submitting a written request to our company secretary at our principal executive offices or by calling 1-800-950-5089. All of our SEC filings are also available on our website at <http://www.tevapharm.com>, as soon as reasonably

practicable after having been electronically filed or furnished to the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at [www.sec.gov](http://www.sec.gov). The information on our website is not, and will not be deemed, a part of this Report or incorporated into any other filings we make with the SEC. We also file our annual reports and other information with the Israeli Securities Authority through its

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fair disclosure electronic system called MAGNA. You may review these filings on the website of the MAGNA system operated by the Israeli Securities Authority at [www.magna.isa.gov.il](http://www.magna.isa.gov.il) or on the website of the Tel Aviv Stock Exchange (the "TASE") at [www.tase.co.il](http://www.tase.co.il).

## **ITEM 1A. RISK FACTORS**

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition and results of operations could be materially adversely affected by any of these risks. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements as a result of certain factors including the risks described below and elsewhere in this report and our other SEC filings. See "Forward-Looking Statements" on page 1.

### **Risks related to our ability to successfully compete in the marketplace**

***Sales of our generic medicines comprise a significant portion of our business, and we are therefore increasingly subject to the significant risks associated with the generic pharmaceutical business.***

In 2018, revenues from sales of our generic medicines in all our business segments were \$9,671 million, or 51.3% of our total revenues. Generic pharmaceuticals are, as a general matter, less profitable than specialty pharmaceuticals, and have faced regular and increasing price erosion each year, placing even greater importance on our ability to continually introduce new products. We expect to be more dependent on sales of our generics medicines and increasingly subject to market and regulatory factors and other risks affecting generic pharmaceuticals worldwide.

Furthermore, our generics business in the United States has been, and we expect will continue to be, negatively impacted by certain developments, including: (i) pricing pressure as a result of customer consolidation into larger buying groups capable of extracting greater price reductions, (ii) an accelerated FDA approval process for generic versions of off-patent medicines, resulting in increased competition for these products and (iii) delays in the launch of some of our new generic products. We have also experienced supply disruptions due to regulatory actions and approval delays, which also had an impact on our ability to timely meet demand for certain products in particular markets.

We have also experienced, and expect to continue to experience, significant adverse challenges in the U.S. generics market deriving from limitations on our ability to influence generic medicine pricing in the long term and a decrease in value from future launches and growth. The developments in the U.S. generics market were the cause of goodwill impairments of \$17.1 billion in 2017. If these trends continue or worsen, or if we experience further difficulty in this market, this may continue to adversely affect our revenues and profits from our North America business segment.

In 2018, we experienced certain challenges in our International Markets business segment, particularly in Japan and Russia, and with our Medis reporting unit. These developments were the cause of goodwill impairments of \$3,027 million in 2018. If these trends continue or worsen, or if we experience further difficulty in International Markets, this may continue to adversely affect our revenues and profits from our International Markets business segment.

***Sales of our generic products may be adversely affected by the continuing consolidation of our customer base and commercial alliances among our customers.***

A significant portion of our sales are made to relatively few U.S. retail drug chains, wholesalers, managed care purchasing organizations, mail order distributors and hospitals. These customers have undergone significant

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consolidation and formed various commercial alliances in recent years, which may continue to increase the pricing pressures that we face in the United States. Additionally, the emergence of large buying groups, and the prevalence and influence of managed care organizations and similar institutions, have increased pressure on price, as well as terms and conditions required to do business. During 2017, certain of these Group Purchasing Organizations ( GPOs ) made aggressive requests for pricing proposals and established commercial alliances resulting in greater bargaining power. Due to such consolidation and commercial alliances, there are three large GPOs that account for approximately 85% of generics purchases in the United States. We expect the trend of increased pricing pressures from our customers and price erosion in the U.S. generics market to continue.

The traditional model for distribution of pharmaceutical products is also undergoing disruption as a result of the entry or potential entry of new competitors and significant mergers among key industry participants. For example, Amazon.com has made initial moves to develop a pharmaceutical distribution business. Also, the consolidation resulting from the merger between CVS Health and Aetna in November 2018 created a vertically integrated organization with increased control over the physician and pharmacy networks and, ultimately, over which medicines are sold to patients. In addition, several major hospital systems in the United States announced a plan to form a nonprofit company that will provide U.S. hospitals with a number of generic drugs. In January 2018, Amazon Inc., Berkshire Hathaway Inc. and JPMorgan Chase & Co., announced that they plan to join forces by forming an independent health care company for their combined one million U.S. employees. This initiative is expected to further increase competition and enhance price erosion. These changes to the traditional supply chain could lead to our customers having increased negotiation leverage and to additional pricing pressure and price erosion.

Our net sales may also be affected by fluctuations in the buying patterns of retail chains, mail order distributors, wholesalers and other trade buyers, whether resulting from seasonality, pricing, wholesaler buying decisions or other factors. In addition, since a significant portion of our U.S. revenues is derived from relatively few key customers, any financial difficulties experienced by a single key customer, or any delay in receiving payments from such a customer, could have a material adverse effect on our business, financial condition and results of operations.

***The increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products may adversely affect our revenues and profits.***

Our ability to achieve continued growth and profitability through sales of generic pharmaceuticals is dependent on our continued success in challenging patents, developing non-infringing products or developing products with increased complexity to provide opportunities with U.S. market exclusivity or limited competition.

To the extent that we succeed in being the first to market a generic version of a product, and particularly if we are the only company authorized to sell during the 180-day period of exclusivity in the U.S. market, as provided under the Hatch-Waxman Act, our sales, profits and profitability can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of an equivalent product. Even after the exclusivity period ends, there is often continuing benefit from having the first generic product in the market.

However, the number of generic manufacturers targeting significant new generic opportunities with exclusivity under the Hatch-Waxman Act, or which are complex to develop, continues to increase. Additionally, many of the smaller generic manufacturers have increased their capabilities, level of sophistication and development resources in recent years. The FDA has also been limiting the availability of exclusivity periods for new products, which reduces the economic benefit from being first-to-file for generic approvals. The failure to maintain our industry-leading performance in the United States on first-to-file opportunities and to develop and commercialize high complexity generic products could adversely affect our sales and profitability.

The 180-day market exclusivity period is triggered by commercial marketing of the generic product. However, the exclusivity period can be forfeited by our failure to obtain tentative or final approval of our product



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within a specified statutory period or to launch a product following final court decisions that are no longer subject to appeal holding the applicable patents to be invalid, unenforceable or not infringed. The Hatch-Waxman Act also contains other forfeiture provisions that may deprive the first Paragraph IV filer of exclusivity if certain conditions are met, some of which may be outside our control. Accordingly, we may face the risk that our exclusivity period is forfeited before we are able to commercialize a product.

### ***Our revenues and profits from generic products will decline as a result of competition from other pharmaceutical companies and changes in policy.***

Our generic drugs face intense competition. Prices of generic drugs may, and often do, decline, sometimes dramatically, especially as additional generic pharmaceutical companies (including low-cost generic producers based in China and India) receive approvals and enter the market for a given product and competition intensifies. Consequently, our ability to sustain our sales and profitability on any given product over time is affected by the number of companies selling such product, including new market entrants, and the timing of their approvals. The goals established under the Generic Drug User Fee Act, and increased funding of the FDA's Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition for some of our products. The FDA has stated that it has established new steps to enhance competition, promote access and lower drug prices and is approving record-breaking numbers of generic applications. While these FDA improvements are expected to benefit Teva's generic product pipeline, they will also benefit competitors that seek to launch products in established generic markets where Teva currently offers products.

Furthermore, brand pharmaceutical companies continue to defend their products vigorously through life cycle management and marketing agreements with payers, pharmacy benefits managers and generic manufacturers. For example, brand companies often sell or license their own generic versions of their products, either directly or through other generic pharmaceutical companies (so-called "authorized generics"). No significant regulatory approvals are required for authorized generics, and brand companies do not face any other significant barriers to entry into such market. Brand companies may seek to delay introductions of generic equivalents through a variety of commercial and regulatory tactics. These actions may increase the costs and risks of our efforts to introduce generic products and may delay or prevent such introduction altogether.

### ***Our leading specialty medicine, COPAXONE, faces increasing competition, including from two generic versions of our 20 mg/mL product and two generic versions of our 40 mg/mL product in the United States, as well as from orally-administered therapies.***

The FDA approved generic versions of COPAXONE 40 mg/mL in October 2017 and February 2018 and a second generic version of COPAXONE 20 mg/mL in October 2017. Hybrid versions of COPAXONE 20 mg/mL and 40 mg/mL were also approved in the European Union. Competitors have launched and may launch additional generic products in the U.S. market and these launches have reduced, and we expect will continue to reduce, our revenues from COPAXONE and our MS market share.

The market for MS treatments continues to develop, particularly with the recent approvals of generic versions of COPAXONE, as well as additional generic versions expected to be approved in the future. Oral treatments for MS, such as Tecfidera®, Gilenya® and Aubagio®, continue to present significant and increasing competition. COPAXONE also continues to face competition from existing injectable products, as well as from monoclonal antibodies.

Our COPAXONE revenues were \$2,365 million, \$3,801 million and \$4,223 million in 2018, 2017 and 2016, respectively. Following the approval of generic competition, COPAXONE's revenues and profitability have decreased and we expect will continue to decrease in the future, which is expected to have a material adverse effect on our

financial results and cash flow.

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***If generic products that compete with any of our specialty products are approved and sold, sales of our specialty products will be adversely affected.***

In addition to COPAXONE, certain of our other leading specialty medicines also face patent challenges and impending patent expirations. For example, our ProAir HFA product is expected to face generic competition in 2019 due to patent expiration in 2018 and TREANDA is expected to face generic competition prior to patent expiration in 2019.

Generic equivalents for branded pharmaceutical products are typically sold at lower costs than the branded products. After the introduction of a competing generic product, a significant percentage of the prescriptions previously written for the branded product are often written for the generic version. Legislation enacted in most U.S. states allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product in the absence of specific instructions from the prescribing physician. Pursuant to the provisions of the Hatch Waxman Act, manufacturers of branded products often bring lawsuits to enforce their patent rights against generic products released prior to the expiration of branded products' patents, but it is possible for generic manufacturers to offer generic products while such litigation is pending. As a result, branded products typically experience a significant loss in revenues following the introduction of a competing generic product, even if subject to an existing patent. Our specialty products are or may become subject to competition from generic equivalents because our patent protection expired or may expire soon. In addition, we may not be successful in our efforts to extend the proprietary protection afforded our specialty products through the development and commercialization of proprietary product improvements and new and enhanced dosage forms.

***Our specialty pharmaceutical products face intense competition from companies that have greater resources and capabilities.***

We face intense competition to our specialty pharmaceutical products. Many of our competitors are larger and/or have substantially longer experience in the development, acquisition and marketing of branded, innovative and consumer-oriented products. They may be able to respond more quickly to new or emerging market preferences or to devote greater resources to the development and marketing of new products and/or technologies than we can. As a result, any products and/or innovations that we develop may become obsolete or noncompetitive before we can recover the expenses incurred in connection with their development. In addition, we must demonstrate the benefits of our products relative to competing products that are often more familiar or otherwise better established to physicians, patients and third-party payers. If competitors introduce new products or new variations on their existing products, our marketed products, even those protected by patents, may be replaced in the marketplace or we may be required to lower our prices. For example, AJOVY, which was launched in the United States in September 2018, faces competition from two products that were introduced into the market around the same time and are competing for market share in the same space.

In addition, our specialty pharmaceutical products require much greater use of a direct sales force than does our core generics business. Our ability to realize significant revenues from direct marketing and sales activities depends on our ability to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. We may also need to enter into co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or sufficiently well-aligned to achieve maximum market penetration. Any failure to attract or retain qualified sales personnel or to enter into third-party arrangements on favorable terms could prevent us from successfully maintaining current sales levels or commercializing new innovative and specialty products.

***We have experienced, and may continue to experience, delays in launches of our new generic products.***

Although we believe we have one of the most extensive pipelines of generic products in the industry, we were unable to successfully execute a number of key generic launches in 2017 and 2018. Certain launches

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planned for 2019 may also be delayed due to unforeseen circumstances. As a result of these delays, we may not realize the economic benefits previously anticipated in connection with these launches due to increased competition in the market for such products or otherwise. If we cannot execute timely launches of new products, we may not be able to offset the increasing price erosion on existing products in the United States resulting from pricing pressures and accelerated generics approvals for competing products. Such delays can be caused by many factors, including delays in regulatory approvals, lack of operational readiness or patent litigation. Delays in launches of new generic products could have a material adverse effect on our business, financial condition and results of operations.

### ***Investments in our pipeline of specialty and other products may not achieve expected results.***

We must invest significant resources to develop specialty medicines, both through our own efforts and through collaborations and in-licensing or acquisition of products from or with third parties. In particular, in light of the recent approvals of generic versions of COPAXONE and the patent challenges and impending patent expirations facing certain of our other specialty medicines, we have in recent years increased our investments in the acquisition and development of products to build our specialty pipeline, including through our acquisitions of Auspex Pharmaceuticals, Inc. and Labrys Biologics, Inc. and in-licensing transactions with Celltrion, Eagle and Regeneron.

The development of specialty medicines involves processes and expertise different from those used in the development of generic medicines, which increase the risk of failure. For example, the time from discovery to commercial launch of a specialty medicine can be 15 years or more and involves multiple stages, including intensive preclinical and clinical testing and highly complex, lengthy and expensive approval processes, which vary from country to country. The longer it takes to develop a new product, the less time that remains to recover development costs and generate profits.

During each stage, we may encounter obstacles that delay the development process and increase expenses, potentially forcing us to abandon a potential product in which we may have invested substantial amounts of time and money. These obstacles may include preclinical failures, difficulty enrolling patients in clinical trials, delays in completing formulation and other work needed to support an application for approval, adverse reactions or other safety concerns arising during clinical testing, insufficient clinical trial data to support the safety or efficacy of the product candidate and delays or failure to obtain the required regulatory approvals for the product candidate or the facilities in which it is manufactured. For example, results of the phase 2 clinical trial evaluating the safety and efficacy of laquinimod as a treatment for Huntington's disease were reported in July 2018, and the product candidate did not meet its primary endpoint. We discontinued and returned the development and commercialization rights for this product to Active Biotech in September 2018. Also, in June 2018, we announced the discontinuation of the fremanezumab trial for chronic cluster headache following a pre-specified futility analysis that revealed that the primary endpoint of mean change from baseline in the monthly average number of cluster headache attacks during the 12-week treatment period is unlikely to be met.

Because of the amounts required to be invested in strengthening our pipeline of specialty and other products, we are increasingly reliant on partnerships and joint ventures with third parties, such as our collaborations with Celltrion, Eagle, Otsuka, Nuvelution and Regeneron, and consequently face the risk that some of these third parties may fail to perform their obligations or fail to reach the levels of success that we are relying on to meet our revenue and profit goals. For example, in January 2018, Celltrion received an FDA warning letter for its facility in Incheon, South Korea, which caused a delay for the approval and launch of AJOVY until September 2018, as well as delays in approval of Truxima and Herzuma. There is a trend in the specialty pharmaceutical industry of seeking to outsource drug development by acquiring companies with promising drug candidates and we face substantial competition from historically innovative companies, as well as companies with greater financial resources than us, for such acquisition targets.



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***We may be unable to take advantage of the increasing number of high-value biosimilar opportunities.***

We aim to be a global leader in biopharmaceuticals and in November and December 2018 we received FDA approvals for Truxima and Herzuma, biosimilar candidates to Herceptin® and Rituxan®, respectively, through our exclusive partnership with Celltrion. We intend to develop a product pipeline and manufacturing capabilities for biosimilar products. Biosimilar products are expected to make up an increasing proportion of the high-value generic opportunities in upcoming years. The development, manufacture and commercialization of biosimilar products require specialized expertise and are very costly and subject to complex regulation, which is still evolving. We are behind many of our competitors in developing biosimilars and will require significant investments and collaborations with third parties to take advantage of these opportunities. Failure to develop and commercialize biosimilars could have a material adverse effect on our business, financial condition, results of operations and prospects.

***If pharmaceutical companies are successful in limiting the use of generic products through their legislative, regulatory and other efforts, our sales of generic products may suffer.***

Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

making changes to the formulation of the brand product and asserting that potential generic competitors must demonstrate bioequivalency or comparable abuse-resistance to the reformulated brand product;

pursuing new patents for existing products which may be granted just before the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generic competitors;

selling the brand product as their own generic equivalent (an authorized generic), either by the brand company directly, through an affiliate or by a marketing partner;

using the Citizen Petition process to request amendments to FDA standards or otherwise delay generic drug approvals;

seeking changes to U.S. Pharmacopeia, an organization which publishes industry recognized compendia of drug standards;

attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled;

using the legislative and regulatory process to set definitions of abuse deterrent formulations to protect brand company patents and profits;

attaching patent extension amendments to unrelated federal legislation;

engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing;

entering into agreements with pharmacy benefit management companies that have the effect of blocking the dispensing of generic products; and

seeking patents on methods of manufacturing certain API.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products may decline. A material decline in generic product sales could have a material adverse effect on our business, financial condition and results of operations.

***From time to time we may need to rely on licenses to proprietary technologies, which may be difficult or expensive to obtain.***

We may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market products. If we are unable to timely obtain these licenses on commercially reasonable



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terms, our ability to commercially market our products may be inhibited or prevented, which could have a material adverse effect on our business, financial condition and results of operations. For example, because we license significant intellectual property with respect to certain of our products, any loss or suspension of our rights to licensed intellectual property could have a material adverse effect on our business, financial condition and results of operations.

***We depend on the effectiveness of our patents, confidentiality agreements and other measures to protect our intellectual property rights.***

The success of our specialty medicines business depends substantially on our ability to obtain patents and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products identical or similar to ours. We have been issued numerous patents covering our specialty medicines, and have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the United States. Currently pending patent applications may not result in issued patents or be approved on a timely basis or at all. Any existing or future patents issued to or licensed by us may not provide us with any competitive advantages for our products or may be challenged or circumvented by competitors or governments.

During 2017 and 2018, generic versions were approved for COPAXONE, and we suffered an adverse court ruling and unfavorable appeal board decisions in lawsuits and proceedings challenging the validity and/or enforceability of the U.S. patents covering COPAXONE 40 mg/mL, which is our most significant single contributor to revenues and profits. Efforts to defend the validity of our patents are expensive and time-consuming, and there can be no assurance that such efforts will be successful. Our ability to enforce our patents also depends on the laws of individual countries and each country's practices regarding the enforcement of intellectual property rights. The loss of patent protection or regulatory exclusivity on specialty medicines could materially impact our business, results of operations, financial condition and prospects.

We also rely on trade secrets, unpatented proprietary know-how, trademarks, regulatory exclusivity and continuing technological innovation that we seek to protect, in part by confidentiality agreements with licensees, suppliers, employees and consultants. These measures may not provide adequate protection for our unpatented technology. If these agreements are breached, it is possible that we will not have adequate remedies. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors or we may not be able to maintain the confidentiality of information relating to such products. If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our intellectual property rights, our results of operations, financial condition and cash flows could suffer.

**Risks related to our substantial indebtedness**

***We have substantial debt of \$28,916 million as of December 31, 2018, which has increased our expenses and restricts our ability to incur additional indebtedness or engage in other transactions.***

Our consolidated debt was \$28,916 million at December 31, 2018, compared to \$32,475 million at December 31, 2017. If we are unable to meet our debt service obligations and other financial obligations, we could be forced to restructure or refinance our indebtedness and other financial transactions, seek additional debt or equity capital or sell our assets. We might then be unable to obtain such financing or capital or sell our assets on satisfactory terms, if at all. Any refinancing of our indebtedness could be at significantly higher interest rates, incur significant transaction fees or include more restrictive covenants. See Item 7 Management's Discussion and Analysis of Financial Condition and

Results of Operations Liquidity and note 11 to our consolidated financial statements for a detailed discussion of our outstanding indebtedness.

We may have lower-than-anticipated cash flows in the future, which could further reduce our available cash. Although we believe that we will have access to cash sufficient to meet our business objectives and capital needs,

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this reduced availability of cash could constrain our ability to grow our business. We may have lower-than-anticipated net income in the future. Our revolving credit facility includes certain restrictive covenants, including the requirement to maintain compliance with a net debt to EBITDA ratio, which becomes more restrictive over time. As of December 31, 2018, we did not have any outstanding debt under the revolving credit facility. Assuming utilization of the revolving credit facility and under specified circumstances, including non-compliance with such covenants and the unavailability of any waiver, amendment or other modification thereto and the expiration of any applicable grace period thereto, substantially all of our other debt could be negatively impacted by non-compliance with such covenants.

As of December 31, 2018, we were in compliance with all applicable financial ratios. We continue to take steps to reduce our debt levels and improve profitability to ensure continual compliance with the financial maintenance covenants. If such covenant will not be met, we believe we will be able to renegotiate and amend the covenants, or refinance the debt with different repayment terms to address such situation as circumstances warrant. We have amended such covenants in the past, including the net debt to EBITDA ratio covenant to permit a higher ratio, most recently on February 1, 2018. Although we have successfully negotiated amendments to our loan agreements in the past, we cannot guarantee that we will be able to amend such agreements on terms satisfactory to us, or at all, if required to maintain compliance in the future. If we experience lower than required earnings and cash flows to continue to maintain compliance and efforts could not be successfully completed on commercially acceptable terms, we may curtail additional planned spending, may divest additional assets in order to generate enough cash to meet our debt requirements and all other financial obligations.

This substantial level of debt and lower levels of cash flow and earnings have severely impacted our business and resulted in the restructuring plan announced in December 2017, including: (i) a substantial reduction in our global workforce; (ii) substantial optimization of our generics medicines portfolio; (iii) the restructuring and optimization of our manufacturing and supply network, including the closure or divestment of a significant number of manufacturing plants around the world; (iv) a thorough review of R&D programs in preparation of the closure or divestment of a significant number of R&D facilities, headquarters and other office locations across all geographies; (v) a review of additional potential divestments of non-core assets; and (vi) the suspension of dividend payments to holders of ordinary shares.

Our substantial net debt could also have other important consequences to our business, including, but not limited to:

making it more difficult for us to satisfy our obligations;

limiting our ability to borrow additional funds and increasing the cost of any such borrowing;

increasing our vulnerability to, and reducing our flexibility to respond to, general adverse economic and industry conditions;

limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;

placing us at a competitive disadvantage as compared to our competitors, to the extent that they are not as highly leveraged; and

restricting us from pursuing certain business opportunities.

***We may need to raise additional funds in the future, which may not be available on acceptable terms or at all.***

We may consider issuing additional debt or equity securities in the future to refinance existing debt or for general corporate purposes, including to fund potential acquisitions or investments. If we issue ordinary equity, convertible preferred equity or convertible debt securities to raise additional funds, our existing shareholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to

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those of our existing shareholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest and potentially lowering our credit ratings. We may not be able to market such issuances on favorable terms, or at all, in which case, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements.

***If our credit ratings are further downgraded by leading rating agencies, we may not be able to raise debt or borrow funds in amounts or on terms that are favorable to us, if at all.***

Our credit ratings impact the cost and availability of future borrowings and, accordingly, our cost of capital. Our ratings at any time will reflect each rating organization's then opinion of our financial strength, operating performance and ability to meet our debt obligations. Following the completion of the Actavis Generics acquisition, Standard and Poor's Financial Services LLC (Standard and Poor's) and Moody's Investor Service, Inc. (Moody's) downgraded our ratings to BBB and Baa2, respectively, compared to A- and A2, respectively, prior to the announcement of the acquisition in July 2015. In February 2017, following the court ruling invalidating our COPAXONE 40 mg/mL patents, both Standard and Poor's and Moody's changed our ratings outlook from stable to negative. In August 2017, following our release of revised 2017 guidance, both Standard and Poor's and Moody's downgraded our rating to BBB- and Baa3, respectively. In November 2017, Fitch Ratings Inc. (Fitch) downgraded our rating to non-investment grade, from BBB- to BB, with a negative outlook. On January 12, 2018, Moody's downgraded our rating to non-investment grade from Baa3 to Ba2, with a stable outlook. On February 8, 2018, Standard and Poor's downgraded our rating to non-investment grade from BBB- to BB, with a stable outlook.

The downgrade of our ratings to non-investment grade by Fitch, Moody's and Standard & Poor's limits our ability to borrow at interest rates consistent with the interest rates that were available to us prior to such downgrades. This may limit our ability to sell additional debt securities or borrow money in the amounts, at the times or interest rates, or upon the terms and conditions that would have been available to us if our previous credit ratings had been maintained.

## **Additional risks related to our business and operations**

***Failure to effectively execute our restructuring plan may adversely affect our business, financial condition and results of operations.***

In December 2017, we announced a comprehensive restructuring plan aimed at restoring our financial security and stabilizing our business by realizing operational efficiencies and reducing our total cost base by \$3 billion by the end of 2019. The restructuring plan includes:

substantial optimization of the generics portfolio globally, and most specifically in the United States, through a more tailored approach to the portfolio with increased focus on profitability;

closure or divestment of a significant number of manufacturing plants in the United States, Europe, Israel and International Markets;

closure or divestment of a significant number of R&D facilities, headquarters and other office locations across all geographies; and

a thorough review of all R&D programs across the Company to prioritize core projects and immediately terminate others.

The restructuring plan is expected to result in the reduction of approximately 25% of Teva's total workforce by the end of 2019. We recorded restructuring charges of approximately \$488 million in 2018 due to the implementation of the restructuring plan.

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We may not be able to achieve the level of benefit that we expect to realize from the restructuring plan within the expected time frame, or at all, due to unforeseen difficulties, delays or costs.

We may face wrongful termination, discrimination or other legal claims from employees affected by the workforce reduction. We may incur substantial costs defending against such claims, regardless of their merits, and such claims may significantly increase our severance costs. Additionally, we may see variances in the estimated severance costs depending on the category of employees and locations in which severance is incurred.

As part of plant closures and the transfer of production of pharmaceutical products to other sites, we are required to obtain the consent of customers and the relevant regulatory agencies. Delay or failure in obtaining such consents may have a material negative impact on our ability to effectively execute the restructuring plan. Withdrawal of business and operations from a market may result in claims for breach of contract from third parties, such as vendors, suppliers, contractors and customers that may materially impact the financial benefits of such move.

Upon the proposed divestiture of any facility in connection with our restructuring plan, we may not be able to divest such facility at a favorable price or in a timely manner. Any divestiture that we are unable to complete may cause additional costs associated with retaining the facility or closing and disposing of the impacted businesses.

The restructuring and streamlining of our manufacturing network and resulting announcements of the sale or closure of a significant number of manufacturing sites around the world could trigger labor unrest or strikes, potentially resulting in significant product supply disruptions.

The restructuring plan may lead to the loss of certain tax benefits we currently receive in Israel, which may have a material impact on our overall financial results.

The workforce reduction and site consolidation in connection with the restructuring plan, specifically the site consolidation in the United States, including the relocation of our principal U.S. headquarters from North Wales, Pennsylvania to Parsippany, New Jersey, may result in the loss of numerous long-term employees, the loss of institutional knowledge and expertise, the reallocation of certain job responsibilities and the disruption of business continuity, all of which could negatively affect operational efficiencies and increase our operating expenses in the short term.

Our failure to effectively execute the restructuring plan may lead to significant volatility, and a decline, in the price of our securities. This may expose us to securities class action and shareholder derivative litigation, potentially resulting in substantial costs and expenses.

We cannot guarantee that the restructuring plan will be successful and we may need to take additional restructuring steps in the future to achieve the goals announced in December 2017.

***Uncertainties related to, and failure to achieve, the potential benefits and success of our senior management team and organizational structure may adversely affect our business, strategy, financial condition and results of operations.***

Effective November 1, 2017, Kåre Schultz joined Teva as President and Chief Executive Officer. Mr. Schultz is our seventh CEO since 2007 and sixth since 2012. In November 2017, we announced a new organizational and leadership structure, including:

the departure of three executive officers from Teva;

the internal promotion of six executives to Teva's executive management team;



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the combination of Teva's generic and specialty global groups into one commercial organization responsible for Teva's entire portfolio, including generics, specialty and OTC, which will operate through three regions, North America, Europe and International Markets;

the combination of Teva's generic and specialty R&D organizations into a global group with overall responsibility for all R&D activities, including generics, specialty and biologics; and

the formation of a Marketing & Portfolio function responsible for overseeing the interface between regions, R&D and operations.

Any significant leadership change or executive management transition involves risks. If there was a failure to effectively transfer knowledge or information as part of the leadership transition process, it may hinder our strategic planning, execution and anticipated performance.

The expected cost savings and operational efficiencies from the organizational structure introduced in November 2017 are based on assumptions and expectations, which are reasonable in our judgment, but may not be accurate due to unforeseen difficulties and challenges that are beyond our control. If these assumptions and expectations are incorrect, our business operations and financial results may be harmed.

The establishment of a new management team following the relatively frequent senior management transitions in recent years may result in difficulty in recruiting, hiring, motivating and retaining talented and skilled personnel and difficulty in negotiating, maintaining or consummating business or strategic relationships or transactions. If we are unable to mitigate these or other potential risks, our business and operating results may be adversely impacted.

### ***The ongoing review of our R&D programs may harm our pipeline of future products.***

During 2018, we closed or sold a significant number of R&D facilities across all geographies after conducting a thorough review of R&D programs across the company. This review led to termination of R&D programs that were in advanced stages, which has caused disruptions to our R&D programs and product pipeline. In addition, we may not realize the anticipated benefits of such closures and divestments, including the efficiencies and substantial cost savings expected, and such closures and divestments may result in difficulty maintaining a substantial pipeline of future generic and specialty products.

### ***Our success depends on our ability to develop and commercialize additional pharmaceutical products.***

Our financial results depend upon our ability to develop and commercialize additional generic, specialty and biopharmaceutical products in a timely manner, particularly in light of the launch of generic competitors to the 40 mg/mL version of our leading specialty medicine, COPAXONE, and patent challenges and impending patent expirations facing certain of our other specialty medicines. Commercialization requires that we successfully develop, test and manufacture pharmaceutical products. All of our products must receive regulatory approval and meet (and continue to comply with) regulatory and safety standards; if health or safety concerns arise with respect to a product, we may be forced to withdraw it from the market. Developing and commercializing additional pharmaceutical products is also subject to difficulties relating to the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients; preclusion from commercialization by the proprietary rights of others; the costs of manufacture and commercialization; costly legal actions brought by our competitors that may delay or prevent development or commercialization of a new product; and delays and costs associated with the approval process of the FDA and other U.S. and international regulatory agencies.

The development and commercialization process, particularly with respect to specialty and biosimilar medicines, as well as the complex generic medicines that we increasingly focus on, is both time-consuming and costly, and involves a high degree of business risk. Our products currently under development, if and when fully developed and tested, may not perform as we expect. Necessary regulatory approvals may not be obtained in a

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timely manner, if at all, and we may not be able to produce and market such products successfully and profitably. Delays in any part of the process or our inability to obtain regulatory approval of our products could adversely affect our operating results by restricting or delaying our introduction of new products.

***We may be subject to further adverse consequences following our resolution with the United States government of our FCPA investigations and related matters.***

We are required to comply with the U.S. Foreign Corrupt Practices Act (the "FCPA") and similar anti-corruption laws in other jurisdictions around the world where we do business. Compliance with these laws has been the subject of increasing focus and activity by regulatory authorities, both in the United States and elsewhere, in recent years. Actions by our employees, or by third-party intermediaries acting on our behalf, in violation of such laws, whether carried out in the United States or elsewhere in connection with the conduct of our business (including the conduct described below) have exposed us, and may further expose us, to significant liability for violations of the FCPA or other anti-corruption laws and accordingly may have a material adverse effect on our reputation, business, financial condition and results of operations.

For several years, we conducted a voluntary worldwide investigation into business practices that may have implications under the FCPA, following the receipt, beginning in 2012, of subpoenas and informal document requests from the SEC and the Department of Justice ("DOJ") with respect to compliance with the FCPA in certain countries. In December 2016, we reached a resolution with the SEC and DOJ to fully resolve these FCPA matters. The resolution, which relates to conduct in Russia, Mexico and Ukraine during 2007-2013, provides for: penalties of approximately \$519 million, which include a fine, disgorgement and prejudgment interest; a three-year deferred prosecution agreement ("DPA"); a guilty plea by our Russian subsidiary to criminal charges of violations of the anti-bribery provisions of the FCPA; consent to entry of a final judgment against us settling civil claims of violations of the anti-bribery, internal controls and books and records provisions of the FCPA; and the retention of an independent compliance monitor for a period of three years. The SEC civil consent and DOJ deferred prosecution agreement have each obtained court approval. A court has also accepted the guilty plea entered by our Russian subsidiary and the negotiated settlement.

Under our DPA with the DOJ, we admitted to the conduct that violated the FCPA described in the statement of facts attached to the DPA and the DOJ agreed to defer the prosecution of certain FCPA-related charges against us and not to bring any further criminal or civil charges against us or any of our subsidiaries related to such conduct. We agreed, among other things, to continue to cooperate with the DOJ, review and maintain our anti-bribery compliance program and retain an independent compliance monitor. If, during the term of the DPA (approximately three years, unless extended), the DOJ determines that we have committed a felony under federal law, provided deliberately false or misleading information or otherwise breached the DPA, we could be subject to prosecution and additional fines or penalties, including the deferred charges.

As a result of the settlement and the underlying conduct, our sales and operations in the affected countries may be negatively impacted, and we may be subject to additional criminal or civil penalties or adverse impacts, including lawsuits by private litigants or investigations and fines imposed by authorities other than the U.S. government. We have received inquiries from governmental authorities in certain of the countries referenced in our resolution with the SEC and DOJ and we entered into a contingent cessation of proceedings arrangement with Israeli authorities regarding an investigation into the conduct that was the subject of the FCPA investigation and resulted in the above-mentioned resolution with the SEC and DOJ, requiring us to pay approximately \$22 million. In addition, there can be no assurance that the remedial measures we have taken and will take in the future will be effective or that there will not be a finding of a material weakness in our internal controls. Any one or more of the foregoing, including any violation of the DPA, could have a material adverse effect on our reputation, business, financial condition and results

of operations.

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***Sanctions and other trade control laws create the potential for significant liabilities, penalties and reputational harm.***

As a company with global operations, we may be subject to national laws as well as international treaties and conventions controlling imports, exports, re-export and diversion of goods (including finished goods, materials, APIs, packaging materials, other products and machines), services and technology. These include import and customs laws, export controls, trade embargoes and economic sanctions, denied party watch lists and anti-boycott measures (collectively "Customs and Trade Controls"). Applicable Customs and Trade Controls are administered by Israel's Ministry of Finance, the U.S. Treasury's Office of Foreign Assets Control (OFAC), other U.S. agencies and multiple other agencies of other jurisdictions around the world where we do business. Customs and Trade Controls relate to a number of aspects of our business, including most notably the sales of finished goods and API as well as the licensing of our intellectual property. Compliance with Customs and Trade Controls has been the subject of increasing focus and activity by regulatory authorities, both in the United States and elsewhere, in recent years. Although we have policies and procedures designed to address compliance with Customs and Trade Controls, actions by our employees, by third-party intermediaries (such as distributors and wholesalers) or others acting on our behalf in violation of relevant laws and regulations may expose us to liability and penalties for violations of Customs and Trade Controls and accordingly may have a material adverse effect on our reputation and our business, financial condition and results of operations.

***Manufacturing or quality control problems may damage our reputation for quality production, demand costly remedial activities and negatively impact our financial results.***

As a pharmaceutical company, we are subject to substantial regulation by various governmental authorities. For instance, we must comply with requirements of the FDA, EMA and other healthcare regulators with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to strictly comply with these regulations and requirements may damage our reputation and lead to financial penalties, compliance expenditures, the recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the applicable regulator's review of our submissions, enforcement actions, injunctions and criminal prosecution. We must register our facilities, whether located in the United States or elsewhere, with the FDA as well as regulators outside the United States, and our products must be made in a manner consistent with cGMP, or similar standards in each territory in which we manufacture. In addition, the FDA and other agencies periodically inspect our manufacturing facilities. Following an inspection, an agency may issue a notice listing conditions that are believed to violate cGMP or other regulations, or a warning letter for violations of regulatory significance that may result in enforcement action if not promptly and adequately corrected.

In recent years, there has been increasing regulatory scrutiny of pharmaceutical manufacturers, resulting in product recalls, plant shutdowns and other required remedial actions. We have been subject to increasing scrutiny of our manufacturing operations and in previous years several of our own facilities and those of our vendors and manufacturing partners have been the subject of significant regulatory actions requiring substantial expenditures of resources to ensure compliance with more stringently applied production and quality control regulations. For example:

we undertook corrective actions in 2017 to address quality issues raised in connection with an FDA audit and warning letter regarding our API production facility in China;

Celltrion received an FDA warning letter for its facility in Incheon, South Korea in January 2018. Although these issues were resolved successfully and we received FDA approval and launched AJOVY in September 2018, if mitigation plans are not completed to the FDA's satisfaction, this could cause future supply constraints;

following an inspection of our manufacturing plant in Davie, Florida, the FDA issued a Form FDA-483 and in October 2018 notified us that the inspection of the site is classified as official action indicated (OAI). On February 5, 2019, we received a warning letter from the FDA that contains four enumerated concerns related to production, quality control, and investigations at this site. If we are unable to

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remediate the warning letter findings to the FDA's satisfaction, we may face additional consequences, including delays in FDA approval for future products from the site, financial implications due to loss of revenues, impairments, inventory write offs, customer penalties, idle capacity charges, costs of additional remediation and possible FDA enforcement action; and

we announced the voluntary recall of valsartan and certain combination valsartan medicines in various countries due to the detection of trace amounts of an unexpected impurity in the API provided by our third party supplier in July 2018.

These regulatory actions also adversely affected our ability to supply various products worldwide and to obtain new product approvals at such facilities. If any regulatory body were to require one or more of our significant manufacturing facilities to cease or limit production, our business and reputation could be adversely affected. In addition, because regulatory approval to manufacture a drug is site-specific, the delay and cost of remedial actions or obtaining approval to manufacture at a different facility could also have a material adverse effect on our business, financial condition and results of operations.

***The manufacture of our products is highly complex, and an interruption in our supply chain or problems with internal or third party information technology systems could adversely affect our results of operations.***

Our products are either manufactured at our own facilities or obtained through supply agreements with third parties. Many of our products are the result of complex manufacturing processes, and some require highly specialized raw materials. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, natural disasters, and environmental factors. For some of our key raw materials, we have only a single, external source of supply, and alternate sources of supply may not be readily available. For instance, AJOVY is currently manufactured solely by Celltrion. If our supply of certain raw materials or finished products is interrupted from time to time, or proves insufficient to meet demand, our cash flows and results of operations could be adversely impacted. Moreover, as we accelerate the streamlining of our manufacturing network, as part of the restructuring plan announced in December 2017, we may become more dependent on certain plants and operations for our supply. Our inability to timely manufacture any of our significant products could have a material adverse effect on our business, financial condition and results of operations.

We also rely on complex shipping arrangements to and from the various facilities of our supply chain. Customs clearance and shipping by land, air or sea routes rely on and may be affected by factors that are not in our full control or are hard to predict.

The workforce reduction and site consolidation in connection with the restructuring plan may result in the loss of numerous long-term employees, the loss of institutional knowledge and expertise, and the reallocation of certain job responsibilities, all of which could negatively affect operational efficiencies.

In addition, we rely on complex information technology systems, including Internet-based systems, to support our supply-chain processes as well as internal and external communications. The size and complexity of our systems make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes that may result in the loss of key information or the impairment of production and other supply chain processes. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operation.

***Significant disruptions of our information technology systems or breaches of our data security could adversely affect our business.***

A significant invasion, interruption, destruction or breakdown of our information technology systems and/or infrastructure by persons with authorized or unauthorized access could negatively impact our business and operations. In the ordinary course of our business, we collect and store sensitive data in our data centers and on



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our networks, including intellectual property, proprietary business information (both ours and that of our customers, suppliers and business partners) and personally identifiable information of our employees. We are subject to laws and regulations governing the collection, use and transmission of personal information, including health information. As the legislative and regulatory landscape for data privacy and protection continues to evolve around the world, there has been an increasing focus on privacy and data protection issues that may affect our business, including the U.S. federal Health Insurance Portability and Accountability Act of 1996, as amended ( HIPAA ), the EU s General Data Protection Regulation ( GDPR ), and other laws and regulations governing the collection, use, disclosure and transmission of data. We could also experience business interruption, information theft, legal claims and liability, regulatory penalties and/or reputational damage from cyber-attacks, which may compromise our systems and lead to data leakage either internally or at our third party providers. Our systems have been, and are expected to continue to be, the target of malware and other cyber-attacks. Although we have invested in measures to reduce these risks, we cannot guarantee that these measures will be successful in preventing compromise and/or disruption of our information technology systems and related data.

***The failure to recruit or retain key personnel, or to attract additional executive and managerial talent, could adversely affect our business.***

Given the size, complexity and global reach of our business and our multiple areas of focus, we are especially reliant upon our ability to recruit and retain highly qualified management and other employees. Our ability to retain key employees may be diminished by the recent restructuring announcements and financial challenges we face. In addition, the success of our R&D activities depends on our ability to attract and retain sufficient numbers of skilled scientific personnel, which may be limited by the streamlining and reduction of our R&D programs as part of our restructuring announced in December 2017. Any loss of service of key members of our organization, or any diminution in our ability to continue to attract high-quality employees, may delay or prevent the achievement of major business objectives.

Our President and CEO, Kåre Schultz, who was appointed after a thorough global search process, initiated the restructuring plan for our business in December 2017. If we cannot retain our CEO, we may have difficulty finding a replacement in a timely manner. This may impact our ability to effect our restructuring plan and business strategy and may also have a material adverse effect on our business, financial condition and results of operation.

***Because our facilities are located throughout the world, we are subject to varying intellectual property laws that may adversely affect our ability to manufacture our products.***

We are subject to intellectual property laws in all countries where we have manufacturing facilities. Modifications of such laws or court decisions regarding such laws may adversely affect us and may impact our ability to produce and export products manufactured in any such country in a timely fashion. Additionally, the existence of third-party patents in such countries, with the attendant risk of litigation, may cause us to move production to a different country (potentially leading to significant production delays) or otherwise adversely affect our ability to export certain products from such countries.

***We have significant operations globally, including in countries that may be adversely affected by political or economic instability, major hostilities or acts of terrorism, which exposes us to risks and challenges associated with conducting business internationally.***

We are a global pharmaceutical company with worldwide operations. Although approximately 49% of our sales are in the United States and Western Europe, an increasing portion of our sales and operational network are located in other regions, such as Latin America, Central and Eastern Europe and Asia, which may be more susceptible to political and

economic instability. Other countries and regions, such as the United States and Western Europe, also face potential instability due to political and other developments. In the United States,

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although the reforms in the U.S. tax code did not include a border adjustment tax or other restrictions on trade, if such tax or restriction were to be implemented in the future, this could interfere with international trade in pharmaceuticals. In addition, in the United States, the executive administration has discussed, and in some cases implemented, changes with respect to certain trade policies, tariffs and other government regulations affecting trade between the United States and other countries. As a company that manufactures most of its products outside the United States, a border adjustment tax or other restriction on trade, if enacted, may have a material adverse effect on our business, financial condition and results of operations. In addition, given that a significant portion of our business is conducted in the European Union, including the U.K., the formal change in the relationship between the U.K. and the European Union caused by the U.K. referendum to leave the European Union, referred to as Brexit, may pose certain implications to our research, commercial and general business operations in the U.K. and the European Union, including the approval and supply of our products. Details on how Brexit will be executed and the impact on the remaining European Union countries will dictate how and whether the broader European Union will be impacted and what the resulting impact on our business may be.

Significant portions of our operations are conducted outside the markets in which our products are sold, and accordingly we often import a substantial number of products into such markets. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship products from any of our sites as a result of a closing of the borders of the countries in which we sell our products, or in which our operations are located, due to economic, legislative, political and military conditions, including hostilities and acts of terror, in such countries. In addition, certain countries have put regulations in place requiring local manufacturing of goods, while foreign-made products are subject to pricing penalties or even bans from participation in public procurement auctions.

We face additional risks inherent in conducting business internationally, including compliance with laws and regulations of many jurisdictions that apply to our international operations. These laws and regulations include data privacy requirements, labor relations laws, tax laws, competition regulations, import and trade restrictions, economic sanctions, export requirements, the Foreign Corrupt Practices Act, the UK Bribery Act 2010 and other local laws that prohibit corrupt payments to governmental officials or certain payments or remunerations to customers. Given the high level of complexity of these laws, there is a risk that some provisions may be breached by us, for example through fraudulent or negligent behavior of individual employees (or third parties acting on our behalf), our failure to comply with certain formal documentation requirements, or otherwise. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violation could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our ability to attract and retain employees, our business, our financial condition and our results of operations.

Our corporate headquarters and a sizable portion of our manufacturing activities are located in Israel. Our Israeli operations are dependent upon materials imported from outside Israel. Accordingly, our operations could be materially and adversely affected by acts of terrorism or if major hostilities were to occur in the Middle East or trade between Israel and its present trading partners were materially impaired, including as a result of acts of terrorism in the United States or elsewhere.

### ***A significant portion of our revenues is derived from sales to a limited number of customers.***

A significant portion of our revenues are derived from sales to a limited number of customers. If we were to experience a significant reduction in or loss of business with one or more such customers, or if one or more such customers were to experience difficulty in paying us on a timely basis, our business, financial condition and results of operations could be materially adversely affected. During the years ended December 31, 2018, 2017 and 2016,

McKesson Corporation represented 12%, 16% and 15% of our revenues, respectively, and AmerisourceBergen Corporation represented 14%, 15% and 19% of our revenues, respectively.

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***We may not be able to find or successfully bid for suitable acquisition targets or licensing opportunities, or consummate and integrate future acquisitions.***

We may evaluate or pursue potential acquisitions, collaborations and licenses, among other transactions. Relying on acquisitions and other transactions as sources of new specialty, biosimilar and other products, or a means of growth, involves risks that could adversely affect our future revenues and operating results. For example:

Appropriate opportunities to enable us to execute our business strategy may not exist, or we may fail to identify them.

Competition in the pharmaceutical industry for target companies and development programs has intensified and has resulted in decreased availability of, or increased prices for, suitable transactions. We may not be able to pursue relevant transactions due to financial capacity constraints.

We may not be able to obtain necessary regulatory approvals, including those of competition authorities, and as a result, or for other reasons, we may fail to consummate an announced acquisition.

The negotiation of transactions may divert management's attention from our existing business operations, resulting in the loss of key customers and/or personnel and exposing us to unanticipated liabilities.

We may fail to integrate acquisitions successfully in accordance with our business strategy or achieve expected synergies and other results. Integrating the operations of multiple new businesses with that of our own is a complex, costly and time-consuming process, which requires significant management attention and resources. The integration process may disrupt the businesses and, if implemented ineffectively, would preclude realization of the full benefits expected by us.

We may not be able to retain experienced management and skilled employees from the businesses we acquire and, if we cannot retain such personnel, we may not be able to attract new skilled employees and experienced management to replace them.

We may purchase a company that has excessive known or unknown contingent liabilities, including, among others, patent infringement or product liability claims, or that otherwise has significant regulatory or other issues not revealed as part of our due diligence.

***We may decide to sell assets, which could adversely affect our prospects and opportunities for growth.***

We may from time to time consider selling certain assets if we determine that such assets are not critical to our strategy or we believe the opportunity to monetize the asset is attractive or for various other reasons, including for the reduction of indebtedness. In connection with our restructuring plan announced in December 2017, we closed or divested a significant number of manufacturing plants and R&D facilities, and may close or divest additional plants and facilities. We have explored and may continue to explore the sale of certain non-core assets. We may fail to

identify appropriate opportunities to divest assets on terms acceptable to us. If divestiture opportunities are found, consummation of any such divestiture may be subject to closing conditions, including obtaining necessary regulatory approvals, including those of competition authorities, and as a result, or for other reasons, we may fail to consummate an announced divestiture. Although our expectation is to engage in asset sales only if they advance or otherwise support our overall strategy, any such sale could reduce the size or scope of our business, our market share in particular markets or our opportunities with respect to certain markets.

#### **Compliance, regulatory and litigation risks**

*We are subject to extensive governmental regulation, which can be costly and subject our business to disruption, delays and potential penalties.*

We are subject to extensive regulation by the FDA and various other U.S. federal and state authorities and the EMA and other foreign regulatory authorities. The process of obtaining regulatory approvals to market a drug

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or medical device can be costly and time-consuming, and approvals might not be granted for future products, or additional indications or uses of existing products, on a timely basis, if at all. Delays in the receipt of, or failure to obtain approvals for, future products, or new indications and uses, could result in delayed realization of product revenues, reduction in revenues and substantial additional costs. For example, in 2017 and 2018 we experienced delays in obtaining anticipated approvals for various generic and specialty products, and we may continue to experience similar delays.

In addition, no assurance can be given that we will remain in compliance with applicable FDA and other regulatory requirements once approval or marketing authorization has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices, product labeling, and advertising and post marketing reporting, including adverse event reports and field alerts due to manufacturing quality concerns. Our facilities are subject to ongoing regulation, including periodic inspection by the FDA and other regulatory authorities, and we must incur expense and expend effort to ensure compliance with these complex regulations. In addition, we are subject to regulations in various jurisdictions, including the Federal Drug Supply Chain Security Act in the U.S., the Falsified Medicines Directive in the EU and many other such regulations in other countries that require us to develop electronic systems to serialize, track, trace and authenticate units of our products through the supply chain and distribution system. Compliance with these regulations may result in increased expenses for us or impose greater administrative burdens on our organization, and failure to meet these requirements could result in fines or other penalties.

Failure to comply with all applicable regulatory requirements may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, shutdown of production, revocation of approvals or the inability to obtain future approvals, or exclusion from future participation in government healthcare programs. Any of these events could disrupt our business and have a material adverse effect on our revenues, profitability and financial condition.

### ***Healthcare reforms, and related reductions in pharmaceutical pricing, reimbursement and coverage, by governmental authorities and third-party payers may adversely affect our business.***

The continuing increase in expenditures for healthcare has been the subject of considerable government attention almost everywhere we conduct business. Both private health insurance funds and government health authorities continue to seek ways to reduce or contain healthcare costs, including by reducing or eliminating coverage for certain products and lowering reimbursement levels. The focus on reducing or containing healthcare costs has been increased by controversies, political debate and publicity about prices for pharmaceutical products that some consider excessive, including Congressional and other inquiries into drug pricing, including with respect to our specialty medicines, which could have a material adverse effect on our reputation. In most of the countries and regions where we operate, including the United States, Western Europe, Israel, Russia, certain countries in Central and Eastern Europe and several countries in Latin America, pharmaceutical prices are subject to new government policies designed to reduce healthcare costs, and may be subject to additional regulatory efforts, funding restrictions, legislative proposals, policy interpretations, investigations and legal proceedings regarding pricing practices. These changes frequently adversely affect pricing and profitability and may cause delays in market entry. Public scrutiny has increased political and other pressures on pharmaceutical pricing, further inhibiting the raising of prices, which, in many cases, had become routine. Certain U.S. states have implemented, and other states are considering, pharmaceutical price controls or patient access constraints under the Medicaid program, and some jurisdictions are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Private third-party payers, such as health plans, increasingly challenge pharmaceutical product pricing, which could result in lower prices, lower reimbursement rates and a reduction in demand for our products. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products,

which could have a material adverse effect on our business, financial condition and results of operations.



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Significant developments that may adversely affect pricing in the United States include (i) the enactment of federal healthcare reform laws and regulations, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the ACA and (ii) trends in the practices of managed care groups and institutional and governmental purchasers, including the impact of consolidation of our customers. Changes to the healthcare system enacted as part of healthcare reform in the United States, as well as the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, may result in increased pricing pressure by influencing, for instance, the reimbursement policies of third-party payers. Healthcare reform legislation has increased the number of patients who have insurance coverage for our products, but provisions such as the assessment of a branded pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs may have an adverse effect on us. It is uncertain how current and future reforms in these areas will influence the future of our business operations and financial condition. In 2017, a new executive administration, which had promised to repeal and replace the ACA, took office in the United States. In December 2018, a U.S. federal district court ruled that the ACA is unconstitutional, but such decision has been stayed and will not take effect while such decision is on appeal. We cannot predict the outcome of litigation regarding the constitutionality of the ACA or the form any replacement of the ACA may take, if any, although it may have the impact of reducing the number of insured individuals as well as coverage for pharmaceutical products.

In addition, tender systems for generic pharmaceuticals have been implemented (by both public and private entities) in a number of significant markets in which we operate, including Germany and Russia, in an effort to lower prices. Under such tender systems, manufacturers submit bids that establish prices for generic pharmaceutical products. These measures impact marketing practices and reimbursement of drugs and may further increase pressure on reimbursement margins. Certain other countries may consider the implementation of a tender system. Failing to win tenders or our withdrawal from participating in tenders, or the implementation of similar systems in other markets leading to further price declines, could have a material adverse effect on our business, financial position and results of operations.

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

Certain governmental and regulatory agencies are focused on the abuse of opioid medications in the United States. Federal, state and local governmental and regulatory agencies are conducting investigations of us, other pharmaceutical manufacturers and other supply chain participants with regard to the manufacture, sale, marketing and distribution of opioid medications. A number of state attorneys general, including a coordinated multistate effort, are investigating our sales and marketing of opioids and we have received subpoena requests from the DOJ seeking documents relating to the manufacture, marketing and sale of opioid medications. In addition, we are currently litigating civil claims brought by various states and political subdivisions as well as private claimants, against various manufacturers, distributors and retail pharmacies throughout the United States. These claims are brought against Teva in connection with our manufacture, sale and distribution of opioids. Responding to governmental investigations and managing legal proceedings is costly and involves a significant diversion of management attention. Such proceedings are unpredictable and may develop over lengthy periods of time. An adverse resolution of any of these lawsuits or investigations may involve substantial monetary penalties and could have a material and adverse effect on our reputation, business, results of operations and cash flows. See Government Investigations and Litigation Relating to Pricing and Marketing in note 13 to our consolidated financial statements.

***Governmental investigations into sales and marketing practices may result in substantial penalties.***

We operate around the world in complex legal and regulatory environments, and any failure to comply with applicable laws, rules and regulations may result in civil and/or criminal legal proceedings. As those rules and regulations change

or as interpretations of those rules and regulations evolve, our prior conduct or that of companies we have acquired may be called into question. In the United States, we are currently responding to

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federal investigations into our marketing practices with regard to several of our specialty pharmaceutical products, which could result in civil litigation brought on behalf of the federal government. Responding to such investigations is costly and involves a significant diversion of management attention. Such proceedings are unpredictable and may develop over lengthy periods of time. Future settlements may involve large monetary penalties. In addition, government authorities have significant leverage to persuade pharmaceutical companies to enter into corporate integrity agreements, which can be expensive and disruptive to operations. See Government Investigations and Litigation Relating to Pricing and Marketing in note 13 to our consolidated financial statements. Following calls in recent years from policy makers and other stakeholders in many countries for governmental intervention against the high prices of certain pharmaceutical products, we may be subject to governmental investigations, claims or other legal action or regulatory action regarding our pricing. It is not possible to predict the ultimate outcome of any such investigations or claims or what other investigations or lawsuits or regulatory responses may result from such assertions, and could have a material adverse effect on our reputation, business, financial condition and results of operations.

***Investigations of the calculation of wholesale prices may adversely affect our business.***

Many government and third-party payers, including Medicare, Medicaid, Health Maintenance Organization ( HMOs ) and Managed Care Organization ( MCOs ), have historically reimbursed doctors, pharmacies and others for the purchase of certain prescription drugs based on a drug's average wholesale price ( AWP ) or wholesale acquisition cost ( WAC ). In the past several years, U.S. state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP and WAC, in which they have suggested that reporting of inflated AWP's or WAC's has led to excessive payments for prescription drugs. These investigations, if leading to successful proceedings or settlements, could adversely affect us and may have a material adverse effect on our business, financial condition and results of operations.

***Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products, and we have sold and may in the future elect to sell products prior to the final resolution of outstanding patent litigation, and, as a result, we could be subject to liability for damages in the United States, Europe and other markets where we do business.***

Our ability to introduce new products depends in large part upon the success of our challenges to patent rights held by third parties or our ability to develop non-infringing products. Based upon a variety of legal and commercial factors, we may elect to sell a product even though patent litigation is still pending, either before any court decision is rendered or while an appeal of a lower court decision is pending. The outcome of such patent litigation could, in certain cases, materially adversely affect our business. For example, we launched a generic version of Protonix® (pantoprazole) despite pending litigation with the company that sells the brand versions, which we eventually settled in 2013 for \$1.6 billion.

If we sell products prior to a final court decision, whether in the United States, Europe or elsewhere, and such decision is adverse to us, we could be required to cease selling the infringing products, causing us to lose future sales revenue from such products and to face substantial liabilities for patent infringement, in the form of either payment for the innovator's lost profits or a royalty on our sales of the infringing products. These damages may be significant, and could materially adversely affect our business. In the United States, in the event of a finding of willful infringement, the damages assessed may be up to three times the profits lost by the patent owner. Because of the discount pricing typically involved with generic pharmaceutical products, patented brand products generally realize a significantly higher profit margin than generic pharmaceutical products. As a result, the damages assessed may be significantly higher than our profits. In addition, even if we do not suffer damages, we may incur significant legal and related expenses in the course of successfully defending against infringement claims.



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### ***We may be susceptible to significant product liability claims that are not covered by insurance.***

Our business inherently exposes us to claims for injuries allegedly resulting from the use of our products. As our portfolio of available products expands, particularly with new specialty products, we may experience increases in product liability claims asserted against us. The potential for product liability claims may increase further upon the implementation of proposed regulations in the United States that would permit companies to change the labeling of their generic products.

With respect to product liability exposure for products we sell outside of the United States, we have limited insurance coverage, which is subject to varying levels of deductibles and/or self-insured retentions. For product liability exposure in the United States, although in the past we have had limited coverage, with very high deductibles and/or self-insured retentions, we are no longer buying coverage for product liability claims arising in the United States. Product liability coverage for pharmaceutical companies, including us, is increasingly expensive and difficult to obtain on reasonable terms. In addition, where claims are made under insurance policies, insurers may reserve the right to deny coverage on various grounds.

### ***Our patent settlement agreements, which are important to our business, face increased government scrutiny in both the United States and Europe, and may expose us to significant damages.***

We have been involved in numerous litigations involving challenges to the validity or enforceability of listed patents (including our own), and therefore settling patent litigations has been and will likely continue to be an important part of our business. Parties to such settlement agreements in the United States, including us, are required by law to file them with the Federal Trade Commission ( FTC ) and the Antitrust Division of the DOJ for review. In June 2013, the United States Supreme Court held, in *Federal Trade Commission v. Actavis, Inc.* (the *AndroGel* case ), that a rule of reason test analyzing settlements in their entirety should be applied to determine whether such settlements violate the federal antitrust laws. This test has resulted in increased scrutiny of Teva's patent settlements, including by the FTC and state and local authorities, and an increased risk of liability in Teva's currently pending antitrust litigations. Accordingly, we may receive formal or informal requests from the FTC for information about a particular settlement agreement, and there is a risk that the FTC, customers, other downstream purchasers or others, may commence an action against us alleging violations of antitrust laws. We are currently defendants in private antitrust actions, as well as actions brought by the FTC, involving numerous settlement agreements.

The European Commission ( EU Commission ) is also placing intense scrutiny on the European pharmaceutical sector in general, including on patent settlement agreements, and has found that several patent settlement agreements had the goal of infringing competition. Such findings were confirmed by the European General Court. The increased scrutiny of the European pharmaceutical sector by the European Commission or other national authorities may also have an adverse impact on our results of operations in Europe. See *Competition Matters* in note 13 to our consolidated financial statements.

### ***Any failure to comply with the complex reporting and payment obligations under the Medicare and Medicaid programs may result in further litigation or sanctions, in addition to those that we have announced in previous years.***

The U.S. laws and regulations regarding Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. The subjective decisions and complex methodologies used in making calculations under these programs are subject to review and challenge, and it is possible that such reviews could result in material changes. A number of state attorney generals and others have filed lawsuits alleging that we and other pharmaceutical companies

reported inflated average wholesale prices, leading to excessive payments by Medicare and/or Medicaid for prescription drugs. Such allegations could, if proven or settled, result in additional monetary penalties (beyond the lawsuits we have already settled) and possible exclusion from Medicare,

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Medicaid and other programs. In addition, we are notified from time to time of governmental investigations regarding drug reimbursement or pricing issues. See Government Investigations and Litigation Relating to Pricing and Marketing in note 13 to our consolidated financial statements. Certain parts of Medicare benefits are under scrutiny, as the U.S. Congress looks for ways to reduce government spending on prescription medicines.

***Our failure to comply with applicable environmental laws and regulations worldwide could adversely impact our business and results of operations.***

We are subject to laws and regulations concerning the environment, safety matters, regulation of chemicals and product safety in the countries where we manufacture and sell our products or otherwise operate our business. These requirements include regulation of the handling, manufacture, transportation, storage, use and disposal of materials, including the discharge of pollutants into the environment. If we fail to comply with these laws and regulations, we may be subject to enforcement proceedings including fines and penalties. In the normal course of our business, we are also exposed to risks relating to possible releases of hazardous substances into the environment, which could cause environmental or property damage or personal injuries, and which could require remediation of contaminated soil and groundwater. Under certain laws, we may be required to remediate contamination at certain of our properties, regardless of whether the contamination was caused by us or by previous occupants or users of the property.

### **Additional financial risks**

***Because we have substantial international operations, our sales and profits may be adversely affected by currency fluctuations and restrictions as well as credit risks.***

In 2018, approximately 48% of revenues were denominated in currencies other than the U.S. dollar. As a result, we are subject to significant foreign currency risks, including repatriation restrictions in certain countries, and may face heightened risks as we enter new markets. An increasing proportion of our sales, particularly in Latin America, Central and Eastern European countries and Asia, are recorded in local currencies, which exposes us to the direct risk of devaluations, hyperinflation or exchange rate fluctuations. Exchange rate movements during 2018 in comparison with 2017 positively impacted overall revenues by \$152 million and positively impacted our operating income by \$4 million. The imposition of price controls or restrictions on the conversion of foreign currencies could also have a material adverse effect on our financial results.

In particular, although the majority of our net sales and operating costs is recorded in, or linked to, the U.S. dollar, our reporting currency, in 2018 we incurred a substantial amount of operating costs in currencies other than the U.S. dollar.

As a result, fluctuations in exchange rates between the currencies in which such costs are incurred and the U.S. dollar may have a material adverse effect on our results of operations, the value of balance sheet items denominated in foreign currencies and our financial condition.

We use derivative financial instruments and hedging techniques to manage some of our net exposure to currency exchange rate fluctuations in the major foreign currencies in which we operate. However, not all of our potential exposure is covered, and some elements of our consolidated financial statements, such as our equity position or operating profit, are not fully protected against foreign currency exposures. Therefore, our exposure to exchange rate fluctuations could have a material adverse effect on our financial results.

***Our intangible assets may continue to lead to significant impairments in the future.***

We regularly review our long-lived assets, including identifiable intangible assets, goodwill and property, plant and equipment, for impairment. Goodwill and acquired indefinite life intangible assets are subject to impairment review on an annual basis and whenever potential impairment indicators are present. Other long-



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lived assets are reviewed when there is an indication that impairment may have occurred. The amount of goodwill, identifiable intangible assets and property, plant and equipment on our consolidated balance sheet has increased significantly in the past five years mainly as a result of our acquisitions. In 2017, we recorded goodwill impairments of \$17.1 billion and impairments of intangible assets of \$3.2 billion. In 2018, we recorded goodwill impairments of \$3,027 million and impairments of intangible assets of \$1,991 million. Changes in market conditions or other changes in the future outlook of value may lead to further impairments in the future. In addition, the potential divestment of certain assets, including the closure or divestment of a significant number of manufacturing plants and R&D facilities, headquarters and other office locations as part of our restructuring plan announced in December 2017, may lead to additional impairments. Future events or decisions may lead to asset impairments and/or related charges. For assets that are not impaired, we may adjust the remaining useful lives. Certain non-cash impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment. Any significant impairment could have a material adverse effect on our results of operations.

### ***Our tax liabilities could be larger than anticipated.***

We are subject to tax in many jurisdictions, and significant judgment is required in determining our provision for income taxes. Likewise, we are subject to audit by tax authorities in many jurisdictions. In such audits, our interpretation of tax legislation may be challenged and tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions under our inter-company agreements.

Although we believe our estimates are reasonable, the ultimate outcome of such audits and related litigation could be different from our provision for taxes and may have a material adverse effect on our consolidated financial statements and cash flows.

The base erosion and profit shifting ( BEPS ) project undertaken by the Organization for Economic Cooperation and Development ( OECD ) may have adverse consequences to our tax liabilities. The BEPS project contemplates changes to numerous international tax principles, as well as national tax incentives, and these changes, when adopted by individual countries, could adversely affect our provision for income taxes. Countries have only recently begun to translate the BEPS recommendations into specific national tax laws, and it remains difficult to predict the magnitude of the effect of such new rules on our financial results.

### ***The termination or expiration of governmental programs or tax benefits, or a change in our business, could adversely affect our overall effective tax rate.***

Our tax expenses and the resulting effective tax rate reflected in our consolidated financial statements may increase over time as a result of changes in corporate income tax rates, other changes in the tax laws of the various countries in which we operate or changes in our product mix or the mix of countries where we generate profit. We have benefited, and currently benefit, from a variety of Israeli and other government programs and tax benefits that generally carry conditions that we must meet in order to be eligible to obtain such benefits. If we fail to meet the conditions upon which certain favorable tax treatment is based, we would not be able to claim future tax benefits and could be required to refund tax benefits already received. Additionally, some of these programs and the related tax benefits are available to us for a limited number of years, and these benefits expire from time to time.

Any of the following could have a material effect on our overall effective tax rate:

some government programs may be discontinued, or the applicable tax rates may increase;

we may be unable to meet the requirements for continuing to qualify for some programs and the restructuring plan may lead to the loss of certain tax benefits we currently receive;

these programs and tax benefits may be unavailable at their current levels;

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upon expiration of a particular benefit, we may not be eligible to participate in a new program or qualify for a new tax benefit that would offset the loss of the expiring tax benefit; or

we may be required to refund previously recognized tax benefits if we are found to be in violation of the stipulated conditions.

### **Equity ownership risks**

***Shareholder rights and responsibilities as a shareholder are governed by Israeli law, which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.***

The rights and responsibilities of the holders of our ordinary shares are governed by our articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders of U.S. corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising his or her rights and performing his or her obligations towards the company and other shareholders, and to refrain from abusing his or her power in the company, including, among other things, in voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

***Provisions of Israeli law and our articles of association may delay, prevent or make difficult an acquisition of us, prevent a change of control and negatively impact our share price.***

Israeli corporate law regulates acquisitions of shares through tender offers and mergers, requires special approvals for transactions involving directors, officers or significant shareholders, and regulates other matters that may be relevant to these types of transactions. Furthermore, Israeli tax considerations may make potential acquisition transactions unappealing to us or to some of our shareholders. For example, Israeli tax law may subject a shareholder who exchanges his or her ordinary shares for shares in a foreign corporation to taxation before disposition of the investment in the foreign corporation. These provisions of Israeli law may delay, prevent or make difficult an acquisition of our company, which could prevent a change of control and, therefore, depress the price of our shares.

In addition, our articles of association contain certain provisions that may make it more difficult to acquire us, such as provisions that provide for a classified Board of Directors and that our Board of Directors may issue preferred shares. These provisions may have the effect of delaying or deterring a change in control of us, thereby limiting the opportunity for shareholders to receive a premium for their shares and possibly affecting the price that some investors are willing to pay for our securities.

***We do not expect to pay dividends in the near future.***

Although we have paid dividends in the past, we do not expect to pay dividends in the near future. Any decision to declare and pay dividends in the future will be made by our Board of Directors, and will depend on, among other things, our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors may deem relevant. Accordingly, investors cannot rely on dividend income from our ordinary shares, and any returns in the near future on an investment in our ordinary shares

will likely depend entirely upon any future appreciation in the price of our ordinary shares.

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***Our ADSs and ordinary shares are traded on different markets and this may result in price variations.***

Our ADSs have been traded in the United States since 1982, and since 2012 on the New York Stock Exchange (the NYSE), and our ordinary shares have been listed on the TASE since 1951. Trading in our securities on these markets takes place in different currencies (our ADSs are traded in U.S. dollars and our ordinary shares are traded in New Israeli Shekels), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Israel). As a result, the trading prices of our securities on these two markets may differ due to these factors. In addition, any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

***It may be difficult to enforce a non-Israeli judgment against us, our officers and our directors.***

We are incorporated in Israel. Certain of our executive officers and directors and our outside auditors are not residents of the United States, and a substantial portion of our assets and the assets of these persons are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce against us or any of those persons in an Israeli court a U.S. court judgment based on the civil liability provisions of the U.S. federal securities laws. It may also be difficult to effect service of process on these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to enforce civil liabilities under U.S. federal securities laws in original actions filed in Israel.

***Substantial future sales or the perception of sales of our ADSs or ordinary shares, or securities convertible into our ADSs or ordinary shares, could cause the price of our ADSs or ordinary shares to decline.***

Sales of substantial amounts of our ADSs or ordinary shares, or securities convertible into our ADSs or ordinary shares, in the public market, or the perception that these sales could occur, could adversely affect the price of our ADSs and ordinary shares, and could impair our ability to raise capital through the sale of such securities.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

We own or lease 90 manufacturing and R&D facilities, occupying approximately 32.3 million square feet. As of December 31, 2018, our manufacturing and R&D facilities are used by our business segments as follows:

<b>Business Segment</b>	<b>Number of Facilities</b>	<b>Square Feet (in thousands)</b>
North America	21	4,970
Europe	31	14,744
International Markets	38	12,548
Worldwide Total Manufacturing and R&D Facilities	90	32,262

In addition to the manufacturing facilities discussed above, we maintain numerous office, distribution and warehouse facilities around the world.

We generally seek to own our manufacturing and R&D facilities, although some, principally in non-U.S. locations, are leased. Office, distribution and warehouse facilities are often leased.

We are committed to maintaining all of our properties in good operating condition and repair, and the facilities are well utilized.

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In Israel, our principal executive offices and corporate headquarters in Petach-Tikva are leased until December 2021. We expect to move our corporate headquarters to a consolidated site in Tel-Aviv in 2020.

In the United States, our principal leased properties are our North American headquarters, warehousing and distribution centers and offices in North Wales and Frazer, Pennsylvania. We are currently in the process of relocating our principal U.S. headquarters to Parsippany, New Jersey.

Following implementation of our comprehensive restructuring plan announced in December 2017, we intend to accelerate the optimization of our manufacturing and supply network, including the closure or divestment of a significant number of manufacturing plants around the world.

## **ITEM 3. LEGAL PROCEEDINGS**

Information pertaining to legal proceedings can be found in Item 8 Financial Statements Note 13b. Contingencies and is incorporated by reference herein.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## **PART II**

## **ITEM 5. MARKET FOR THE COMPANY'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

### **American Depositary Shares ( ADSs )**

Our ADSs, which have been traded in the United States since 1982, were admitted to trade on the Nasdaq National Market in October 1987 and were subsequently traded on the Nasdaq Global Select Market. On May 30, 2012, we transferred the listing of our ADSs to the New York Stock Exchange (the NYSE ). The ADSs are quoted under the symbol TEVA. Citibank, N.A. serves as depositary for the ADSs. Each ADS represents one ordinary share.

Various other stock exchanges quote derivatives and options on our ADSs under the symbol TEVA.

### **Ordinary Shares**

Our ordinary shares have been listed on the Tel Aviv Stock Exchange ( TASE ) since 1951.

### **Holders**

The number of record holders of ADSs at December 31, 2018 was 2,906.

The number of record holders of ordinary shares at December 31, 2018 was 200.

The number of record holders is based upon the actual number of holders registered on our books at such date and does not include holders of shares in street names or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depositary trust companies.

## **Dividends**

In December 2017, we announced an immediate suspension of dividends on our ordinary shares and ADSs.



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We suspended cash dividends on our mandatory convertible preferred shares in the fourth quarter of 2017, due to our accumulated deficit. The mandatory conversion date of the mandatory convertible preferred shares was December 17, 2018. All of the accumulated and unpaid dividends on the mandatory convertible preferred shares were paid in ADSs, at a ratio of 3.0262 ADSs per mandatory convertible preferred share, according to the conversion mechanism set forth in the terms of the mandatory convertible preferred shares.

Our dividend policy is regularly reviewed by our Board of Directors based upon conditions then existing, including our earnings, financial condition, capital requirements and other factors. Our ability to pay cash dividends in the future may be restricted by instruments governing our debt obligations. When paid, dividends are declared in U.S. dollars and are paid by the depositary of our ADSs for the benefit of owners of ADSs.

Dividends paid by an Israeli company to non-Israeli residents are generally subject to withholding of Israeli income tax at a rate of up to 25%. Such tax rates apply unless a lower rate is provided in a treaty between Israel and the shareholder's country of residence. In our case, the applicable withholding tax rate will depend on the particular Israeli production facilities that have generated the earnings that are the source of the specific dividend and, accordingly, the applicable rate may change from time to time. A 20% tax is generally withheld on dividends declared and distributed.

## **Unregistered Sales of Equity Securities and Use of Proceeds**

None.

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**Performance Graph**

Set forth below is a performance graph comparing the cumulative total return (assuming reinvestment of dividends), in U.S. dollars, for the calendar years ended December 31, 2014, 2015, 2016, 2017 and 2018, of \$100 invested on December 31, 2013 in the Company's ADSs, the Standard & Poor's 500 Index and the Dow Jones U.S. Pharmaceuticals Index.

\* \$100 invested on December 31, 2013 in stock or index including reinvestment of dividends. Indexes calculated on month-end basis

**Repurchase of shares**

In December 2011, our Board of Directors authorized us to repurchase up to an aggregate amount of \$3.0 billion of our ordinary shares or ADSs, of which \$1.3 billion remained available for purchase, when in October 2014, the Board of Directors authorized us to increase our share repurchase program by \$1.7 billion to \$3.0 billion, of which \$2.1 billion remained available as of December 31, 2018.

We did not repurchase any of our shares during 2018 and currently cannot do so due to our accumulated deficit. The repurchase program has no time limit. Repurchases may be commenced or suspended at any time, subject to applicable law.

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA****Operating Data**

	For the year ended December 31,				
	2018	2017	2016	2015	2014
	(U.S. dollars in millions, except share and per share amounts)				
Income Statement Data: <sup>(a)</sup>					
Net revenues	18,854	22,385	21,903	19,652	20,272
Cost of sales <sup>(b)</sup>	10,558	11,770	10,250	8,532	9,644
Gross profit	8,296	10,615	11,653	11,120	10,628
Research and development expenses	1,213	1,778	2,077	1,525	1,488
Selling and marketing expenses <sup>(b)</sup>	2,916	3,395	3,583	3,242	3,433
General and administrative expenses	1,298	1,451	1,390	1,360	1,314
Intangible assets impairment	1,991	3,238	589	265	224
Goodwill impairment	3,027	17,100	900		
Other asset impairments, restructuring and other items	987	1,836	830	911	426
Legal settlements and loss contingencies	(1,208)	500	899	631	(111)
Other Income	(291)	(1,199)	(769)	(166)	(97)
Operating income (loss)	(1,637)	(17,484)	2,154	3,352	3,951
Financial expenses net	959	895	1,330	1,000	313
Income (loss) before income taxes	(2,596)	(18,379)	824	2,352	3,638
Income taxes (benefit)	(195)	(1,933)	521	634	591
Share in (profits) losses of associated companies net	71	3	(8)	121	5
Net income (loss)	(2,472)	(16,449)	311	1,597	3,042
Net income (loss) attributable to non-controlling interests	(322)	(184)	(18)	9	(13)
Net income (loss) attributable to Teva	(2,150)	(16,265)	329	1,588	3,055
Accrued dividends on preferred shares	249	260	261	15	
Net income (loss) attributable to ordinary shareholders	(2,399)	(16,525)	68	1,573	3,055
Earnings (loss) per share attributable to ordinary shareholders:					
Basic (\$)	(2.35)	(16.26)	0.07	1.84	3.58
Diluted (\$)	(2.35)	(16.26)	0.07	1.82	3.56

Weighted average number of shares (in millions):

Basic	1,021	1,016	955	855	853
Diluted	1,021	1,016	961	864	858
Cash dividends paid per ordinary share	\$ 0.51	\$ 1.36	\$ 1.36	\$ 1.36	\$ 1.36

- (a) For a discussion of items that affected the comparability of results for the years 2018, 2017 and 2016, refer to Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations.
- (b) During the fourth quarter of 2018, we changed our accounting policy for the presentation of royalty payments to third parties that are not involved in the production of products. We previously accounted for royalty payments to such third parties in S&M expenses. Royalties paid to a party that is involved in the production process are classified as cost of sales. We believe this change in accounting policy is preferable in order to be aligned with industry practice of classifying all royalty payments related to currently marketed products in cost of sales. We now report all royalty payments as cost of sales. We have retrospectively adjusted prior periods to reflect this change and the impact was a \$210 million, \$206 million, \$236 million

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and \$428 million increase in cost of sales with an offsetting decrease in S&M for the years ended December 31, 2017, 2016, 2015 and 2014, respectively. The impact of the change in accounting policy for the year ended December 31, 2018 was an increase in cost of sales of \$142 million with an offsetting decrease in S&M.

**Balance Sheet Data**

	2018	As at December 31, (U.S. dollars in millions)				2014
Financial assets (cash, cash equivalents and investment in securities)	1,845	1,060	1,949	8,404		2,601
Identifiable intangible assets, net	14,005	17,640	21,487	7,675		5,512
Goodwill	24,917	28,414	44,409	19,025		18,408
Working capital (operating assets minus liabilities)	(186)	(384)	303	32		1,642
Total assets	60,683	70,615	93,057	54,233		46,420
Short-term debt, including current maturities	2,216	3,646	3,276	1,585		1,761
Long-term debt, net of current maturities	26,700	28,829	32,524	8,358		8,566
Total debt	28,916	32,475	35,800	9,943		10,327
Total equity	15,794	18,745	34,993	29,927		22,355

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# **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

## **Business Overview**

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

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

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

## **Our Business Segments**

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

In addition to these three segments, we have other activities, primarily the sale of APIs to third parties and certain contract manufacturing services.

In December 2017, we announced a comprehensive restructuring plan intended to significantly reduce our cost base, unify and simplify our organization and improve business performance, profitability, cash flow generation and productivity. This plan is intended to reduce our total cost base by \$3 billion by the end of 2019.

The data presented in this report for prior periods have been conformed to reflect our current segment reporting, which commenced in the first quarter of 2018.

## **Highlights**

Significant highlights of 2018 included:

In September 2018, we launched AJOVY for the preventive treatment of migraine in adults in the United States. AUSTEDO revenues in the U.S. in 2018 were \$204 million.

Our revenues in 2018 were \$18,854 million, a decrease of 16% in both U.S. dollar and local currency terms compared to 2017, mainly due to generic competition to COPAXONE, a decline in revenues in our U.S. generics business and loss of revenues following the divestment of certain products and discontinuation of certain activities.

Our North America segment generated revenues of \$9,297 million and profit of \$2,837 million in 2018. Revenues decreased by 23%, mainly due to a decline in revenues of COPAXONE, our U.S. generics business, ProAir and QVAR, as well as the loss of revenues from the sale of our women's health business, partially offset by higher revenues from AUSTEDO and our Anda business. Profit decreased by 39%, mainly due to lower revenues from COPAXONE and a decline in sales of generic and other specialty products, partially offset by cost reductions and efficiency measures as part of the restructuring plan.

Our Europe segment generated revenues of \$5,186 million and profit of \$1,273 million in 2018. Revenues decreased by 5%, or 9% in local currency terms, mainly due to the loss of revenues from the

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closure of our distribution business in Hungary, the sale of our women's health business and a decline in COPAXONE revenues due to the entry of competing glatiramer acetate products, partially offset by new generic product launches. Profit increased by 24%, mainly due to cost reductions and efficiency measures as part of the restructuring plan.

Our International Markets segment generated revenues of \$3,005 million and profit of \$498 million in 2018. Revenues decreased by 11%, or 9% in local currency terms, mainly due to lower sales in Russia and Japan, the effect of the deconsolidation of our subsidiaries in Venezuela and loss of revenues from the sale of our women's health business. Profit increased by 17%, mainly due to cost reductions and efficiency measures as part of the restructuring plan.

Impairment of identifiable intangible assets were \$1,991 million and \$3,238 million in the years ended December 31, 2018 and 2017, respectively. The impairment expenses in 2018 were related to identifiable product rights of \$1,068 million and IPR&D assets of \$923 million.

We recorded goodwill impairments of \$3,027 million in 2018, mainly with respect to our International Markets segment. Goodwill impairments in 2017 were \$17,100 million.

Other asset impairments, restructuring and other items were \$987 million in 2018, mainly comprising impairments of property, plant and equipment of \$500 million and restructuring expenses of \$488 million. Other asset impairments, restructuring and other items were \$1,836 million in 2017.

In 2018, we recorded an income of \$1,208 million in legal settlements and loss contingencies compared to an expense of \$500 million in 2017.

Operating loss was \$1,637 million in 2018, compared to \$17,484 million in 2017, mainly due to higher impairment charges recorded in 2017.

Financial expenses were \$959 million in 2018, compared to \$895 million in 2017. Financial expenses in 2018 and 2017 were mainly comprised of interest expenses of \$920 million and \$875 million, respectively.

In 2018, we recognized a tax benefit of \$195 million, or 8%, on pre-tax loss of \$2,596 million. In 2017, we recognized a tax benefit of \$1,933 million, or 11%, on pre-tax loss of \$18,379 million. Our tax rate for 2018 was mainly affected by one-time legal settlements and divestments that had a low corresponding tax effect. Additionally, in 2018 we recorded impairments, some of which did not have a corresponding tax effect.

Exchange rate movements during 2018, in comparison with 2017, positively impacted revenues by \$152 million and operating income by \$4 million.



As of December 31, 2018, our debt was \$28,916 million, compared to \$32,475 million at December 31, 2017. This decrease was mainly due to senior notes and term loans repaid at maturity or prepaid with cash generated during the year and cash proceeds from sales of assets.

Cash flow generated from operating activities was \$2,446 million in 2018, an increase of \$221 million, or 10%, compared to 2017. This increase was mainly due to the working capital adjustment with Allergan and the Rimsa settlement in 2018, partially offset by lower profit in our North America segment.

## **Transactions**

### ***Certain Women's Health and Other Specialty Products***

On January 31, 2018, we completed the sale of a portfolio of products to CVC Capital Partners Fund VI for \$703 million in cash. The portfolio of products, which is marketed and sold outside of the United States, includes the women's health products OVALEAP®, ZOELY®, SEASONIQUE®, COLPOTROPHINE® and other specialty products such as ACTONEL®.

**Table of Contents*****PGT Healthcare***

On July 1, 2018, our PGT Healthcare joint venture with P&G was dissolved. As part of the separation, we transferred shares we held in New Chapter Inc. and ownership rights in an OTC plant located in India to P&G. We will continue to maintain our OTC business on an independent basis. We continue to provide certain services to P&G after the separation for a transition period.

**Results of Operations**

The following table sets forth, for the periods indicated, certain financial data derived from our financial statements, presented according to generally accepted accounting principles in the United States ( U.S. GAAP ), presented as percentages of net revenues, and the percentage change for each item as compared to the previous year.

	Percentage of Net Revenues Year Ended December 31,			Percentage Change Comparison	
	2018	2017	2016	2018-2017	2017-2016
	%	%	%	%	%
Net revenues	100	100	100	(16)	2
Gross profit	44.0	47.4	53.2	(22)	(9)
Research and development expenses	6.4	7.9	9.5	(32)	(14)
Selling and marketing expenses	15.5	15.2	16.4	(14)	(5)
General and administrative expenses	6.9	6.5	6.3	(11)	4
Intangible assets impairments	10.6	14.5	2.7	(39)	450
Goodwill impairment	16.1	76.4	4.1	(82)	1,800
Other asset impairments, restructuring and other items	5.2	8.2	3.8	(46)	121
Legal settlements and loss contingencies	(6.4)	2.2	4.1	n/a	(44)
Other Income	(1.5)	(5.4)	(3.5)	(76)	56
Operating (loss) income	(8.7)	(78.1)	9.8	(91)	n/a
Financial expenses net	5.1	4.0	6.1	7	(33)
Income (loss) before income taxes	(13.8)	(82.1)	3.7	(86)	n/a
Income taxes (benefit)	(1.0)	(8.6)	2.4	(90)	n/a
Share in (profits) losses of associated companies net	*	*	*	2,267	(138)
Net income (loss) attributable to non-controlling interests	(1.7)	(0.8)	*	75	922
Net income (loss) attributable to Teva	(11.4)	(72.7)	1.5	(87)	n/a

\* Represents an amount less than 0.5%.

**Table of Contents****Segment Information****North America Segment**

The following table presents revenues, expenses and profit for our North America segment for the past three years:

	Year ended December 31,					
	2018		2017		2016	
	(U.S.\$ in millions / % of Segment Revenues)					
Revenues	9,297	100%	12,141	100.0%	11,778	100.0%
Gross profit	4,979	53.6%	7,322	60.3%	8,404	71.4%
R&D expenses	713	7.7%	969	8.0%	1,040	8.8%
S&M expenses	1,154	12.4%	1,288	10.6%	1,362	11.6%
G&A expenses	484	5.2%	533	4.4%	496	4.2%
Other income	(209)	(2.2%)	(92)	(0.8%)	(30)	\$
Segment profit*	2,837	30.5%	4,624	38.1%	5,536	47.0%

\* Segment profit does not include amortization and certain other items. The data presented for prior periods have been conformed to reflect the changes to our segment reporting commencing in the first quarter of 2018. See note 20 to our consolidated financial statements and Teva Consolidated Results Operating Income below for additional information.

\$ 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 2018 were \$9,297 million, a decrease of \$2,844 million, or 23%, compared to 2017, mainly due to a decline in revenues of COPAXONE, our U.S. generics business, ProAir and QVAR and the loss of revenues from the sale of our women's health business, partially offset by higher revenues from AUSTEDO and our Anda business.

*Comparison of 2017 to 2016.* Revenues from our North America segment in 2017 were \$12,141 million, compared to \$11,778 million in 2016. This increase was mainly due to the inclusion of Actavis Generics revenues for the full year of 2017, compared to five months in 2016.

***Revenues by Major Products and Activities***

The following table presents revenues for our North America segment by major products and activities for the past three years:

Year ended December 31,  
2018      2017      2016  
(U.S.\$ in millions)

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Generic products	\$ 4,056	\$ 5,203	\$ 4,654
COPAXONE	1,759	3,116	3,543
BENDEKA / TREANDA	642	656	661
ProAir	397	501	565
QVAR	182	313	409
AUSTEDO	204	24	
Anda	1,347	1,153	301

**Generic products** revenues in our North America segment in 2018 decreased by 22% to \$4,056 million, compared to 2017, mainly due to additional competition to methylphenidate extended-release tablets (Concerta®)

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authorized generic), portfolio optimization primarily as part of the restructuring plan, as well as market dynamics and price erosion in our U.S. generics business, partially offset by new generic product launches.

Among the most significant generic products we sold in North America in 2018 were methylphenidate extended-release tablets (Concerta® authorized generic), daptomycin injection (the generic equivalent of Cubicin®) and tadalafil tablets (the generic equivalent of Cialis®).

In 2018, we led the U.S. generics market in total prescriptions and new prescriptions, with approximately 504 million total prescriptions (based on trailing twelve months), representing 13% of total U.S. generic prescriptions according to IQVIA data.

*Comparison of 2017 to 2016.* Revenues from generic products in our North America segment in 2017 were \$5,203 million, compared to \$4,654 million in 2016. This increase was mainly due to the inclusion of Actavis Generics revenues for the full year of 2017, compared to five months in 2016.

**COPAXONE** revenues in our North America segment in 2018 decreased by 44% to \$1,759 million, compared to 2017, mainly due to generic competition in the United States.

COPAXONE revenues in the United States were \$1,697 million in 2018.

Revenues of COPAXONE in our North America segment were 74% of global COPAXONE revenues in 2018, compared to 82% in 2017.

COPAXONE global sales accounted for approximately 13% of our global revenues in 2018 and a significantly higher percentage of our profits and cash flow from operations during this period.

For more information on COPAXONE, see Item 1 Business Our Product Portfolio and Business Offering Specialty Medicines COPAXONE.

*Comparison of 2017 to 2016.* COPAXONE revenues in our North America segment in 2017 were \$3,116 million, compared to \$3,543 million in 2016. This decrease was mainly due to generic competition, which resulted in higher rebates and lower volumes, partially offset by a price increase of 7.9% in January 2017 for both the 20 mg/mL and 40 mg/mL versions.

**BENDEKA** and **TREANDA** combined revenues in our North America segment in 2018 decreased by 2% to \$642 million, compared to 2017.

*Comparison of 2017 to 2016.* BENDEKA and TREANDA combined revenues in our North America segment in 2017 were \$656 million, compared to \$661 million in 2016.

**ProAir** revenues in our North America segment in 2018 decreased by 21% to \$397 million, compared to 2017, mainly due to higher sales reserves recorded in the fourth quarter of 2018 in anticipation of generic competition to the short-acting beta-agonist class of drugs, including an approved generic version of Ventolin HFA. In the albuterol inhaler category, approximately 40% of prescriptions are written as generic albuterol, which means that the launch of any generic inhaler may cause patient migration to such generic products. We launched our own ProAir authorized generic in the United States in January 2019. ProAir is the second-largest short-acting beta-agonist in the market, with an exit market share of 46.1% in terms of total number of prescriptions during 2018, compared to 47% in 2017.

*Comparison of 2017 to 2016.* ProAir revenues in our North America segment in 2017 were \$501 million, compared to \$565 million in 2016. This decrease was mainly due to negative net pricing effects.

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**QVAR** revenues in our North America segment in 2018 decreased by 42% to \$182 million, compared to 2017. The decrease in sales in 2018 was mainly due to lower volumes in connection with the launch of QVAR® RediHaler and lower net pricing. QVAR maintained its second-place position in the inhaled corticosteroids category in the United States, with an exit market share of 21.5% in terms of total number of prescriptions during 2018, compared to 35.3% in 2017.

*Comparison of 2017 to 2016.* QVAR revenues in our North America segment in 2017 were \$313 million, compared to \$409 million in 2016. This decrease was mainly due to net pricing effects.

**AUSTEDO** revenues in our North America segment in 2018 were \$204 million. AUSTEDO was approved by the FDA and launched in April 2017 in the United States for the treatment of chorea associated with Huntington disease. In August 2017, the FDA approved AUSTEDO for the treatment of tardive dyskinesia.

**Anda** revenues in our North America segment in 2018 increased by 17% to \$1,347 million, compared to 2017, mainly due to higher volumes.

*Comparison of 2017 to 2016.* Anda revenues in our North America segment in 2017 were \$1,153 million, compared to \$301 million in 2016. This increase was mainly due to the inclusion of Anda's revenues commencing in the fourth quarter of 2016.

**Product Launches and Pipeline**

In 2018, we launched the generic version of the following branded products in North America:

<b>Product Name</b>	<b>Brand Name</b>	<b>Launch Date</b>	<b>Total Annual U.S. Branded Sales at Time of Launch (U.S. \$ in millions (IQVIA))*</b>
Estradiol Vaginal Cream, USP, 0.01%	Estrace®	January	\$ 304
Methylphenidate Hydrochloride Extended-Release Capsules (LA), CII 20 mg, 30 mg & 40 mg	Ritalin LA® ER	January	\$ 97
Busulfan Injection 6 mg/mL, 60 mg	Busulfex®	January	\$ 86
Trientine Hydrochloride Capsules, USP 250 mg	Syprine®	February	\$ 147
Hydrocortisone Butyrate Cream USP, 0.1% (Lipophilic)	Locoid Lipocream®	February	\$ 6
Minocycline Hydrochloride Extended-Release Tablets, USP 65 mg & 115 mg	Solodyn® ER	February	\$ 148
Lansoprazole Delayed-Release Orally Disintegrating Tablets 15 mg & 30 mg	Prevacid® SoluTab DR ODT	March	\$ 184

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Tiagabine Hydrochloride Tablets 12 mg & 16 mg **	Gabitril®	March	\$	9
Palonosetron Hydrochloride Injection 0.05 mg/mL, 0.25 mg	Aloxi®	March	\$	452
Mesalamine Delayed-Release Tablets, USP 1.2 g	Lialda® DR	March	\$	1,128
Potassium Citrate Extended-Release Tablets, USP 540 mg, 1080 mg & 1620 mg	Urocit®-K			
	ER	May	\$	100
Budesonide Extended-Release Tablets, 9 mg	Uceris® ER	July	\$	199
Romidepsin for Injection, 10 mg/vial	Istodax®	August	\$	52



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<b>Product Name</b>	<b>Brand Name</b>	<b>Launch Date</b>	<b>Total Annual U.S. Branded Sales at Time of Launch (U.S. \$ in millions (IQVIA))*</b>
Cisatracurium Besylate Injection, USP 2 mg/mL, 10 mg, 10 mg/mL, 200 mg & 2 mg/mL, 20 mg	Nimbex®	September	\$ 49
Tadalafil Tablets, USP 2.5 mg, 5 mg, 10 mg & 20 mg	Cialis®	September	\$ 1,926
Testosterone topical gel, 10 mg/0.5 gm	Fortesta®	November	\$ 46
Abiraterone acetate tablets, USP 250 mg	Zytiga®	November	\$ 1,290
Azelaic acid gel, 15%	Finacea®	November	\$ 64
Buprenorphine transdermal system, 5 mcg/hour, 10 mcg/hour, 15 mcg/hour & 20 mcg/hour	Butrans®	November	\$ 237
Epinephrine injection, USP (auto-injector), 0.3 mg/0.3 mL	EpiPen®	November	\$ 617
Fluoxetine tablets, USP, 60 mg		December	\$ 47
Pimecrolimus cream, 1%	Elidel®	December	\$ 217
Cinacalcet hydrochloride tablets, 30mg, 60 mg & 90 mg	Sensipar®	December	\$ 1,746

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

\*\* Authorized generic.

Our generic products pipeline in the United States includes, as of December 31, 2018, 297 product applications awaiting FDA approval, including 92 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 September 30, 2018 exceeding \$114 billion, according to IQVIA. Approximately 70% of pending applications include a paragraph IV patent challenge and we believe we are first to file with respect to 107 of these products, or 132 products including final approvals where launch is pending a settlement agreement or court decision. Collectively, these first to file opportunities represent over \$74 billion in U.S. brand sales for the twelve months ended September 30, 2018, 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 2018, we received tentative approvals for generic equivalents of the products listed in the table below, excluding overlapping applications. A tentative approval indicates that the FDA has substantially completed its review of an application and final approval is expected once the relevant patent expires, a court decision is reached, a 30-month regulatory stay lapses or a 180-day exclusivity period awarded to another manufacturer either expires or is forfeited.

Generic Name	Brand Name	Total U.S. Annual Branded Market (U.S. \$ in millions (IQVIA))*	
Axitinib tablets, 1 mg & 5 mg	Inlyta®	\$	120
Azelaic acid foam, 15%	Finacea®	\$	58
Buprenorphine and naloxone buccal film, 2.1 mg/0.3 mg, 4.2 mg/0.7 mg & 6.3 mg/1 mg	Bunavail®	\$	19

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<b>Generic Name</b>	<b>Brand Name</b>	<b>Total U.S. Annual Branded Market (U.S. \$ in millions (IQVIA))*</b>
Clindamycin phosphate and benzoyl peroxide gel, 1.2%/3.75%	Onexton®	\$ 125
Eltrombopag tablets, 12.5 mg, 25 mg & 75 mg	Promacta®	\$ 200
Esomeprazole magnesium delayed-release capsules, 20 mg	Nexium®	
	DR	\$ 85
Fulvestrant injection, 250 mg/5 mL (50 mg/mL)	Faslodex®	\$ 511
Ingenol mebutate gel, 0.015% & 0.05%	Picato®	\$ 78
Mesalamine delayed-release capsules, 400mg	Delzicol®	\$ 140
Mesalamine extended-release capsules USP, 375 mg	Apriso®	\$ 282
Methylergonovine maleate tablets, USP, 0.2 mg	Methergine®	\$ 69
Methylphenidate extended-release oral disintegrating tablets, 8.6 mg, 17.3 mg & 25.9 mg	Cotempla XR®	\$ 49
Mifepristone tablets, 300 mg	Korlym®	\$ 2
Naloxone HCl nasal spray, 4 mg	Narcan®	\$ 66
Nicotine polacrilex mini mint lozenges, 2 mg & 4 mg	Nicorette®	\$ 68
Oxcarbazepine extended-release tablets, 150 mg, 300 mg & 600 mg	Oxtellar®XR	\$ 123
Perampanel tablets, 2 mg, 4 mg, 6 mg, 8 mg & 10 mg	Fycompa®	\$ 68
Rotigotine transdermal system, 1 mg/24 hr, 2 mg/24 hr, 3 mg/24 hr, 4 mg/24 hr, 6 mg/24 hr & 8 mg/24 hr	Neupro®	\$ 143
Saxagliptin tablets, 2.5mg & 5mg	Onglyza®	\$ 383
Ticagrelor tablets, 60 mg & 90 mg	Brilinta®	\$ 712
Tobramycin inhalation solution, 300mg/4mL	Bethkis®	\$ 27

\* For the twelve months ended in the calendar quarter immediately prior to the receipt of tentative approval. For a description of our specialty product pipeline, see Item 1 Business Our Product Portfolio and Business Offering Specialty Medicines above.

**North America Gross Profit**

Gross profit from our North America segment in 2018 was \$4,979 million, a decrease of 32% compared to \$7,322 million in 2017. The decrease was mainly due to lower revenues from COPAXONE and a decline in sales of generic and other specialty products.

Gross profit margin for our North America segment in 2018 decreased to 53.6% from 60.3% in 2017. This decrease was mainly due to lower COPAXONE revenues (3.5 points), lower revenues of our generic products (2.5 points) and other specialty products (1.0 point).

*Comparison of 2017 to 2016.* Gross profit from our North America segment in 2017 was \$7,322 million, compared to \$8,404 million in 2016. This decrease was mainly due to loss of exclusivity for COPAXONE and other specialty products, as well as price erosion in the U.S. generics market.

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### ***North America R&D Expenses***

R&D expenses relating to our North America segment in 2018 were \$713 million, a decrease of 26% compared to \$969 million in 2017.

For a description of our R&D expenses in 2018, see [Teva Consolidated Results Research and Development \(R&D\) Expenses](#) below.

*Comparison of 2017 to 2016.* R&D expenses relating to our North America segment in 2017 were \$969 million, compared to \$1,040 million in 2016.

### ***North America S&M Expenses***

S&M expenses relating to our North America segment in 2018 were \$1,154 million, a decrease of 10% compared to \$1,288 million in 2017. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

*Comparison of 2017 to 2016.* S&M expenses relating to our North America segment in 2017 were \$1,288 million, compared to \$1,362 million in 2016. This decrease was mainly due to generic competition to COPAXONE and loss of exclusivity of other key specialty products.

### ***North America G&A Expenses***

G&A expenses relating to our North America segment in 2018 were \$484 million, a decrease of 9% compared to \$533 million in 2017. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

*Comparison of 2017 to 2016.* G&A expenses relating to our North America segment in 2017 were \$533 million, compared to \$496 million in 2016.

### ***North America Other Income***

Other income from our North America segment in 2018 was \$209 million, compared to \$92 million in 2017. This increase was mainly due to higher Section 8 recoveries from multiple cases in Canada and recovery of lost profits in cases in which U.S. patent infringement litigation had previously prevented the sale of certain products.

*Comparison of 2017 to 2016.* Other income from our North America segment in 2017 was \$92 million, compared to \$30 million in 2016. This increase was mainly due to higher Section 8 recoveries in Canada.

### ***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. The data presented for prior periods have been conformed to reflect the changes to our segment reporting commencing in the first quarter of 2018. See note 20 to our consolidated financial statements and [Teva Consolidated Results Operating Income](#) below.

Profit from our North America segment in 2018 was \$2,837 million, a decrease of 39% compared to \$4,624 million in 2017. The decrease was mainly due to lower revenues from COPAXONE and a decline in sales of generic and other specialty products, partially offset by cost reductions and efficiency measures as part of the restructuring plan.

*Comparison of 2017 to 2016.* Profit from our North America segment in 2017 was \$4,624 million, compared to \$5,536 million in 2016. This decrease was mainly due to lower gross profit.

**Table of Contents****Europe Segment**

The following table presents revenues, expenses and profit for our Europe segment for the past three years:

	Year ended December 31,					
	2018		2017		2016	
	(U.S.\$ in millions / % of Segment Revenues)					
Revenues	5,186	100%	5,466	100%	4,969	100%
Gross profit	2,884	55.6%	2,887	52.8%	2,685	54.0%
R&D expenses	283	5.5%	390	7.1%	383	7.7%
S&M expenses	1,003	19.3%	1,130	20.7%	1,267	25.5%
G&A expenses	325	6.3%	354	6.5%	377	7.6%
Other income		\$	(16)	\$	(9)	\$
Segment profit*	1,273	24.5%	1,029	18.8%	667	13.4%

\* Segment profit does not include amortization and certain other items. The data presented for prior periods have been conformed to reflect the changes to our segment reporting commencing in the first quarter of 2018. See note 20 to our consolidated financial statements and Teva Consolidated Results Operating Income below for additional information.

\$ Represents an amount less than 0.5%.

**Europe Revenues**

Our Europe segment includes the European Union and certain other European countries. Revenues from our Europe segment in 2018 were \$5,186 million, a decrease of \$280 million, or 5%, compared to 2017. In local currency terms, revenues decreased by 9%, mainly due to the loss of revenues from the closure of our distribution business in Hungary, the sale of our women's health business and a decline in COPAXONE revenues due to the entry of competing glatiramer acetate products, partially offset by new generic product launches.

*Comparison of 2017 to 2016.* Revenues from our Europe segment in 2017 were \$5,466 million, compared to \$4,969 million in 2016. This increase was mainly due to the acquisition of Actavis Generics, the launch of BRALTUS in 2017 and new generic product launches.

**Revenues by Major Products and Activities**

The following table presents revenues for our Europe segment by major products and activities for the past three years:

	Year ended December 31,		
	2018	2017	2016
	(U.S.\$ in millions)		
Generic products	\$ 3,593	\$ 3,471	\$ 3,155

COPAXONE	535	595	585
Respiratory products	402	368	239

**Generic products** revenues in our Europe segment in 2018, including OTC products, increased by 4% to \$3,593 million, compared to 2017. In local currency terms, revenues decreased by 1%, mainly due to the loss of revenues from the termination of the PGT joint venture and the impact of the valsartan voluntary recall, partially offset by new generic product launches.

*Comparison of 2017 to 2016.* Generic products revenues in our Europe segment in 2017 were \$3,471 million, compared to \$3,155 million in 2016. This increase was mainly due to the acquisition of Actavis Generics.



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**COPAXONE** revenues in our Europe segment in 2018 decreased by 10% to \$535 million, compared to 2017. In local currency terms, revenues decreased by 14%, mainly due to price reductions resulting from the entry of competing glatiramer acetate products.

Revenues of COPAXONE in our Europe segment were 23% of global COPAXONE revenues in 2018, compared to 16% in 2017.

For more information on COPAXONE, see Item 1 Business Our Product Portfolio and Business Offering Specialty Medicines COPAXONE.

*Comparison of 2017 to 2016.* COPAXONE revenues in our Europe segment in 2017 were \$595 million, compared to \$585 million in 2016. In local currency terms, revenues were flat compared to 2016.

**Respiratory products** revenues in our Europe segment in 2018 increased by 9% to \$402 million, compared to 2017. In local currency terms, revenues increased by 5%, mainly due to the launch of BRALTUS in 2017.

*Comparison of 2017 to 2016.* Respiratory products revenues from our Europe segment in 2017 were \$368 million, compared to \$239 million in 2016. This increase was mainly due to the launch of BRALTUS in 2017.

## ***Product Launches and Pipeline***

As of December 31, 2018, our generic products pipeline in Europe included 734 generic approvals relating to 98 compounds in 195 formulations, and approximately 1,267 marketing authorization applications pending approval in 37 European countries, relating to 157 compounds in 323 formulations, including two applications pending with the EMA for one strength in 30 countries.

For a description of our specialty product pipeline, see Item 1 Business Our Product Portfolio and Business Offering Specialty Medicines above.

## ***Europe Gross Profit***

Gross profit from our Europe segment in 2018 was \$2,884 million, flat compared to 2017. Gross profit was affected by the loss of revenues from the sale of our women's health business and a decline in COPAXONE revenues, offset by new generic product launches and lower cost of goods sold.

Gross profit margin for our Europe segment in 2018 increased to 55.6% from 52.8% in 2017. This increase was mainly due to lower cost of goods sold (1.0 points) and the closure of our distribution business in Hungary (1.6 points).

*Comparison of 2017 to 2016.* Gross profit from our Europe segment in 2017 was \$2,887 million, compared to \$2,685 million in 2016. This increase was mainly due to the acquisition of Actavis Generics and the BRALTUS launch.

## ***Europe R&D Expenses***

R&D expenses relating to our Europe segment in 2018 were \$283 million, a decrease of 27% compared to \$390 million in 2017.

For a description of our R&D expenses in 2018, see [Teva Consolidated Results Research and Development \(R&D\) Expenses](#) below.

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*Comparison of 2017 to 2016.* R&D expenses relating to our Europe segment in 2017 were \$390 million, compared to \$383 million in 2016.

### ***Europe S&M Expenses***

S&M expenses relating to our Europe segment in 2018 were \$1,003 million, a decrease of 11% compared to \$1,130 million in 2017. This decrease was mainly due to cost reductions as part of the restructuring plan.

*Comparison of 2017 to 2016.* S&M expenses relating to our Europe segment in 2017 were \$1,130 million, compared to \$1,267 million in 2016. This decrease was mainly due to lower promotional and medical spend.

### ***Europe G&A Expenses***

G&A expenses relating to our Europe segment in 2018 were \$325 million, a decrease of 8% compared to \$354 million in 2017. This decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

*Comparison of 2017 to 2016.* G&A expenses relating to our Europe segment in 2017 were \$354 million, compared to \$377 million in 2016.

### ***Europe Profit***

Profit of our Europe segment consists of gross profit less R&D expenses, S&M expenses, G&A expenses and any other income related to this segment. Segment profit does not include amortization and certain other items. The data presented for prior periods have been conformed to reflect the changes to our segment reporting commencing in the first quarter of 2018. See note 20 to our consolidated financial statements and Teva Consolidated Results Operating Income below.

Profit from our Europe segment in 2018 was \$1,273 million, an increase of 24% compared to \$1,029 million in 2017. This increase was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

*Comparison of 2017 to 2016.* Profit from our Europe segment in 2017 was \$1,029 million, compared to \$667 million in 2016. This increase was mainly due to the inclusion of the Actavis Generics business and cost efficiency measures.

**Table of Contents****International Markets Segment**

The following table presents revenues, expenses and profit for our International Markets segment for the past three years:

	Year ended December 31,					
	2018		2017		2016	
	(U.S.\$ in millions / % of Segment Revenues)					
Revenues	3,005	100%	3,395	100%	4,015	100%
Gross profit	1,254	41.7%	1,433	42.2%	1,811	45.1%
R&D expenses	96	3.2%	154	4.5%	205	5.1%
S&M expenses	518	17.2%	672	19.8%	754	18.8%
G&A expenses	153	5.1%	189	5.6%	226	5.6%
Other income	(11)	\$	(8)	\$	(10)	\$
Segment profit*	498	16.6%	426	12.5%	636	15.9%

\* Segment profit does not include amortization and certain other items. The data presented for prior periods have been conformed to reflect the changes to our segment reporting commencing in the first quarter of 2018. See note 20 to our consolidated financial statements and Teva Consolidated Results Operating Income below for additional information.

\$ Represents an amount less than 0.5%.

***International Markets Revenues***

Our International Markets segment includes all countries other than those in our North America and Europe segments. Our key international markets are Japan, Israel and Russia. The countries in this category range from highly regulated, pure generic markets, such as Israel, to hybrid markets, such as Japan, to branded generics oriented markets, such as Russia and certain Commonwealth of Independent States (CIS), Latin American and Asia Pacific markets.

Revenues from our International Markets segment in 2018 were \$3,005 million, a decrease of \$390 million, or 11%, compared to 2017. In local currency terms, revenues decreased by 9%, compared to 2017, mainly due to lower sales in Russia and Japan, the effect of the deconsolidation of our subsidiaries in Venezuela and loss of revenues from the sale of our women's health business.

*Comparison of 2017 to 2016.* Revenues from our International Markets segment in 2017 were \$3,395 million, compared to \$4,015 million in 2016. This decrease was mainly due to adjustments made to the exchange rate we utilized for Venezuela.

***Revenues by Major Products and Activities***

The following table presents revenues for our International Markets segment by major products and activities for the past three years:

	Year ended December 31,		
	2018	2017	2016
	(U.S.\$ in millions)		
Generic products	\$ 2,022	\$ 2,370	\$ 3,129
COPAXONE	72	91	95
Distribution	602	550	458

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**Generic products** revenues in our International Markets segment in 2018, which include OTC products, decreased by 15% to \$2,022 million, compared to 2017. In local currency terms, revenues decreased by 12%, mainly due to lower revenues in Russia, lower sales in Japan resulting from regulatory pricing reductions and generic competition to off-patented products, loss of revenues from the termination of the PGT joint venture and the effect of the deconsolidation of our subsidiaries in Venezuela.

*Comparison of 2017 to 2016.* Generic products revenues in our International Markets segment in 2017 were \$2,370 million, compared to \$3,129 million in 2016. This decrease was mainly due to adjustments made to the exchange rate we utilized for Venezuela.

**COPAXONE** revenues in our International Markets segment in 2018 decreased by 21% to \$72 million, compared to 2017. In local currency terms, revenues decreased by 8%.

For more information on COPAXONE, see [Item 1 Business Our Product Portfolio and Business Offering Specialty Medicines COPAXONE](#).

*Comparison of 2017 to 2016.* COPAXONE revenues in our International Markets segment in 2017 were \$91 million, compared to \$95 million in 2016.

**Distribution** revenues in our International Markets segment in 2018 increased by 9% to \$602 million, compared to 2017. In local currency terms, revenues increased by 11%, mainly due to agreements with new distribution partners.

*Comparison of 2017 to 2016.* Distribution revenues in our International Markets segment in 2017 were \$550 million, compared to \$458 million in 2016. This increase was mainly due to agreements with new distribution partners.

***International Markets Gross Profit***

Gross profit from our International Markets segment in 2018 was \$1,254 million, a decrease of 12% compared to \$1,433 million in 2017.

Gross profit margin for our International Markets segment in 2018 decreased to 41.7% from 42.2% in 2017. This decrease was mainly due to the Venezuela deconsolidation (1.8 points) and lower gross profit resulting from changes in product mix in certain countries, mainly Russia (1.2 points) and Japan (0.7 points), partially offset by Israel (1.2 points), Chile (0.4 points) and Mexico (0.3 points), as well as cost reductions and efficiency measures as part of the restructuring plan (1.3 points).

*Comparison of 2017 to 2016.* Gross profit from our International Markets segment in 2017 was \$1,433 million, compared to \$1,811 million in 2016. This decrease was mainly due to adjustments made to the exchange rate we utilized for Venezuela.

***International Markets R&D Expenses***

R&D expenses relating to our International Markets segment in 2018 were \$96 million, a decrease of 38% compared to \$154 million in 2017.

For a description of our R&D expenses in 2018, see [Teva Consolidated Results Research and Development \(R&D\) Expenses](#) below.

*Comparison of 2017 to 2016.* R&D expenses relating to our International Markets segment in 2017 were \$154 million, compared to \$205 million in 2016.

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### ***International Markets S&M Expenses***

S&M expenses relating to our International Markets segment in 2018 were \$518 million, a decrease of 23% compared to \$672 million in 2017. The decrease was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

*Comparison of 2017 to 2016.* S&M expenses relating to our International Markets segment in 2017 were \$672 million, compared to \$754 million in 2016.

### ***International Markets G&A Expenses***

G&A expenses relating to our International Markets segment in 2018 were \$153 million, a decrease of 19% compared to \$189 million in 2017. The decrease was mainly due to cost reductions as part of the restructuring plan.

*Comparison of 2017 to 2016.* G&A expenses relating to our International Markets segment in 2017 were \$189 million, compared to \$226 million in 2016.

### ***International Markets Profit***

Profit of our International Markets segment consists of gross profit less R&D expenses, S&M expenses, G&A expenses and any other income related to this segment. Segment profit does not include amortization and certain other items. The data presented for prior periods have been conformed to reflect the changes to our segment reporting commencing in the first quarter of 2018. See note 20 to our consolidated financial statements and Teva Consolidated Results Operating Income below.

Profit from our International Markets segment in 2018 was \$498 million, an increase of 17% compared to \$426 million in 2017. The increase was mainly due to cost reductions and efficiency measures as part of the restructuring plan.

During the fourth quarter of 2017, we deconsolidated our subsidiaries in Venezuela from our financial results after concluding that we did not meet the accounting criteria for control over our wholly-owned subsidiaries in Venezuela and that we no longer had significant influence over such subsidiaries. Consequently, results of operations of our subsidiaries in Venezuela are not included in our financial results for 2018. We recorded \$99 million in revenues and \$40 million in operating income in 2017 with respect to our subsidiaries in Venezuela. We exclude these changes in revenues and operating profit in Venezuela from any discussion of local currency results.

*Comparison of 2017 to 2016.* Profit from our International Markets segment in 2017 was \$426 million, compared to \$636 million in 2016. This decrease was mainly due to adjustments made to the exchange rate we utilized for Venezuela.

### ***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 2018 decreased by 1% to \$1,366 million compared to 2017. In local currency terms, revenues decreased by 3%.

API sales to third parties in 2018 decreased by 1% to \$746 million, in both U.S. dollar and local currency terms.

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*Comparison of 2017 to 2016.* Revenues from other activities in 2017 were \$1,383 million, compared to \$1,141 million in 2016. This increase was mainly due to higher revenues from our contract manufacturing services.

## **Teva Consolidated Results**

### **Revenues**

Revenues in 2018 were \$18,854 million, a decrease of 16% in both U.S. dollar and local currency terms, compared to 2017, mainly due to generic competition to COPAXONE, a decline in revenues in our U.S. generics business and loss of revenues following the divestment of certain products and discontinuation of certain activities. See North America Revenues, Europe Revenues, International Markets Revenues and Other Activities above.

Exchange rate movements during 2018 positively impacted revenues by \$152 million, compared to 2017.

*Comparison of 2017 to 2016.* Revenues in 2017 were \$22,385 million, an increase of 2% compared to 2016. The increase was primarily due to (i) an increase in our generic medicines segment from the inclusion of Actavis Generics revenues for the full year of 2017, compared to five months in 2016, partially offset by the adverse market dynamics in the United States and (ii) the acquisition of Anda in the fourth quarter of 2016, partially offset by a decrease in our specialty medicines segment due to generic competition to certain of our key products.

### **Gross Profit**

Gross profit in 2018 was \$8,296 million, a decrease of 22% compared to 2017.

The decrease was mainly a result of the factors discussed above under North America Gross Profit, Europe Gross Profit and International Markets Gross Profit.

Gross profit as a percentage of revenues was 44.0% in 2018, compared to 47.4% in 2017.

The decrease in gross profit as a percentage of revenues was mainly due to lower profitability in North America resulting from a decline in COPAXONE revenues due to generic competition and a decline in revenues in our U.S. generics business (5.1 points), higher accelerated depreciation (0.3 points) and higher divestment expenses (0.2 points), partially offset by lower amortization expenses (1.3 points) and higher profitability in Europe (0.7 points).

*Comparison of 2017 to 2016.* Gross profit in 2017 was \$10,615 million, a decrease of 9% compared to 2016. Gross profit as a percentage of revenues was 47.4% in 2017, compared to 53.2% in 2016. The decrease in gross profit as a percentage of revenues primarily reflects lower profitability of our generic segment, higher amortization of purchased intangible assets, lower profitability of our specialty medicines segment, the inclusion of Anda and lower profitability of our other activities, partially offset by lower inventory step-up expenses, inventory related expenses in connection with the devaluation in Venezuela and lower costs related to regulatory actions taken in certain facilities.

### **Research and Development (R&D) Expenses**

Net R&D expenses for 2018 were \$1,213 million, a decrease of 32% compared to 2017.

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.

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Our R&D activities for specialty products in each of our segments include costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, clinical trials and product registration costs. These expenditures are reported net of contributions received from collaboration partners. Our spending takes place throughout the development process, including (i) early-stage projects in both discovery and preclinical phases; (ii) middle-stage projects in clinical programs up to phase 3; (iii) late-stage projects in phase 3 programs, including where a new drug application is currently pending approval; (iv) life cycle management and post-approval studies for marketed products; and (v) indirect expenses that support our overall specialty R&D efforts but are not allocated by product or to specific R&D projects, such as the costs of internal administration, infrastructure and personnel.

In 2018, our R&D expenses were primarily related to generic products in our North America segment, as well as specialty product candidates in the pain, migraine, headache and respiratory therapeutic areas, with additional activities in selected other areas.

Our lower R&D expenses in 2018 compared to 2017 primarily resulted from pipeline optimization and project terminations, phase 3 studies that have ended and related headcount reductions.

R&D expenses as a percentage of revenues were 6.4% in 2018, compared to 7.9% in 2017.

*Comparison of 2017 to 2016.* In 2017, R&D expenses were \$1,778 million, a decrease of 14% compared to 2016. R&D expenses as a percentage of revenues were 7.9% in 2017, compared to 9.5% in 2016.

## **Selling and Marketing (S&M) Expenses**

S&M expenses in 2018 were \$2,916 million, a decrease of 14% compared to 2017. Our S&M expenses were primarily the result of the factors discussed above under North America Segment S&M Expenses, Europe Segment S&M Expenses and International Markets Segment S&M Expenses.

S&M expenses as a percentage of revenues were 15.5% in 2018, compared to 15.2% in 2017.

*Comparison of 2017 to 2016.* S&M expenses in 2017 were \$3,395 million, a decrease of 5% compared to 2016. S&M expenses as a percentage of revenues were 15.2% in 2017, compared to 16.4% in 2016.

## **General and Administrative (G&A) Expenses**

G&A expenses in 2018 were \$1,298 million, a decrease of 11% compared to 2017. Our G&A expenses were primarily the result of the factors discussed above under North America Segment G&A Expenses, Europe Segment G&A Expenses and International Markets Segment G&A Expenses, as well as cost reductions in certain corporate functions as part of the restructuring plan.

G&A expenses as a percentage of revenues were 6.9% in 2018, compared to 6.5% in 2017.

*Comparison of 2017 to 2016.* G&A expenses in 2017 were \$1,451 million, an increase of 4% compared to 2016. G&A expenses as a percentage of revenues were 6.5% in 2017, compared to 6.3% in 2016.

## **Identifiable Intangible Asset Impairments**

We recorded expenses of \$1,991 million for identifiable intangible asset impairments in 2018, compared to expenses of \$3,238 million in 2017. See note 8 to our consolidated financial statements.

*Comparison of 2017 to 2016.* Identifiable intangible asset impairments in 2017 were \$3,238 million, an increase of \$2,649 million compared to 2016.

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**Goodwill Impairment**

We recognized goodwill impairments of \$3,027 million and \$17,100 million in 2018 and 2017, respectively. The goodwill impairment in 2018 was mainly attributable to goodwill associated with our International Markets reporting unit and Medis reporting unit. See note 7 to our consolidated financial statements.

*Comparison of 2017 to 2016.* Goodwill impairments in 2017 were \$17,100 million, an increase of \$16,200 million compared to 2016. The goodwill impairment in 2017 was mainly in connection with our U.S. generics reporting unit.

**Other Asset Impairments, Restructuring and Other Items**

We recorded expenses of \$987 million for other asset impairments, restructuring and other items in 2018, compared to expenses of \$1,836 million in 2017. See note 18 to our consolidated financial statements.

*Comparison of 2017 to 2016.* We recorded expenses of \$1,836 million for other asset impairments, restructuring and other items in 2017, compared to \$830 million in 2016.

***Significant regulatory events***

In July 2018, the FDA completed an inspection of our manufacturing plant in Davie, Florida in the United States, and issued a Form FDA-483 to the site. In October 2018, the FDA notified us that the inspection of the site is classified as official action indicated (OAI). On February 5, 2019, we received a warning letter from the FDA that contains four enumerated concerns related to production, quality control, and investigations at this site. We are working diligently to investigate the FDA's concerns in a manner consistent with current good manufacturing practice (CGMP) requirements, and to address those concerns as quickly and as thoroughly as possible. If we are unable to remediate the warning letter findings to the FDA's satisfaction, we may face additional consequences, including delays in FDA approval for future products from the site, financial implications due to loss of revenues, impairments, inventory write offs, customer penalties, idle capacity charges, costs of additional remediation and possible FDA enforcement action. We expect to generate approximately \$255 million in revenues from this site in 2019, assuming remediation or enforcement does not cause any unscheduled slowdown or stoppage at the facility.

In July 2018, we announced the voluntary recall of valsartan and certain combination valsartan medicines in various countries due to the detection of trace amounts of a previously unknown impurity called NDMA found in valsartan API supplied to us by Zhejiang Huahai Pharmaceutical. Since July 2018, we have been actively engaged with regulatory agencies around the world in reviewing our valsartan and other sartan products for NDMA and other related impurities and, where necessary, have initiated additional voluntary recalls. The impact of this recall on our 2018 financial statements was \$51 million, primarily related to inventory reserves. We expect to continue to experience loss of revenues and profits in connection with this matter. In addition, multiple lawsuits have been filed in connection with this matter. We may also incur customer penalties, impairments and litigation costs going forward.

***Restructuring***

In 2018, we recorded \$488 million of restructuring expenses, compared to \$535 million in 2017. The expenses in 2018 were primarily related to headcount reductions across all functions, as part of the restructuring plan announced in 2017.

The two-year restructuring plan announced in 2017 is intended to reduce our total cost base by \$3 billion by the end of 2019.

Since the announcement, we reduced our global headcount by approximately 10,300 full-time-equivalent employees.

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*Comparison of 2017 to 2016.* Restructuring expenses in 2017 were \$535 million, compared to \$245 million in 2016.

### **Legal Settlements and Loss Contingencies**

In 2018, we recorded an income of \$1,208 million in legal settlements and loss contingencies compared to an expense of \$500 million in 2017. This income primarily consisted of the working capital adjustment with Allergan, the Rimsa settlement and reversal of the reserve recorded in the second quarter of 2017 with respect to the carvedilol patent litigation.

*Comparison of 2017 to 2016.* Legal settlements and loss contingencies in 2017 amounted to \$500 million, compared to \$899 million in 2016. The expenses in 2017 primarily consisted of a reserve for the carvedilol jury trial loss.

### **Other Income**

Other income in 2018 was \$291 million, compared to \$1,199 million in 2017. The decline in other income was primarily the result of non-recurring income related to the sale of our women's health business in 2017.

*Comparison of 2017 to 2016.* Other income in 2017 was \$1,199 million, compared to \$769 million in 2016. This increase in 2017 was mainly due higher income from the sale of assets.

### **Operating Income (Loss)**

Operating loss was \$1,637 million in 2018, compared to \$17,484 million in 2017, mainly due to higher impairment charges recorded in 2017.

Operating loss as a percentage of revenues was 8.7% in 2018, compared to 78.1% in 2017. The increase was mainly due higher goodwill impairment charges (60.3 points), higher intangible assets impairments (3.9 points) and other asset impairments, restructuring and other items (3.0 points) recorded in 2017.

*Comparison of 2017 to 2016.* Operating loss in 2017 was \$17,484 million, compared to operating income of \$2,154 in 2016. Operating loss as a percentage of revenues was 78.1% in 2017, compared to operating income as a percentage of revenues of 9.8% in 2016.



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The following table presents a reconciliation of our segment profits to Teva's consolidated operating income (loss) and to consolidated income (loss) before income taxes for the past three years:

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S.\$ in millions)</b>		
North America profit	\$ 2,837	\$ 4,624	\$ 5,536
Europe profit	1,273	1,029	667
International Markets profit	498	426	636
Total segment profit	4,608	6,079	6,839
Profit (loss) of other activities	115	(6)	8
	4,723	6,073	6,847
Amounts not allocated to segments:			
Amortization	\$ 1,166	\$ 1,444	\$ 993
Other asset impairments, restructuring and other items	987	1,836	830
Goodwill impairment	3,027	17,100	900
Intangible asset impairments	1,991	3,238	589
Gain on divestitures, net of divestitures related costs	(66)	(1,083)	(720)
Inventory step-up		67	383
Other R&D expenses	83	221	426
Costs related to regulatory actions taken in facilities	14	47	153
Legal settlements and loss contingencies	(1,208)	500	899
Other unallocated amounts	366	187	240
Consolidated operating income (loss)	(1,637)	(17,484)	2,154
Financial expenses, net	959	895	1,330
Consolidated income (loss) before income taxes	\$ (2,596)	\$ (18,379)	\$ 824

During the fourth quarter of 2017, we deconsolidated our subsidiaries in Venezuela from our financial results. Consequently, results of operations of our subsidiaries in Venezuela are not included in our financial results for 2018.

**Financial Expenses, Net**

Financial expenses were \$959 million in 2018, compared to \$895 million in 2017.

Financial expenses in 2018 were mainly comprised of interest expenses of \$920 million. Financial expenses in 2017 were mainly comprised of interest expenses of \$875 million.

*Comparison of 2017 to 2016.* In 2017, financial expenses were \$895 million, compared to \$1,330 million in 2016.

**Tax Rate**

In 2018, we recognized a tax benefit of \$195 million, or 8%, on pre-tax loss of \$2,596 million. In 2017, we recognized a tax benefit of \$1,933 million, or 11%, on pre-tax loss of \$18,379 million. Our tax rate for 2018 was mainly affected by one-time legal settlements and divestments that had a low corresponding tax effect. Additionally, in 2018, we recorded impairments, some of which did not have a corresponding tax effect.

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The statutory Israeli corporate tax rate was 23% in 2018. Our tax rate differs from the Israeli statutory tax rate mainly due to generation of profits in various jurisdictions in which tax rates are different than the Israeli tax rate, tax benefits in Israel and other countries, as well as infrequent or nonrecurring items.

In the future, our effective tax rate is expected to increase following the enactment of the Tax Cuts and Jobs Act in the United States.

## **Share In (Profits) Losses of Associated Companies    Net**

Share in losses of associated companies, net in 2018 was \$71 million, compared to \$3 million in 2017.

*Comparison of 2017 to 2016.* Share in losses of associated companies, net in 2017 was \$3 million, compared to a profit of \$8 million in 2016.

## **Net Income (Loss)**

Net loss was \$2,472 million in 2018, compared to net loss of \$16,449 million in 2017.

*Comparison of 2017 to 2016.* Net loss in 2017 was \$16,449 million, compared to net income of \$311 million in 2016.

## **Diluted Shares Outstanding and Earnings (Loss) Per Share**

The weighted average diluted shares outstanding used for the fully diluted share calculation for 2018, 2017 and 2016 were 1,021 million, 1,016 million and 961 million shares, respectively.

In computing loss per share for the twelve months ended December 31, 2018 and 2017, no account was taken of the potential dilution by the assumed exercise of employee stock options and non-vested RSUs granted under employee stock compensation plans and convertible senior debentures, since they had an anti-dilutive effect on loss per share.

Additionally, no account was taken of the potential dilution by the mandatory convertible preferred shares, amounting to 74 million shares (including shares that were issued due to unpaid dividends until that date) for the period between January 1, 2018 and December 17, 2018 and 59 million shares for the twelve months ended December 31, 2017, since they had an anti-dilutive effect on loss per share.

On December 17, 2018, the mandatory convertible preferred shares automatically converted into ordinary shares at a ratio of 1 mandatory convertible preferred share to 16 ADSs, and all of the accumulated and unpaid dividends on the mandatory convertible preferred shares were paid in ADSs, at a ratio of 3.0262 ADSs per mandatory convertible preferred share, all in accordance with the conversion mechanism set forth in the terms of the mandatory convertible preferred shares. As a result of this conversion, we issued 70.6 million ADSs.

Diluted loss per share was \$2.35 for the year ended December 31, 2018, compared to loss per share of \$16.26 for the year ended December 31, 2017.

## **Share Count for Market Capitalization**

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



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As of December 31, 2018 and 2017, the fully diluted share count for purposes of calculating our market capitalization was approximately 1,100 million and 1,086 million, respectively.

### **Impact of Currency Fluctuations on Results of Operations**

In 2018, approximately 48% of our revenues were denominated in currencies other than the U.S. dollar. Because our results are reported in U.S. dollars, we are subject to significant foreign currency risks. Accordingly, changes in the rate of exchange between the U.S. dollar and the local currencies in the markets in which we operate (primarily the euro, British pound, Japanese yen, Israeli shekel, Canadian dollar, Polish zloty, Argentinean peso, Turkish lira and Russian ruble) impact our results.

During 2018, the following main currencies relevant to our operations decreased in value against the U.S. dollar (each on an annual average compared to annual average basis): the Argentinian peso by 37%, the Turkish lira by 22% and the Russian ruble by 7%. The following main currencies relevant to our operations increased in value against the U.S. dollar: the euro by 5%, the Polish zloty by 5%, the British pound by 4%, the Japanese yen by 2%, the Hungarian forint by 2% and the Swiss franc by 1%.

As a result, exchange rate movements during 2018, in comparison with 2017, positively impacted overall revenues by \$152 million and positively impacted our operating income by \$4 million.

Commencing in the third quarter of 2018, the cumulative inflation in Argentina exceeded 100% or more over a 3-year period. Although this triggered highly inflationary accounting treatment, it did not have a material impact on our results of operations.

### **Liquidity and Capital Resources**

Total balance sheet assets were \$60,683 million as of December 31, 2018, compared to \$70,615 million as of December 31, 2017.

Our working capital balance, which includes trade receivables net of SR&A, inventories, prepaid expenses and other current assets, trade payables, employee-related obligations, accrued expenses and other current liabilities, was negative \$186 million as of December 31, 2018, compared to negative \$384 million as of December 31, 2017.

Accrued expenses, as of December 31, 2018, were \$1,868 million, compared to \$3,014 million as of December 31, 2017. The decrease was mainly due to lower legal settlements of approximately \$670 million, a milestone payment of \$150 million to Labrys and a decrease in accrued restructuring expenses of \$150 million.

Investment in property, plant and equipment in 2018 was \$651 million, compared to \$874 million in 2017. Depreciation was \$676 million in 2018, compared to \$632 million in 2017.

Cash and cash equivalents and short-term and long-term investments, as of December 31, 2018, were \$1,846 million, compared to \$1,060 million as of December 31, 2017. The increase was mainly due to proceeds from the issuance of senior notes, proceeds from the sale of our women's health business, proceeds from the working capital adjustment with Allergan and the legal settlement with Rimsa, as well as other free cash flow generated during the year, offset by debt repayments as discussed below.

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



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### **2018 Debt Balance and Movements**

As of December 31, 2018, our debt was \$28,916 million, compared to \$32,475 million as of December 31, 2017. The decrease was mainly due to senior notes and term loans repaid at maturity or prepaid with cash generated during the year and cash proceeds from sales of assets.

In January 2018, we prepaid in full \$15 million of our U.S. dollar debentures.

During the first quarter of 2018, we prepaid in full \$2.3 billion of our 3-year and 5-year U.S. dollar term loans, as well as JPY 156.8 billion of our term loans.

In March 2018, we completed debt issuances for an aggregate principal amount of \$4.4 billion, consisting of senior notes with aggregate principal amounts of \$2.5 billion and EUR 1.6 billion with maturities ranging from four to ten years. The effective average interest rate of the notes issued is 5.3% per annum. See note 11 to our consolidated financial statements.

In March 2018, we redeemed in full our \$1.5 billion 1.4% senior notes due in July 2018 and our EUR 1.0 billion 2.875% senior notes due in April 2019.

In July 2018, we repaid at maturity our CHF 300 million 0.13% senior notes.

In September 2018, we completed a debt tender offer which resulted in a debt decrease of \$405 million, comprised of:

\$300 million of our \$2.0 billion 1.7% senior notes due in July 2019

EUR 90 million of our EUR 1.75 billion 0.38% senior notes due in July 2020

In October 2018, we repaid at maturity our CHF 450 million 1.5% senior notes.

Our debt as of December 31, 2018 was effectively denominated in the following currencies: 66% in U.S. dollars, 32% in euros and 2% in Swiss francs.

The portion of total debt classified as short-term as of December 31, 2018 was 8%, compared to 11% as of December 31, 2017, due to a decrease in current maturities.

Our financial leverage was 65% as of December 31, 2018, compared to 63% as of December 31, 2017.

Our average debt maturity was approximately 6.8 years as of December 31, 2018, compared to 6.4 years as of December 31, 2017.

### **2017 Debt Balance and Movements**

In January 2017, we repaid our GBP 510 million short-term loan.

In March 2017, we repaid at maturity a JPY 8.0 billion term loan.

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In March 2017, we entered into a JPY 86.8 billion term loan agreement, consisting of two tranches: JPY 58.5 billion with five years maturity and JPY 28.3 billion with one year maturity with an optional six month extension.

In April 2017, we repaid at maturity a JPY 65.5 billion term loan.

In August 2017, we repaid at maturity \$0.25 billion of our 5 year term loan.



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During 2017, we prepaid \$2.2 billion of our 3 year term loan and \$0.25 billion of our 5 year term loan.

During 2017, we repaid \$1.2 billion of our revolving credit facility.

## **Total Equity**

Total equity was \$15,794 million as of December 31, 2018, compared to \$18,745 million as of December 31, 2017. This decrease was mainly due to net loss of \$2,472 million and currency devaluations of \$713 million, partially offset by an increase of \$155 million in stock-based compensation expenses and \$115 million in unrealized gain associated with hedging activities.

Exchange rate fluctuations affected our balance sheet, as approximately 39% of our net assets (including both non-monetary and monetary assets) were in currencies other than the U.S. dollar. When compared to December 31, 2017, changes in currency rates had a negative impact of \$713 million on our equity as of December 31, 2018, mainly due to the change in value against the U.S. dollar of: the euro by 5%, the Russian ruble by 21%, the Polish zloty by 8%, the Canadian dollar by 8%, the Indian rupee by 10%, the Chilean peso by 13%, the British pound by 6% and the Argentine peso by 102%. All comparisons are on a year-end to year-end basis.

## **Cash Flow**

Cash flow generated from operating activities in 2018 was \$2,446 million, an increase of \$221 million, or 10%, compared to 2017. This increase was mainly due to the working capital adjustment with Allergan and the Rimsa settlement in 2018, partially offset by lower profit in our North America segment.

Cash flow generated from operating activities in 2018, in addition to \$1,735 million in beneficial interest collected in exchange for securitized trade receivables and \$149 million in proceeds from sale of property, plant and equipment and intangible assets, net of \$651 million in cash used for capital investments, was \$3,679 million. Cash flow generated from operating activities in 2017, in addition to \$1,282 million in beneficial interest collected in exchange for securitized trade receivables and \$60 million in proceeds from sale of property, plant and equipment and intangible asset, net of \$874 million in cash used for capital investments, was \$2,693 million. The increase in 2018 resulted mainly from the higher cash flow generated from operating activities, higher beneficial interest collected in exchange for securitized trade receivables and lower capital expenditures. See note 16 to our consolidated financial statements.

## **Dividends**

In December 2017, we announced an immediate suspension of dividends on our ordinary shares and ADSs.

We suspended cash dividends on our mandatory convertible preferred shares in the fourth quarter of 2017, due to our accumulated deficit. The mandatory conversion date of the mandatory convertible preferred shares was December 17, 2018. All of the accumulated and unpaid dividends on the mandatory convertible preferred shares were paid in ADSs, at a ratio of 3.0262 ADSs per mandatory convertible preferred share, according to the conversion mechanism set forth in the terms of the mandatory convertible preferred shares.

## **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.

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In September 2016, we entered into an agreement to develop and commercialize Regeneron's pain medication product, fasinumab. We paid Regeneron \$250 million upfront and will share equally with Regeneron in the global commercial benefits of this product, as well as ongoing associated R&D costs of approximately \$1.0 billion. Milestone payments of \$25 million, \$35 million and \$60 million were paid in the second quarter of 2017, the first quarter of 2018 and the fourth quarter of 2018, respectively.

In October 2016, we entered into an exclusive partnership with Celltrion to commercialize two of Celltrion's biosimilar products in development for the U.S. and Canadian markets. We paid Celltrion \$160 million, of which up to \$60 million is refundable or creditable under certain circumstances. We will share the profit from the commercialization of these products with Celltrion. These two products, Truxima and Herzuma, were approved by the FDA in November and December 2018, respectively.

In September 2017, we entered into a partnership agreement with Nuvelution for development of AUSTEDO for the treatment of Tourette syndrome in pediatric patients in the United States. Nuvelution will fund and manage clinical development, driving all operational aspects of the phase 3 program, and we will lead the regulatory process and be responsible for commercialization. Upon and subject to FDA approval of AUSTEDO for Tourette syndrome, we will pay Nuvelution a pre-agreed return.

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

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

Our principal sources of short-term liquidity are our existing cash investments, liquid securities and available credit facilities, primarily our \$3 billion syndicated revolving credit facility (RCF), which was not utilized as of December 31, 2018, as well as internally generated funds.

In connection with the requirements of the RCF, we entered into negative pledge agreements with certain banks and institutional investors. Under the agreements, we and our subsidiaries have undertaken not to register floating charges on assets in favor of any third parties without the prior consent of the banks, to maintain certain financial ratios, including the requirement to maintain compliance with a net debt to EBITDA ratio, which becomes more restrictive over time, and to fulfill other restrictions, as stipulated by the agreements. As of December 31, 2018, we did not have any outstanding debt under the RCF, which is our only debt subject to the net debt to EBITDA covenant, and met all financial covenants thereunder.

We expect that we will continue to have sufficient cash resources to support our debt service payments and all other financial obligations for at least twelve months from the date of this report, without utilizing the RCF.

If we experience lower than required cash flows to support our debt service payments, we may need to draw additional debt under the RCF. Under such circumstances, we will need to maintain compliance with our net debt to EBITDA ratio covenant. If such covenant will not be met, we believe we will be able to renegotiate and amend the covenants, or refinance the debt with different repayment terms to address such situation as circumstances warrant.



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Assuming utilization of the RCF, and under specified circumstances, including non-compliance with such covenants and the unavailability of any waiver, amendment or other modification thereto and the expiration of any applicable grace period thereto, substantially all of our debt could be negatively impacted by non-compliance with such covenants.

Although we have been successful in the past in obtaining financing and renegotiating debt covenants at commercially acceptable terms, there are no guarantees we will be able to do so in the future. If such efforts could not be successfully completed on commercially acceptable terms, we may curtail additional planned spending or divest additional assets in order to generate enough cash to meet our debt requirements and all other financial obligations.

## **Supplemental Non-GAAP Income Data**

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

our management and Board of Directors use the non-GAAP measures to evaluate our operational performance, to compare against work plans and budgets, and ultimately to evaluate the performance of management;

our annual budgets are prepared on a non-GAAP basis; and

senior management's annual compensation is derived, in part, using these non-GAAP measures. While qualitative factors and judgment also affect annual bonuses, the principal quantitative element in the determination of such bonuses is performance targets tied to the work plan, which is based on the non-GAAP presentation set forth below.

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

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

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

amortization of purchased intangible assets;

legal settlements and/or loss contingencies, due to the difficulty in predicting their timing and scope;

impairments of long-lived assets, including intangibles, property, plant and equipment and goodwill;

restructuring expenses, including severance, retention costs, contract cancellation costs and certain accelerated depreciation expenses primarily related to the rationalization of our plants or to certain other strategic activities, such as the realignment of R&D focus or other similar activities;

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acquisition- or divestment- related items, including changes in contingent consideration, integration costs, banker and other professional fees, inventory step-up and in-process R&D acquired in development arrangements;

expenses related to our equity compensation;

significant one-time financing costs and devaluation losses;

deconsolidation charges;

material tax and other awards or settlement amounts, both paid and received;

other exceptional items that we believe are sufficiently large that their exclusion is important to facilitate an understanding of trends in our financial results, such as impacts due to changes in accounting, significant costs for remediation of plants, such as inventory write-offs or related consulting costs, or other unusual events; and

tax effects of the foregoing items.

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

	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S. \$ in millions)</b>		
Amortization of purchased intangible assets	1,166	1,444	993
Goodwill impairment	3,027	17,100	900
Legal settlements and loss contingencies	(1,208)	500	899
Impairment of long-lived assets	500	544	157
Intangible assets impairment	1,991	3,238	589
Other R&D expenses	83	221	426
Inventory step-up		67	383
Acquisition, integration and related expenses	13	105	261
Restructuring expenses	488	535	245
Costs related to regulatory actions taken in facilities	14	47	153
Equity compensation	152	129	121
Contingent consideration	57	154	83
Gain on sales of business	(66)	(1,083)	(720)
Venezuela deconsolidation charge		396	
Other non-GAAP items	143	160	203
Financial expense (income)	66	(13)	888

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Tax effect and other income tax items*	(714)	(2,721)	(593)
Impairment of equity investment-net	103	47	3
Minority interest changes	(431)	(270)	(76)

\* Includes \$1.0 billion related to the effect of the U.S Tax Cuts and Jobs Act.



**Table of Contents****Year Ended December 31, 2018****(U.S. \$ and shares in millions, except per share amounts)**

	GAAP		Excluded for non GAAP measurement											Non GAAP	
		Amortization of purchased intangible assets	Goodwill impairment	Legal settlements and loss contingencies	Impairment of long-lived assets	Acquisition, integration and other R&D expenses	Regulatory actions taken	Costs related to restructuring and impairment	Equity consideration	Gain on sale of business	Other non GAAP items	Other items			
COGS	10,558	1,004					14	28			204		9,308		
R&D	1,213					83		26			2		1,102		
S&M	2,916	162						43			(7)		2,718		
G&A	1,298							55			15		1,228		
Other income	(291)									(66)			(225)		
Legal settlements and loss contingencies	(1,208)			(1,208)											
Impairments, restructuring and other	987				500	13	488		57		(71)				
Intangible assets impairment	1,991				1,991										
Goodwill impairment	3,027		3,027												
Financial expenses	959											66	893		
Corresponding tax effect	(195)											(714)	519		
Share in losses of associated companies net	71											103	(32)		
Net income attributable to non-controlling interests	(322)											(431)	109		
Total reconciled items		1,166	3,027	(1,208)	2,491	83	13	488	14	152	57	(66)	143	(976)	

EPS Basic	(2.35)	5.27	2.92
EPS Diluted	(2.35)	5.27	2.92

The non-GAAP diluted weighted average number of shares was 1,024 million for the year ended December 31, 2018.

The non-GAAP weighted average number of shares for the year ended December 31, 2018 does not take into account the potential dilution of the mandatory convertible preferred shares, which have an anti-dilutive effect on non-GAAP earnings per share.

**Table of Contents****Year ended December 31, 2017****(U.S. \$ and shares in millions, except per share amounts)**

	GAAP		Excluded for non GAAP measurement												Non GAAP
			Amortization of purchased intangible assets	Goodwill impairment	Legal settlements and contingencies	Impairment of long-lived assets	Other R&D expenses	Inventory	Acquisition, integration and related costs	Restructuring costs	Costs related to regulatory actions taken	Equity	Contingent consideration	Other non GAAP items	Other items
COGS	11,770	1,235						67			47	23		47	10,351
R&D	1,778						221					22		20	1,515
S&M	3,395	209										38		(1)	3,149
G&A	1,451											46		(8)	1,413
Other income	(1,199)													(1,083)	(116)
Legal settlements and loss contingencies	500				500										
Impairments, restructuring and other	1,836					544			105	535			154	498	
Intangible assets impairment	3,238					3,238									
Goodwill impairment	17,100			17,100											
Financial expenses	895														(13) 908
Corresponding tax effect	(1,933)														(2,721) 788
Share in losses of associated companies net	3														47 (44)
Net income attributable to non-controlling interests	(184)														(270) 86
Total reconciled items			1,444	17,100	500	3,782	221	67	105	535	47	129	154	(527)	(2,957)

EPS	Basic	(16.26)	20.27	4.01
EPS	Diluted	(16.26)	20.27	4.01

The non-GAAP diluted weighted average number of shares was 1,018 million for the year ended December 31, 2017. The non-GAAP weighted average number of shares for the year ended December 31, 2017 does not take into account the potential dilution of the mandatory convertible preferred shares (amounting to 59 million weighted average shares), which have an anti-dilutive effect on non-GAAP earnings per share.

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Year ended December 31, 2016

U.S. \$ and shares in millions (except per share amounts)

	GAAP		Excluded for non GAAP measurement											Non GAAP	
			Amortization of purchased intangible assets	Goodwill impairment	Legal settlements and loss contingencies	Impairment of long-lived R&D assets	Other R&D expenses	Inventory step-up	Acquisition, integration and restructuring costs	Costs related to regulatory actions taken	Equity impairment	Contingent considerations	Other non GAAP items	Other items	
COGS	10,250	881						383		153	14		128		8,691
R&D	2,077						426					20			1,631
S&M	3,583	112										35	(1)		3,437
G&A	1,390											52	(8)		1,346
Other income	(769)												(720)		(49)
Legal settlements and loss contingencies	899				899										
Impairments, restructuring and other	830					157			261	245		83	84		
Intangible assets impairment	589					589									
Goodwill impairment	900			900											
Financial expenses	1,330													888	442
Corresponding tax effect	521													(593)	1,114
Share in losses of associated companies net	(8)													3	(11)
Net income attributable to non-controlling interests	(18)													(76)	58
Total reconciled items			993	900	899	746	426	383	261	245	153	121	83	(517)	222

EPS Basic	0.07	5.15	5.22
EPS Diluted	0.07	5.07	5.14

The non-GAAP diluted weighted average number of shares was 1,020 million for the year ended December 31, 2016. The non-GAAP weighted average number of shares for the year ended December 31, 2016 does not take into account the potential dilution of the mandatory convertible preferred shares (amounting to 59 million weighted average shares), which had an anti-dilutive effect on non-GAAP earnings per share.

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### **Non-GAAP Effective Tax Rate**

The non-GAAP income taxes for 2018 were \$519 million on non-GAAP pre-tax income of \$3,830 million. The non-GAAP income taxes in 2017 were \$788 million on non-GAAP pre-tax income of \$5,165 million. Non-GAAP income taxes in 2016 were \$1,114 million on non-GAAP pre-tax income of \$6,405 million. The non-GAAP tax rate for 2018 was 14%, compared to 15% in 2017 and 17% in 2016. Our annual non-GAAP effective tax rate for 2018 was lower than our non-GAAP effective tax rate for 2017 primarily due to the reduction in the U.S. corporate tax rate following the U.S. tax reform.

In the future, our non-GAAP effective tax rate is expected to increase following changes in the portfolio of products we sell and the enactment of the Tax Cuts and Jobs Act in the United States.

### **Trend Information**

The following factors are expected to have a significant effect on our 2019 results:

execution of our restructuring plan, which will significantly affect our business and operations, and the risk of incurring additional restructuring expenses;

success of our recently launched specialty products, AJOVY and AUSTEDO;

ability to successfully execute key generic launches in a timely manner;

our high debt levels and non-investment grade credit rating will have a negative effect on our ability to borrow additional funds and may increase the cost of any such borrowing;

a decrease in sales of COPAXONE following the launches of generic versions to the product, and the possibility of additional generic competition in the future;

a decrease in sales of other specialty products due to potential loss of exclusivity or generic competition;

we expect continued competition for our generic products where multiple similar generic products have been launched, resulting in pricing pressure in the generics markets. We do, however, also see certain generic segments in which opportunities exist to grow our business, our portfolio of new drug applications and our portfolio of approved complex products; and

continued impact of currency fluctuations on revenues and net income, as well as on various balance sheet line items.

For additional information, please see Item 1 Business and elsewhere in this Item 7.

**Aggregated Contractual Obligations**

The following table summarizes our material contractual obligations and commitments as of December 31, 2018:

	Total	Payments Due by Period			More than 5 years
		Less than 1 year	1-3 years	3-5 years	
		(U.S. \$ in millions)			
Long-term debt obligations, including estimated interest*	\$ 36,155	\$ 2,518	\$ 8,348	\$ 7,733	\$ 17,556
Operating lease obligations	905	193	272	157	283
Purchase obligations (including purchase orders)	1,899	1,489	410		
Total	\$ 38,959	\$ 4,200	\$ 9,030	\$ 7,890	\$ 17,839

\* Long-term debt obligations mainly include senior notes and convertible senior debentures as disclosed in notes 11 to our consolidated financial statements.



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The total gross amount of unrecognized tax benefits for uncertain tax positions was \$1,072 million at December 31, 2018. Payment of these obligations would result from settlements with tax authorities. Due to the difficulty in determining the timing and magnitude of settlements, these obligations are not included in the table above. Correspondingly, it is difficult to ascertain whether we will pay any significant amount related to these obligations within the next year.

We have committed to make potential future milestone payments to third parties under various agreements. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, we may be required to pay such amounts. As of December 31, 2018, if all milestones and targets, for compounds in phase 2 and more advanced stages of development, are achieved, the total contingent payments could reach an aggregate amount of up to \$420 million.

We have committed to pay royalties to owners of know-how, partners in alliances and other certain arrangements and to parties that financed research and development, at a wide range of rates as a percentage of sales or of the gross margin of certain products, as defined in the underlying agreements.

Due to the uncertainty of the timing of these payments, these amounts, and the amounts described in the previous paragraph, are not included in the table above.

## **Off-Balance Sheet Arrangements**

Except for securitization transactions, which are disclosed in note 16 (d) to our consolidated financial statements, we do not have any material off-balance sheet arrangements.

## **Critical Accounting Policies**

For a description of our significant accounting policies, see note 1 to our consolidated financial statements.

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the accompanying consolidated financial statements and related footnotes. Actual results may differ from these estimates. We base our judgments on our experience and on various assumptions that we believe to be reasonable under the circumstances.

Of our policies, the following are considered critical to an understanding of our consolidated financial statements as they require the application of the most subjective and complex judgment, involving critical accounting estimates and assumptions impacting our consolidated financial statements. We have applied our policies and critical accounting estimates consistently across our businesses, including the Actavis Generics, Anda and Rimsa businesses acquisitions and our Teva Takeda business venture.

The significant accounting estimates that we believe are important to aid in fully understanding and evaluating our reported financial results include the following:

Revenue Recognition and SR&A

Income Taxes

Contingencies

Inventories

Asset Impairment Reviews

Identifiable Intangible Assets

Goodwill

Restructuring Costs

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### **Revenue Recognition and SR&A**

Our gross product revenues are subject to a variety of deductions which are generally estimated and recorded in the same period that the revenues are recognized, and primarily represent chargebacks, rebates and sales allowances to wholesalers, retailers and government agencies with respect to our pharmaceutical products. Those deductions represent estimates of rebates and discounts related to gross sales for the reporting period and, as such, knowledge and judgment of market conditions and practice are required when estimating the impact of these revenue deductions on gross sales for a reporting period.

Historically, our changes of estimates reflecting actual results or updated expectations have not been material to our overall business. Product-specific rebates, however, may have a significant impact on year-over-year individual product growth trends. If any of our ratios, factors, assessments, experiences or judgments are not indicative or accurate predictors of our future experience, our results could be materially affected. The sensitivity of our estimates can vary by program, type of customer and geographic location. However, estimates associated with governmental allowances, U.S. Medicaid and other performance-based contract rebates are most at risk for material adjustment because of the extensive time delay between the recording of the accrual and its ultimate settlement, an interval that can generally range up to one year. Because of this time lag, in any given quarter, our adjustments to actual can incorporate revisions of several prior quarters.

### **Income Taxes**

The provision for income tax is calculated based on our assumptions as to our entitlement to various benefits under the applicable tax laws in the jurisdictions in which we operate. The entitlement to such benefits depends upon our compliance with the terms and conditions set out in these laws.

Accounting for uncertainty in income taxes requires that it be more likely than not that the tax benefits recognized in the financial statements be sustained based on technical merits. The amount of benefits recorded for these positions is measured as the largest benefit more likely than not to be sustained. Significant judgment is required in making these determinations.

Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. In the determination of the appropriate valuation allowances, we have considered the most recent projections of future business results and prudent tax planning alternatives that may allow us to realize the deferred tax assets. Taxes which would apply in the event of disposal of investments in subsidiaries have not been taken into account in computing deferred taxes, as it is our intention to hold these investments rather than realize them.

Deferred taxes have not been provided for tax-exempt income, as the Company intends to permanently reinvest these profits and does not currently foresee a need to distribute dividends out of these earnings. Furthermore, we do not expect our non-Israeli subsidiaries to distribute taxable dividends in the foreseeable future, as their earnings and excess cash are used to pay down the group's external liabilities, while we expect to have sufficient resources in the Israeli companies to fund our cash needs in Israel. In addition, the Company announced a suspension of dividend distribution on ordinary shares and ADSs in 2017. An assessment of the tax that would have been payable had the Company's foreign subsidiaries distributed their income to the Company is not practicable because of the multiple levels of corporate ownership and multiple tax jurisdictions involved in each hypothetical dividend distribution.

For a discussion of the valuation allowance, deferred tax and valuation allowance estimates see notes 1 and 15 of our consolidated financial statements.

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### ***U.S. Tax Cuts and Jobs Act***

We accounted for the tax effects of the Tax Cuts and Jobs Act, enacted on December 22, 2017, on a provisional basis in our 2017 consolidated financial statements. We completed our accounting analysis in the fourth quarter of 2018, within the one year measurement period from the enactment date. See Note 15 in the notes to the consolidated financial statements for additional information.

### **Contingencies**

We and our subsidiaries are involved in various patent, product liability, commercial, government investigations, environmental claims and other legal proceedings that arise from time to time in the ordinary course of business. Except for income tax contingencies or contingent consideration acquired in a business combination, we record accruals for these types of contingencies to the extent that we conclude that their occurrence is probable and that the related liabilities are estimable. When accruing these costs, we will recognize an accrual in the amount within a range of loss that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, we accrue for the minimum amount within the range. We record anticipated recoveries under existing insurance contracts that are probable of occurring at the gross amount that is expected to be collected.

We review the adequacy of the accruals on a periodic basis and may determine to alter our reserves at any time in the future if we believe it would be appropriate to do so. As such accruals are based on management's judgment as to the probability of losses and, where applicable, actuarially determined estimates, accruals may materially differ from actual verdicts, settlements or other agreements made with regards to such contingencies.

### **Inventories**

Inventories are valued at the lower of cost or net realizable value. Cost of raw and packaging materials is determined mainly on a moving average basis. Cost of purchased products is determined mainly on a standard cost basis, approximating average costs. Cost of manufactured finished products and products in process is calculated assuming normal manufacturing capacity as follows: raw and packaging materials component is determined mainly on a moving average basis, while the capitalized production costs are determined either on an average basis over the production period, or on a standard cost basis, approximating average costs.

Our inventories generally have a limited shelf life and are subject to impairment as they approach their expiration dates. We regularly evaluate the carrying value of our inventories and when, in our opinion, factors indicate that impairment has occurred, we establish a reduction in the cost basis against the inventories' carrying value. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires us to utilize significant judgment. Although we make every effort to ensure the accuracy of forecasts of future product demand, any significant unanticipated decreases in demand could have a material impact on the carrying value of our inventories and reported operating results.

Our policy is to capitalize saleable product for unapproved inventory items when economic benefits are probable. We evaluate expiry, legal risk and likelihood of regulatory approval on a regular basis. If at any time approval is deemed not to be probable, the inventory is written down to its net realizable value. To date, inventory allowance adjustments in the normal course of business have not been material. However, from time to time, due to a regulatory action or lack of approval or delay in approval of a product, we may experience a more significant impact.

### **Asset Impairment Reviews**

Our long-lived, non-current assets mainly consist of goodwill, identifiable intangible assets and property, plant and equipment.

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We review all of our long-lived assets for impairment indicators throughout the year. We review goodwill and purchased intangible assets with indefinite lives for impairment annually and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. The provisions of the accounting standard for goodwill and other intangibles allow us to first assess qualitative factors to determine whether it is necessary to perform the next goodwill impairment quantitative test.

When necessary, we record charges for impairments of long-lived assets for the amount by which the carrying amount exceeds the fair value of these assets.

Examples of events or circumstances that may be indicative of impairment include:

A significant adverse change in legal factors or in the business climate that could affect the value of the asset. For example, a successful challenge of our patent rights would likely result in generic competition earlier than expected.

A significant adverse change in the extent or manner in which an asset is used. For example, restrictions imposed by the FDA or other regulatory authorities could affect our ability to manufacture or sell a product.

A projection or forecast that indicates losses or reduced profits associated with an asset. This could result, for example, from a change in a government reimbursement program that results in an inability to sustain projected product revenues and profitability. This also could result from the introduction of a competitor's product that results in a significant loss of market share or the inability to achieve the previously projected revenue growth, as well as the lack of acceptance of a product by patients, physicians and payers.

For IPR&D projects, this could result from, among other things, a change in outlook based on clinical trial data, a delay in the projected launch date or additional expenditures to commercialize the product.

## **Identifiable Intangible Assets**

Identifiable intangible assets are comprised of definite life intangible assets and indefinite life intangible assets.

Definite life intangible assets consist mainly of acquired product rights and other rights relating to products for which marketing approval was received from the FDA or the equivalent agencies in other countries. These assets are amortized using mainly the straight-line method over their estimated period of useful life, or based on economic benefit models, if more appropriate, which is determined by identifying the period and manner in which substantially all of the cash flows are expected to be generated. Amortization of acquired developed products is recorded under cost of sales. Amortization of marketing and distribution rights is recorded under selling and marketing expenses when separable

Impairment of identifiable intangible assets amounted to \$1,991 million, \$3,238 million and \$589 million in the years ended December 31, 2018, 2017 and 2016, respectively. See note 8 to our consolidated financial statements.

The fair value of acquired identifiable intangible assets is generally determined using an income approach. This method starts with a forecast of all expected future net cash flows associated with the asset and then adjusts the

forecast to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams.



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

The more significant estimates and assumptions inherent in the estimate of the fair value of identifiable intangible assets include (i) all assumptions associated with forecasting product profitability, including sales and cost to sell projections, (ii) tax rates which seek to incorporate the geographic diversity of the projected cash flows, (iii) expected impact of competitive, legal and/or regulatory forces on the projections and the impact of technological risk, R&D expenditure for ongoing support of product rights or continued development of IPR&D, and (iv) estimated useful lives and IPR&D expected launch dates. Additionally, for IPR&D assets the risk of failure has been factored into the fair value measure.

While all intangible assets other than goodwill can face events and circumstances that can lead to impairment, in general, intangible assets other than goodwill that are most at risk of impairment include IPR&D assets and newly acquired or recently impaired indefinite-lived brand assets. IPR&D assets are high-risk assets, as R&D is an inherently risky activity. Newly acquired and recently impaired indefinite-lived assets are more vulnerable to impairment as the assets are recorded at fair value and are then subsequently measured at the lower of fair value or carrying value at the end of each reporting period. As such, immediately after acquisition or impairment, even small declines in the outlook for these assets can negatively impact our ability to recover the carrying value and can result in an impairment charge.

## **Goodwill**

Goodwill reflects the excess of the consideration transferred, including the fair value of any contingent consideration and any non-controlling interest in the acquiree, over the assigned fair values of the identifiable net assets acquired. Goodwill is not amortized, and is assigned to reporting units and tested for impairment at least annually, in the fourth quarter of the fiscal year.

An interim goodwill impairment test may be required in advance of the annual impairment test if events occur that indicate impairment might be present.

In our annual goodwill impairment test, we may elect to bypass the qualitative assessment and perform a quantitative fair value test.

The Company estimates the fair values of all reporting units using a discounted cash flow model which utilizes Level 3 unobservable inputs. The carrying value of each reporting unit is determined by assigning the assets and liabilities, including the existing goodwill, to those reporting units.

For all of our reporting units, there are a number of future events and factors that may impact future results and the outcome of subsequent goodwill impairment testing. For a list of these factors, see the Forward-Looking Statements section and Item 1A Risk Factors.

See note 7 and note 20 to our consolidated financial statements for further details on the goodwill impairment recognized in 2018 and 2017 and for the change in segments.



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### **Restructuring Costs**

Restructuring costs have been recorded in connection with the restructuring plan announced in December 2017 and designed to restore our financial stability by significantly reducing the Company's cost base. As a result, our management has made estimates and judgments regarding future plans, mainly related to employee termination benefit costs, with additional charges possible following decisions on closures or divestments of manufacturing plants, R&D facilities, headquarters and other office locations. In connection with these actions, management also assesses the recoverability of long-lived assets employed in the business. In certain instances, asset lives have been shortened based on changes in the expected useful lives of the affected assets. Asset-related impairments and severance and other related costs are reflected within asset impairments, restructuring and others.

### **Recently Issued Accounting Pronouncements**

See note 1 to our consolidated financial statements.

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**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

**General**

The objective of our financial risk management measures is to minimize the impact of risks arising from foreign exchange and interest rate fluctuations. To reduce these risks, we take various operational measures in order to achieve a natural hedge and may enter, from time to time, into financial derivative instruments. Our derivative transactions are executed through global and local banks. We believe that due to our diversified derivative portfolio, the credit risk associated with any of these banks is minimal. No derivative instruments are entered into for trading purposes.

**Exchange Rate Risk Management**

We operate our business worldwide and, as such, we are subject to foreign exchange risks on our results of operations, our monetary assets and liabilities and our foreign subsidiaries' net assets. For further information on currencies in which we operate, see Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Impact of Currency Fluctuations on Results of Operations.

We generally prefer to borrow in U.S. dollars, however from time to time we borrow funds in other currencies, such as the euro, Swiss franc, Japanese yen and new Israeli shekel, in order to benefit from same currency revenues in relation to same currency costs and same currency assets in relation to same currency liabilities.

***Cash Flow Exposure***

Total revenues were \$18,854 million in 2018. Of these revenues, approximately 48% of our revenues were denominated in currencies other than the U.S. dollar, 19% in euros, 5% in Japanese yen and the rest in other currencies, none of which accounted for more than 4% of total revenues in 2018. In most currencies, we record corresponding expenses.

In certain currencies, primarily the euro, our revenues generally exceed our expenses. Conversely, in other currencies, primarily the new Israeli shekel and the Indian rupee, our expenses generally exceed our revenues.

For those currencies which do not have a sufficient natural hedge, we may choose to hedge in order to reduce the impact of foreign exchange fluctuations on our operating results.

In certain cases, we may hedge exposure arising from a specific transaction, executed in currency other than the functional currency, by entering into forward contracts and or by using plain-vanilla and exotic option strategies. We generally limit hedging transactions up to twelve months.

***Balance Sheet Exposure***

With respect to our monetary assets and liabilities, the exposure arises when the monetary assets and/or liabilities are denominated in currencies other than the functional currency of our subsidiaries. We strive to limit our exposure through natural hedging. Most of the remaining exposure is hedged by entering into financial derivative instruments. To the extent possible, the hedging activity is carried out on a consolidated level.



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The table below presents exposures exceeding \$50 million in absolute values:

Net exposure as of	
December 31, 2018	
Liability/Asset	(U.S. \$ in millions)
GBP/EUR	420
USD/JPY	378
USD/CHF	359
BGN/EUR	196
PLN/EUR	128
CAD/EUR	111
USD/EUR	103
GBP/USD	95
INR/USD	80
USD/ILS	66
EUR/CHF	57
USD/MXN	51

**Outstanding Foreign Exchange Hedging Transactions**

As of December 31, 2018, we had long and short forwards and currency option contracts with a corresponding notional amount of approximately \$3.4 billion and \$210 million, respectively. As of December 31, 2017, we had long and short forwards and currency option contracts with corresponding notional amounts of approximately \$2.8 billion and \$270 million, respectively.

The table below presents financial derivatives entered into as of December 31, 2018 in order to reduce currency exposure arising from our cash flow and balance sheet exposures. The table below presents only currency paired with hedged net notional values exceeding \$50 million.

Currency (sold)	Cross Currency (bought)	Net Notional Value		Fair Value		2018 Weighted Average Cross Currency Prices or Strike Prices
		2018	2017	2018	2017	
		(U.S. \$ in millions)				
Forward:						
EUR	GBP	416	467	(3.0)	0.5	0.89
JPY	USD	283	106	(5.0)	1.5	112.17
CHF**	USD	274	70	(1.0)	1.0	0.98
EUR**	USD	147	191	2.0	3.0	1.16
EUR	CAD	140	102	(4.0)		1.52
EUR	PLN	115	50	1.0	0.5	4.33
USD	INR	70	***	2.0		72.67
NIS	USD	66	132		(1.0)	3.75
USD	GBP	60	***			1.28

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CHF**	EUR	53	416	(1.0)	(1.0)	1.14
RUB	EUR	***	70		(1.0)	
MXN	USD	***	60		2.5	

**Options:**

CHF	USD	99	***			1.00
JPY	USD	77	71			114.00
EUR	PLN	***	70			

\* The table presents only currency pairs with hedged net notional values of more than \$50 million as of December 31, 2018.

\*\* Change in position compared to previous year.

\*\*\* Represents amounts less than \$50 million.

**Table of Contents****Foreign Subsidiaries Net Assets**

Under certain market conditions, we may hedge against possible fluctuations in foreign subsidiaries' net assets ( net investment hedge ). In these cases, we may use cross currency swaps and forward contracts. During 2017 we entered into a cross currency swap agreement, to hedge \$1 billion of our subsidiaries' euro denominated net assets. As of December 31, 2018, the fair value of this cross currency swap liability was \$41 million.

**Interest Rate Risk Management**

We are subject to interest rate risk on our investments and on our borrowings. We manage interest rate risk in the aggregate, while focusing on our immediate and intermediate liquidity needs.

We raise capital through various debt instruments including senior notes that bear a fixed or variable interest rate, syndicated bank loans that bear a fixed or floating interest rate, securitizations and convertible debentures that bear a fixed and floating interest rate. In some cases, as described below, we have swapped from a fixed to a floating interest rate ( fair value hedge ), from a floating to a fixed interest and from a fixed to a fixed interest rate with an exchange from a currency other than the functional currency ( cash flow hedge ), reducing overall interest expenses or hedging risks associated with interest rate fluctuations.

In certain cases, we may hedge, in whole or in part, against exposure arising from a specific transaction, such as debt issuances related to an acquisition or debt refinancing, by entering into forward and interest rate swap contracts and/or by using options.

The table below presents the aggregate outstanding notional amounts of the hedged items as of December 31, 2018 and 2017:

				December 31,					
				2018		2017			
				U.S. \$ in millions					
Cross currency swap cash flow hedge				\$ 588		\$ 588			
Interest rate swap fair value hedge				\$ 500		\$ 500			
Currency	Total Amount	Interest Rate Ranges		2019	2020	2021	2022	2023	2024 & thereafter
(U.S. dollars in millions)									
Fixed Rate:									
USD	18,131	1.70%	6.75%	1,700	700	3,618	860	2,493	8,760
Euro	9,148	0.38%	4.50%		1,896	587	801	1,480	4,384
CHF	712	0.50%	1.00%				356		356
USD convertible debentures*	514	0.25%	0.25%	514					
Floating Rate:									
USD	500	2.80%	2.80%					500	
Others	15	4.30%	13.00%	2					13



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Total:	29,020	\$ 2,216	\$ 2,596	\$ 4,205	\$ 2,017	\$ 4,473	\$ 13,513
Less debt issuance costs	(104)						
Total:	\$ 28,916						

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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEAR ENDED DECEMBER 31, 2018**

<b><u>Report of Independent Registered Public Accounting Firm</u></b>	<b>Page</b> 96
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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of Teva Pharmaceutical Industries Limited

***Opinions on the Financial Statements and Internal Control over Financial Reporting***

We have audited the accompanying consolidated balance sheets of Teva Pharmaceutical Industries Limited and its subsidiaries (the Company) as of December 31, 2018 and 2017, and the related consolidated statements of income (loss), of comprehensive income (loss), of changes in equity and of cash flows for each of the three years in the period ended December 31, 2018, including the related notes and schedule of valuation and qualifying accounts for each of the three years in the period ended December 31, 2018 listed in the index appearing under Item 15(a) (collectively referred to as the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control Integrated Framework* (2013) issued by the COSO.

***Change in Accounting Principle***

As discussed in Note 1(b) to the consolidated financial statements, the Company changed the manner in which it accounts for cash receipts and cash payments in 2018.

***Basis for Opinions***

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in *Report of Teva Management on Internal Control Over Financial Reporting* appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated

financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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***Definition and Limitations of Internal Control over Financial Reporting***

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Kesselman & Kesselman  
Kesselman & Kesselman  
Certified Public Accountants (Isr.)  
A member of PricewaterhouseCoopers  
International Limited

Tel-Aviv, Israel  
February 19, 2019

We have served as the Company's auditor since at least 1976. We have not been able to determine the specific year we began serving as the auditor of the company.

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONSOLIDATED BALANCE SHEETS**

(U.S. dollars in millions)

	<b>December 31, 2018</b>	<b>December 31, 2017</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 1,782	\$ 963
Trade receivables	5,822	7,128
Inventories	4,731	4,924
Prepaid expenses	899	1,100
Other current assets	468	701
Assets held for sale	92	566
<b>Total current assets</b>	<b>13,794</b>	<b>15,382</b>
<b>Deferred income taxes</b>	<b>368</b>	<b>574</b>
<b>Other non-current assets</b>	<b>731</b>	<b>932</b>
<b>Property, plant and equipment, net</b>	<b>6,868</b>	<b>7,673</b>
<b>Identifiable intangible assets, net</b>	<b>14,005</b>	<b>17,640</b>
<b>Goodwill</b>	<b>24,917</b>	<b>28,414</b>
<b>Total assets</b>	<b>\$ 60,683</b>	<b>\$ 70,615</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities:</b>		
Short-term debt	\$ 2,216	\$ 3,646
Sales reserves and allowances	6,711	7,881
Trade payables	1,853	2,069
Employee-related obligations	870	549
Accrued expenses	1,868	3,014
Other current liabilities	804	724
Liabilities held for sale		38
<b>Total current liabilities</b>	<b>14,322</b>	<b>17,921</b>
<b>Long-term liabilities:</b>		
Deferred income taxes	2,140	3,277
Other taxes and long-term liabilities	1,727	1,843
Senior notes and loans	26,700	28,829
<b>Total long-term liabilities</b>	<b>30,567</b>	<b>33,949</b>
<b>Commitments and contingencies, see note 13</b>		

<b>Total liabilities</b>	44,889	51,870
<b>Equity:</b>		
<b>Teva shareholders equity:</b>		
Preferred shares of NIS 0.10 par value per mandatory convertible preferred share; December 31, 2018: no shares authorized or issued; December 31, 2017: authorized 5.0 million shares; issued 3.7 million shares		3,631
Ordinary shares of NIS 0.10 par value per share; December 31, 2018 and December 31, 2017: authorized 2,495 million shares; issued 1,196 million shares and 1,124 million shares, respectively	56	54
Additional paid-in capital	27,210	23,479
Accumulated deficit	(5,958)	(3,803)
Accumulated other comprehensive loss	(2,459)	(1,853)
Treasury shares as of December 31, 2018 and December 31, 2017: 106 million ordinary shares and 107 million ordinary shares, respectively	(4,142)	(4,149)
	14,707	17,359
<b>Non-controlling interests</b>	1,087	1,386
<b>Total equity</b>	15,794	18,745
<b>Total liabilities and equity</b>	\$ 60,683	\$ 70,615

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

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

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
Net revenues	\$ 18,854	\$ 22,385	\$ 21,903
Cost of sales	10,558	11,770	10,250
Gross profit	8,296	10,615	11,653
Research and development expenses	1,213	1,778	2,077
Selling and marketing expenses	2,916	3,395	3,583
General and administrative expenses	1,298	1,451	1,390
Intangible assets impairments	1,991	3,238	589
Goodwill impairment	3,027	17,100	900
Other asset impairments, restructuring and other items	987	1,836	830
Legal settlements and loss contingencies	(1,208)	500	899
Other income	(291)	(1,199)	(769)
Operating (loss) income	(1,637)	(17,484)	2,154
Financial expenses net	959	895	1,330
Income (loss) before income taxes	(2,596)	(18,379)	824
Income taxes (benefit)	(195)	(1,933)	521
Share in (profits) losses of associated companies net	71	3	(8)
Net income (loss)	(2,472)	(16,449)	311
Net loss attributable to non-controlling interests	(322)	(184)	(18)
Net income (loss) attributable to Teva	(2,150)	(16,265)	329
Accrued dividends on preferred shares	249	260	261
Net income (loss) attributable to ordinary shareholders	\$ (2,399)	\$ (16,525)	\$ 68
Earnings (loss) per share attributable to ordinary shareholders:			
Basic	\$ (2.35)	\$ (16.26)	\$ 0.07
Diluted	\$ (2.35)	\$ (16.26)	\$ 0.07
Weighted average number of shares (in millions):			
Basic	1,021	1,016	955
Diluted	1,021	1,016	961



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

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

**(U.S. dollars in millions)**

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
Net income (loss)	\$ (2,472)	\$ (16,449)	\$ 311
Other comprehensive income (loss), net of tax:			
Currency translation adjustment*	(713)	1,516	(445)
Unrealized gain (loss) on derivative financial instruments, net	115	(140)	(477)
Unrealized gain (loss) on available-for-sale securities, net		3	(319)
Unrealized gain (loss) on defined benefit plans, net	13	(10)	(23)
Total other comprehensive income (loss)	(585)	1,369	(1,264)
Total comprehensive loss	(3,057)	(15,080)	(953)
Comprehensive loss attributable to non-controlling interests	(296)	(121)	(78)
Comprehensive loss attributable to Teva	\$ (2,761)	\$ (14,959)	\$ (875)

\* In 2017 includes amount that was released from accumulated other comprehensive loss as part of the deconsolidation of the Venezuelan subsidiaries and is included in Venezuela deconsolidation charge under other asset impairment, restructuring and other items.

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

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## TEVA PHARMACEUTICAL INDUSTRIES LIMITED

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Teva shareholders' equity									
	Ordinary shares		Retained earnings and other comprehensive income (loss)					Total Teva shareholders' equity	Non-controlling interests	Total equity
	Number of shares (in millions)	Stated value	MCPS*	Additional paid-in capital	accumulated deficit	accumulated (loss)	Treasury shares			
(U.S. dollars in millions)										
Balance at January 1, 2016	1,016	\$ 52	\$ 3,291	\$ 17,757	\$ 14,851	\$ (1,955)	\$ (4,227)	\$ 29,769	\$ 158	\$ 29,927
Changes during 2016:										
Comprehensive income (loss)					329	(1,204)		(875)	(78)	(953)
Ordinary shares issuance***	106	2		5,389				5,391		5,391
MCPS issuance***			329					329		329
Exercise of options by employees and vested RSUs	1	*		2			33	35		35
Stock-based compensation expense				159				159		159
Dividends to ordinary shareholders					(1,303)			(1,303)		(1,303)
Accrued dividends to preferred shareholders					(261)			(261)		(261)
Transactions with non-controlling interests				111				111	1,573	1,684
Other		.		(9)	(9)			(18)	3	(15)
Balance at December 31,	1,123	54	3,620	23,409	13,607	(3,159)	(4,194)	33,337	1,656	34,993

**2016****Changes during 2017:**

Comprehensive income (loss)				(16,265)	1,306		(14,959)	(121)	(15,080)
Exercise of options by employees and vested RSUs	1	*		(45)		45	*		*
Stock-based compensation expense				133			133		133
Dividends to ordinary shareholders				(901)			(901)		(901)
Dividends to preferred shareholders			11	(11)	(249)		(249)		(249)
Transactions with non-controlling interests								(111)	(111)
Other				(7)	5		(2)	(38)	(40)

**Balance at December 31, 2017**

1,124	54	3,631	23,479	(3,803)	(1,853)	(4,149)	17,359	1,386	18,745
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**Changes during 2018:**

Cumulative effect of new accounting standard (See Note 1)				(5)	5				
Comprehensive income (loss)				(2,150)	(611)		(2,761)	(296)	(3,057)
Issuance of Treasury Shares		*		(3)		7	4		4
Stock-based compensation expense				155			155		155
Issuance of shares****	72	2	(3,880)	3,826			(52)		(52)
Dividends to preferred shareholders			249	(249)					
Transactions with non-controlling interests				2			2	(3)	(1)

**Balance at  
December 31,  
2018**

1,196 \$56 \$ 27,210 \$ (5,958) \$(2,459) \$(4,142) \$ 14,707 \$ 1,087 \$ 15,794

\* Represents an amount less than 0.5 million.

\*\* Mandatory convertible preferred shares.

\*\*\* Net of issuance costs.

\*\*\*\* Mainly MCPS conversion, net of tax withholding.

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

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONSOLIDATED STATEMENTS OF CASH FLOWS****(U.S. dollars in millions)**

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
<b>Operating activities:</b>			
Net income (loss)	\$ (2,472)	\$ (16,449)	\$ 311
Adjustments to reconcile net income to net cash provided by operations:			
Impairment of long-lived assets	5,621	20,882	1,645
Depreciation and amortization	1,842	2,112	1,524
Net change in operating assets and liabilities	(1,823)	(1,645)	(116)
Deferred income taxes net and uncertain tax positions	(837)	(2,331)	15
Stock-based compensation	155	133	124
Other items	(135)	13	(14)
Research and development in process	114	175	422
Net loss from sale of long-lived assets and investments	(19)	(1,090)	(764)
Venezuela deconsolidation loss		383	
Venezuela impairment of net monetary assets		42	603
Other-than-temporary impairment			140
<b>Net cash provided by operating activities</b>	<b>2,446</b>	<b>2,225</b>	<b>3,890</b>
<b>Investing activities:</b>			
Beneficial interest collected in exchange for securitized trade receivables	1,735	1,282	1,335
Proceeds from sales of long-lived assets and investments	890	3,477	2,002
Purchases of property, plant and equipment	(651)	(874)	(901)
Purchases of investments and other assets	(119)	(200)	(481)
Other investing activities	11	(282)	(212)
Acquisitions of businesses, net of cash acquired		43	(36,148)
<b>Net cash provided by (used in) investing activities</b>	<b>1,866</b>	<b>3,446</b>	<b>(34,405)</b>
<b>Financing activities:</b>			
Repayment of senior notes and loans and other long-term liabilities	(7,446)	(3,300)	(999)
Proceeds from senior notes and loans, net of issuance costs	4,434	506	25,252
Net change in short-term debt	(260)	(1,683)	1,998
Other financing activities	(57)	(74)	(169)
Dividends paid on ordinary shares**	(12)	(901)	(1,303)
Dividends paid on preferred shares**	(10)	(260)	(255)
Proceeds from exercise of options by employees	*	*	35
Dividends paid to non-controlling interests		(38)	

Proceeds from issuance of ordinary shares, net of issuance costs			329
Proceeds from issuance of mandatory convertible preferred shares, net of issuance costs			329
<b>Net cash provided by (used in) financing activities</b>	<b>(3,351)</b>	<b>(5,750)</b>	<b>25,217</b>
<b>Translation adjustment on cash and cash equivalents</b>	<b>(142)</b>	<b>54</b>	<b>(660)</b>
<b>Net change in cash and cash equivalents</b>	<b>819</b>	<b>(25)</b>	<b>(5,958)</b>
<b>Balance of cash and cash equivalents at beginning of year</b>	<b>963</b>	<b>988</b>	<b>6,946</b>
<b>Balance of cash and cash equivalents at end of year</b>	<b>\$ 1,782</b>	<b>\$ 963</b>	<b>\$ 988</b>

\* Represent an amount less than 0.5 million

\*\* In 2018, the amounts consist of tax withholding payments made on dividends paid in 2017.

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

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)**

**(U.S. dollars in millions)**

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
<b>Supplemental cash flow information:</b>			
Non-cash financing and investing activities:			
Beneficial interest obtained in exchange for securitized trade receivables	\$ 1,716	\$ 1,295	\$ 1,365
Conversion of mandatory convertible preferred shares into ordinary shares	3,880		
Share issuance to Allergan plc for the Actavis Generics acquisition			5,065
Shares transferred to Takeda as part of the establishment of Teva Takeda			1,825
Actavis Generics contingent consideration			302
Cash paid during the year for:			
Interest	\$ 815	\$ 795	\$ 290
Income taxes, net of refunds	\$ 420	\$ 106	\$ 341
Net change in operating assets and liabilities:			

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
Other current assets	\$ (1,437)	\$ 658	\$ (517)
Trade payables, accrued expenses, employee-related obligations and other current liabilities	(500)	(3,083)	(695)
Trade receivables net of sales reserves and allowances	88	514	343
Inventories	26	199	370
Inventory step-up		67	383
	\$ (1,823)	\$ (1,645)	\$ (116)

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



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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements**

**NOTE 1 SIGNIFICANT ACCOUNTING POLICIES:**

**a. General:**

*Operations*

Teva Pharmaceutical Industries Limited (the Parent Company), headquartered in Israel, together with its subsidiaries and associated companies (the Company, Teva or the Group), is engaged in the development, manufacturing, marketing and distribution of generics, specialty medicines and biopharmaceuticals. The majority of the Group's revenues are in the United States and Europe.

*Basis of presentation and use of estimates*

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP).

In preparing the Company's consolidated financial statements, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reported years. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to determining the valuation and recoverability of intangible assets and goodwill; assessing sales reserves and allowances, and contingent consideration; assessing compliance with debt covenants; uncertain tax positions, valuation allowances, contingencies, inventory valuation and restructuring.

*Accounting for Venezuelan Operations*

Until November 30, 2017, the financial position and results of operations of Teva's Venezuelan business, conducted through a number of wholly-owned subsidiaries, were included in Teva's consolidated financial statements and reported under highly-inflationary accounting principles, with the functional currency of the U.S. dollar.

Effective November 30, 2017, Teva deconsolidated its Venezuelan subsidiaries and began accounting for its investments in its Venezuelan operations using the cost method of accounting under the measurement alternative. The estimated fair value of the investments was immaterial based on expected future cash flow, considering ongoing hyper-inflation and economic and political uncertainty in Venezuela. The assigned values are considered Level 3 measurements within the fair value hierarchy.

Teva's financial results include sales of finished goods to the Venezuelan subsidiaries, to the extent cash payments are received from these subsidiaries, while cost of sales is recorded when goods are imported to Venezuela. The Venezuelan subsidiaries' results were immaterial in terms of assets, liabilities, operating results and cash flows for the eleven months ended November 30, 2017.

Upon assessing the facts as of December 31, 2018, Teva continues to believe its previous conclusion regarding its lack of control or significant influence over its Venezuelan operations is appropriate. Teva will continue to monitor the conditions in Venezuela and their impact on its prospective accounting treatment and related disclosures.

*Functional currency*

A major part of the Group's operations is carried out by the Company in the United States, Israel and certain other countries. The functional currency of these entities is the U.S. dollar ( dollar or \$ ).

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

The functional currency of certain subsidiaries and associated companies is their local currency. The financial statements of those companies are included in the consolidated financial statements, translated into U.S. dollars. Assets and liabilities are translated at year-end exchange rates, while revenues and expenses are translated at monthly average exchange rates during the year. Differences resulting from translation are presented as other comprehensive income (loss) in the consolidated statements of comprehensive income (loss).

In the event of a divestiture of a foreign subsidiary, the related foreign currency translation results are reversed from equity to income. Foreign currency exchange gains and losses are included in net income (loss).

*Principles of consolidation*

The consolidated financial statements include the accounts of the Company and its majority-owned subsidiaries and VIEs for which the Company is considered the primary beneficiary. For those consolidated subsidiaries where Teva owns less than 100%, the outside shareholders' interests are shown as non-controlling interests in equity. Investments in affiliates over which the Company has significant influence but not a controlling interest, are carried on the equity basis.

For VIEs, the Company performs an analysis to determine whether the variable interests give a controlling financial interest in a VIE. The Company periodically reassesses whether it controls its VIEs.

Intercompany transactions and balances are eliminated on consolidation; profits from intercompany sales, not yet realized outside the Group, are also eliminated.

**b. New accounting pronouncements**

*Recently adopted accounting pronouncements*

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

In May 2017, the FASB issued ASU 2017-09 Stock Compensation Scope of Modification Accounting. This guidance addresses changes to terms and conditions of share-based payment awards. The amendment provides guidance about which changes to terms and conditions of a share-based payment award require an entity to apply modification accounting. The guidance is effective for the fiscal year beginning on January 1, 2018, including interim periods within that year. Teva adopted the provisions of this update as of January 1, 2018. The impact that this new standard has on Teva's financial statements after adoption will depend on any modification of share-based compensation after the adoption.

In February 2017, the FASB issued ASU 2017-05 Other Income Gains and Losses from the Derecognition of Nonfinancial Assets: Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of

Nonfinancial Assets . The amendments address the recognition of gains and losses on the transfer (i.e., sale) of nonfinancial assets to counterparties other than customers. The guidance conforms de-recognition of nonfinancial assets to the model for transactions in the new revenue standard. Teva adopted the provisions of this update as of January 1, 2018 with no material impact on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15 Statement of Cash Flows Classification of Certain Cash Receipts and Cash Payments . The guidance addresses eight specific issues: debt prepayment or debt

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

extinguishment costs; settlement of certain debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interest in securitization transactions; and separately identifiable cash flows and application of the predominance principle. The amendments should be applied retrospectively. Teva adopted the provisions of this update as of January 1, 2018. This resulted in the reclassification of \$1,735 million, \$1,282 million and \$1,335 million of beneficial interest in securitization transactions from operating activities to investing activities for the twelve-month periods ended December 31, 2018, 2017 and 2016, respectively.

In January 2016, the FASB issued ASU 2016-01 Recognition and Measurement of Financial Assets and Financial Liabilities Accounting Standards Update Financial Accounting . This guidance updates certain aspects of recognition, measurement, presentation and disclosure of equity investments. The guidance requires entities to recognize changes in fair value in net income rather than in accumulated other comprehensive income. Teva adopted this update as of January 1, 2018. Following the adoption, the Company recorded a \$5 million opening balance reclassification from accumulated other comprehensive loss to retained earnings. See note 14.

*Recently issued accounting pronouncements, not yet adopted*

In November 2018, the FASB issued ASU 2018-18 Collaborative Arrangements (Topic 808) Clarifying the interaction between Topic 808 and Topic 606 . The amendments provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606. It also specifically (i) addresses when the participant should be considered a customer in the context of a unit of account, (ii) adds unit-of-account guidance in ASC 808 to align with guidance in ASC 606, and (iii) precludes presenting revenue from a collaborative arrangement together with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer. The guidance will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted and should be applied retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15 Intangibles Goodwill and other Internal-use software (Subtopic 350-40): Customer s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract . This guidance aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance will be effective for fiscal years beginning after December 15, 2019, although early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13 Fair Value Measurement (Topic 820) Disclosure Framework Changes to the Disclosure Requirements for Fair Value Measurement . This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to

develop Level 3 fair value measurements. Certain disclosures required by this guidance must be applied on a retrospective basis and others on a prospective basis. The guidance will be effective for fiscal years beginning after December 15, 2019, although early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07 *Improvement to Nonemployee Share-Based Payments Accounting* . This guidance simplifies the accounting for non-employee share-based payment transactions. The

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

amendments specify that ASC 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The guidance is effective for fiscal years beginning after December 31, 2018. The Company does not expect that the adoption of this guidance will have a significant impact on its consolidated financial statements.

In February 2018, the FASB issued ASU 2018-02 *Income Statement Reporting Comprehensive Income: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*. The guidance allows reclassification of stranded tax effects resulting from the Tax Cuts and Jobs Act from accumulated other comprehensive income to retained earnings. This guidance is effective for fiscal years beginning after December 15, 2018. The adoption of this guidance has no material impact on the Company's consolidated financial statements.

In August 2017, the FASB issued ASU 2017-12 *Derivatives and Hedging: Targeted Improvements to Accounting for Hedging Activities*. This guidance expands and refines hedge accounting for both non-financial and financial risk components and aligns the recognition and presentation of the effects of the hedging instrument and the hedged item in the financial statements. The guidance will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company does not expect that the adoption of this guidance will have a significant impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13 *Financial Instruments: Credit Losses: Measurement of Credit Losses on Financial Instruments*. This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance will be effective for the fiscal year beginning on January 1, 2020, including interim periods within that year. Teva is currently evaluating the potential effect of the guidance on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02 *Leases*. The guidance establishes a right-of-use model (ROU) that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The guidance became effective on January 1, 2019. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (i) its effective date or (ii) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. If an entity chooses the second option, the transition requirements for existing leases also apply to leases entered into between the date of initial application and the effective date. The entity must then also recast its comparative period financial statements and provide the disclosures required by the new standard for the comparative periods. Teva expects to adopt the new standard on January 1, 2019 and uses the effective date as Teva's date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019.

The new standard provides a number of optional practical expedients in transition. Teva does not expect to elect the package of practical expedients, which permits the Company not to reassess its prior conclusions regarding lease identification, lease classification and initial direct costs under the new standard. In addition, Teva also does not

expect to elect the practical expedient pertaining to land easements. However, the Company does expect to elect the practical expedient pertaining to the use-of hindsight.

Teva expects that the adoption of this standard will have a material effect on Teva's financial statements. While Teva continues to assess all the effects of adoption, Teva currently believes that the most significant impact will be reflected in: (i) the recognition of new ROU assets and lease liabilities on Teva's balance sheet for



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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

its operating leases of real estate, vehicles and equipment, and (ii) the requirement to provide significant new disclosures regarding Teva's leasing activities. The Company, however, does not expect a material impact to its consolidated statements of income and consolidated statements of cash flow.

Following adoption of the new standard, Teva expects to recognize additional operating liabilities ranging from \$560 million to \$660 million, with corresponding ROU assets of approximately the same amount based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases.

The new standard also provides practical expedients for an entity's ongoing accounting. Teva expects to elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases, Teva will not recognize ROU assets or lease liabilities, including not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Teva also expects to elect the practical expedient to not separate lease and non-lease components for all of Teva's leases, other than leases of real estate.

The Company has performed, and will continue to perform a comprehensive evaluation of the impact of this guidance on the Company, including assessing the Company's lease portfolio, implementation of a new enterprise-wide lease management system to meet reporting requirements, assessing the impact to business processes and implementation of internal controls over financial reporting and related disclosure requirements. The Company is working closely with the software system developer, as the timely readiness of the lease software system is critical to ensure an efficient and effective adoption of the standard.

**c. Acquisitions:**

Teva's consolidated financial statements include the operations of an acquired business from the date of the acquisition's consummation. Acquired businesses are accounted for using the acquisition method of accounting, which requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of acquired in process research and development (IPR&D) be recorded on the balance sheet. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired is recorded as goodwill. When Teva acquires net assets that do not constitute a business, as defined under U.S. GAAP, no goodwill is recognized and acquired IPR&D is expensed.

Contingent consideration incurred in a business combination is included as part of the acquisition price and recorded at a probability weighted assessment of its fair value as of the acquisition date. The fair value of the contingent consideration is re-measured at each reporting period, with any adjustments in fair value recognized in earnings under impairments, restructuring and others.

**d. Collaborative arrangements:**

Collaborative agreements are contractual arrangements in which the parties are active participants to the arrangement and are exposed to the significant risks and rewards that are dependent on the ultimate commercial success of the

endeavor.

The Company recognizes revenue generated and costs incurred on sales to third parties as it relates to collaborative agreements as gross or net. If the Company is the principal participant in a transaction, revenues and costs are recorded on a gross basis; otherwise, revenues are recorded on a net basis.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**e. Equity investments:**

The Company measures equity investments at fair value with changes in fair value now recognized in net income. The Company accounts for equity investments that do not have a readily determinable fair value as cost method investments under the measurement alternative prescribed within ASU 2016-01 Financial Instruments Recognition and Measurement of Financial Assets and Financial Liabilities, to the extent such investments are not subject to consolidation or the equity method. Under the measurement alternative, these financial instruments are carried at cost, less any impairment (assessed quarterly), adjusted for changes resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer. In addition, income is recognized when dividends are received only to the extent they are distributed from net accumulated earnings of the investee. Otherwise, such distributions are considered returns of investment and are recorded as a reduction of the cost of the investment.

**f. Fair value measurement:**

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

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

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

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

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

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

**g. Investment in securities:**

Investment in securities consists of debt securities classified as available-for-sale and recorded at fair value. The fair value of quoted securities is based on current market value. When debt securities do not have an active market, fair value is determined using a valuation model. This model is based on reference to other instruments with similar characteristics, or a discounted cash flow analysis, or other pricing models making use of market inputs and relying as little as possible on entity-specific inputs.

Unrealized gains of available for sale securities, net of taxes, are reflected in other comprehensive income. Unrealized losses considered to be temporary are reflected in other comprehensive income; unrealized losses that are considered to be other-than-temporary are charged to income as an impairment charge. Realized gains and losses for debt securities are included in financial expense, net.

The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. For debt securities, an other-than-temporary

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in financial expense, net, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in other comprehensive income.

**h. Cash and cash equivalents:**

All highly liquid investments, which include short-term bank deposits and money market instruments, that are not restricted as to withdrawal or use, and investment in short-term debentures, the period to maturity of which did not exceed three months at the time of investment, are considered to be cash equivalents.

**i. Trade receivables:**

Trade receivables are stated at their net realizable value. The allowance against gross trade receivables reflects the best estimate of losses inherent in the receivables portfolio determined on the basis of historical experience, specific allowances for known troubled accounts and other currently available information. As of December 31, 2018, and 2017, an allowance for doubtful debts in the amount of \$232 million is reflected in net trade receivables. Trade receivables are written off after all reasonable means to collect the full amount have been exhausted.

**j. Concentration of credit risks:**

Most of Teva's cash and cash equivalents (which, along with investment in securities, totaled \$1,845 million at December 31, 2018) were deposited with European, U.S. and Israeli banks and financial institutions and were comprised mainly of cash deposits.

The pharmaceutical industry, particularly in the United States, has been significantly affected by consolidation among managed care providers, large pharmacy chains, wholesaling organizations and other buyer groups. The U.S. market constituted approximately 48% of Teva's consolidated revenues in 2018. The exposure of credit risks relating to other trade receivables is limited, due to the relatively large number of group customers and their wide geographic distribution. Teva performs ongoing credit evaluations of its customers for the purpose of determining the appropriate allowance for doubtful accounts and generally does not require collateral. An appropriate allowance for doubtful accounts is included in the accounts and netted against trade receivables.

**k. Inventories:**

Inventories are valued at the lower of cost or net realizable value. Cost of raw and packaging materials, purchased products, manufactured finished products, products in process and capitalized production costs are determined predominantly on a standard cost basis, approximating average costs. Other methods which are utilized for determining the value of inventories are moving average, cost basis and the first in first out method. Teva regularly reviews its inventories for obsolescence and other impairment risks and reserves are established when necessary.

Inventories acquired in a business combination are stepped-up to their estimated fair value and amortized to cost of sales as that inventory is sold.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**I. Long-lived assets:**

Teva's long-lived, non-current assets are comprised mainly of goodwill, identifiable intangible assets and property, plant and equipment. All long-lived assets are monitored for impairment indicators throughout the year. Impairment testing for goodwill and all identifiable intangible assets is performed at least annually. When necessary, charges for impairments of long-lived assets are recorded for the amount by which the fair value is less than the carrying value of these assets.

*Goodwill*

Goodwill reflects the excess of the consideration transferred, including the fair value of any contingent consideration and any non-controlling interest in the acquiree, over the assigned fair values of the identifiable net assets acquired. Goodwill is not amortized, and is assigned to reporting units and tested for impairment at least on an annual basis, in the fourth quarter of the fiscal year.

The goodwill impairment test is performed according to the following principles:

1. An initial qualitative assessment may be performed to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount.
2. If the Company concludes it is more likely than not that the fair value of the reporting unit is less than its carrying amount, a quantitative fair value test is performed. An impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value is recognized.

An interim goodwill impairment test may be required in advance of the annual impairment test if events occur that indicate impairment might be present. For example, a substantial decline in the Company's market capitalization, unexpected adverse business conditions, economic factors and unanticipated competitive activities may indicate that an interim impairment test is required. In the event that the Company's market capitalization declines below its book value, the Company considers the length and severity of the decline and the reason for the decline when assessing whether potential goodwill impairment exists.

*Identifiable intangible assets*

Identifiable intangible assets are comprised of definite life intangible assets and indefinite life intangible assets.

Definite life intangible assets consist mainly of acquired product rights and other rights relating to products for which marketing approval was received from the U.S. Food and Drug Administration (FDA) or the equivalent agencies in other countries. These assets are amortized mainly using the straight-line method over their estimated period of useful life, or based on economic benefit models, if more appropriate, which is determined by identifying the period and manner in which substantially all of the cash flows are expected to be generated. Amortization of acquired developed products is recorded under cost of sales. Amortization of marketing and distribution rights is recorded under selling

and marketing ( S&M ) expenses when separable.

Indefinite life intangible assets are mainly comprised of research and development in-process assets. Teva monitors these assets for items such as research and development milestones and progress to identify any triggering events. Teva determines the fair value of the asset annually or when triggering events are present, based on discounted cash flows and records an impairment loss if book value exceeds fair value.

IPR&D acquired in a business combination is capitalized as an indefinite life intangible asset until the related research and development efforts are either completed or abandoned. In the reporting period where they



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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

are treated as indefinite life intangible assets, they are not amortized but rather are monitored triggering events and tested for impairment. Upon completion of the related research and development efforts, management determines the useful life of the intangible assets and amortizes them accordingly. In case of abandonment, the related research and development assets are impaired.

Whenever impairment indicators are identified for definite life intangible assets, Teva reconsiders the asset's estimated life, calculates the undiscounted value of the asset's or asset group's cash flows and compares such value against the asset's or asset group's carrying amount. If the carrying amount is greater, Teva records an impairment loss for the excess of book value over fair value based on the discounted cash flows.

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

*Property, plant and equipment*

Property, plant and equipment are stated at cost, after deduction of the related investment grants, and depreciated using the straight-line method over the estimated useful life of the assets: buildings, mainly 40 years; machinery and equipment, mainly between 15 to 20 years; and other assets, between 5 to 10 years.

For property, plant and equipment, whenever impairment indicators are identified, Teva reconsiders the asset's estimated life, calculates the undiscounted value of the asset's cash flows and compares such value against the asset's carrying amount. If the carrying amount is greater, Teva records an impairment loss for the excess of book value over fair value.

**m. Contingencies:**

The Company is involved in various patent, product liability, commercial, government investigations, environmental claims and other legal proceedings that arise from time to time in the ordinary course of business. Except for income tax contingencies, contingent consideration, other contingent liabilities incurred or acquired in a business combination, Teva records accruals for these types of contingencies to the extent that Teva concludes their occurrence is probable and that the related liabilities are estimable. When accruing these costs, the Company will recognize an accrual in the amount within a range of loss that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company accrues for the minimum amount within the range. Teva records anticipated recoveries under existing insurance contracts that are probable of occurring at the gross amount that is expected to be collected. Legal costs are expensed as incurred.

The Company recognizes gain contingencies when they are realized or when all related contingencies have been resolved.

**n. Treasury shares:**

Treasury shares are presented as a reduction of Teva shareholders' equity and carried at their cost to Teva, under treasury shares.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**o. Stock-based compensation:**

Teva recognizes the estimated fair value of share-based awards, restricted share units ( RSUs ) and performance share units ( PSUs ) under stock-based compensation costs. The compensation expense for PSUs is recognized only if it is probable that the performance condition will be achieved.

Teva measures compensation expense for share-based awards based on estimated fair values on the date of grant using the Black-Scholes option-pricing model. This option pricing model requires estimates as to the option s expected term and the price volatility of the underlying stock. Teva amortizes the value of share-based awards to expense over the vesting period on a straight-line basis.

Teva measures compensation expense for the RSUs and PSUs based on the market value of the underlying stock at the date of grant, less an estimate of dividends that will not accrue to the RSU and PSU holders prior to vesting.

**p. Deferred income taxes:**

Deferred income taxes are determined utilizing the asset and liability method based on the estimated future tax effects of temporary differences between the financial accounting and tax basis of assets and liabilities under the applicable tax laws, and on tax rates anticipated to be in effect when the deferred income taxes are expected to be paid or realized. A valuation allowance is provided if, based upon the weight of available evidence, it is more likely than not that a portion of the deferred income tax assets will not be realized. In determining whether a valuation allowance is needed, Teva considers all available evidence, including historical information, long range forecast of future taxable income and evaluation of tax planning strategies. Amounts recorded for valuation allowance can result from a complex series of judgments about future events and can rely on estimates and assumptions. Deferred income tax liabilities and assets are classified as non-current.

Deferred tax has not been provided on the following items:

1. Taxes that would apply in the event of disposal of investments in subsidiaries, as it is generally the Company s intention to hold these investments, not to realize them. The determination of the amount of related unrecognized deferred tax liability is not practicable.
2. Amounts of tax-exempt income generated from the Company s current Approved Enterprises and unremitted earnings from foreign subsidiaries retained for reinvestment in the Group. See note 15f.

**q. Uncertain tax positions:**

Teva recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax

benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. Teva regularly re-evaluates its tax positions based on developments in its tax audits, statute of limitations expirations, changes in tax laws and new information that can affect the technical merits and change the assessment of Teva's ability to sustain the tax benefit. In addition, the Company classifies interest and penalties recognized in the financial statements relating to uncertain tax position under the income taxes line item.

Provisions for uncertain tax positions, whereas Teva has net operating losses to offset additional income taxes that would result from the settlement of the tax position, are presented as a reduction of the deferred tax assets for such net operating loss.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**r. Derivatives and hedging:**

The Group carries out transactions involving derivative financial instruments (mainly forward exchange contracts, currency options, cross-currency swap contracts, interest rate swap contracts and treasury locks). The transactions are designed to hedge the Company's currency and interest rate exposures. The Company does not enter into derivative transactions for trading purposes.

Derivative instruments are recognized on the balance sheet at their fair value.

For derivative instruments that are designated and qualify as a fair value hedge, the gain or loss on the derivative instrument as well as the offsetting gain or loss on the hedged item attributable to the hedged risk is recognized in financial expenses net in the statements of income in the period that the changes in fair value occur.

For derivative instruments that are designated and qualify as a cash-flow hedge, the effective portion of the gain or loss on the derivative instrument is reported as a component of other comprehensive income and reclassified into earnings in the same line item associated with the anticipated transaction in the same period or periods during which the hedged transaction affects earnings. The remaining gain or loss on the derivative instrument (i.e., the ineffective portion), if any, is recognized in the statement of income during the current period.

For derivative instruments that are designated as net-investment hedge, the effective portion of the gain or loss on the derivative instrument is reported as a component of other comprehensive income. The effective portion is determined by looking into changes in spot exchange rate. The change in fair value attributable to changes other than those due to fluctuations in the spot exchange rate are excluded from the assessment of hedge effectiveness and are recognized in the statement of income under financial expenses-net.

For derivative instruments that qualify for hedge accounting, the cash flows associated with these derivatives are reported in the consolidated statements of cash flows consistently with the classification of the cash flows from the underlying hedged items that these derivatives are hedging.

Derivative instruments that do not qualify for hedge accounting are recognized on the balance sheet at their fair value, with changes in the fair value recognized as a component of financial expenses net in the statements of income. The cash flows associated with these derivatives are reflected as cash flows from operating activities in the consolidated statements of cash flows.

**s. Revenue recognition:**

*The Company's revenue recognition accounting policy until December 31, 2017, prior to the adoption of the new revenue standard*

The Company recognizes revenues from product sales, including sales to distributors when persuasive evidence of an arrangement exists, delivery has occurred, the selling price is fixed or determinable and collectability is reasonably assured. This generally occurs when products are shipped and title and risk and rewards for the products are

transferred to the customer.

Revenues from product sales are recorded net of provisions for estimated chargebacks, rebates, returns, prompt pay discounts and other deductions, such as shelf stock adjustments, which can be reasonably estimated. When sales provisions are not considered reasonably estimable by Teva, the revenue is deferred to a future period when more information is available to evaluate the impact.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

Provisions for chargebacks, rebates including Medicaid and other governmental program discounts and other promotional items, such as shelf stock adjustments, are included in sales reserves and allowances ( SR&A ). These provisions are recognized concurrently with the sales of products. Prompt payment discounts are netted against trade receivables.

Calculations for these deductions from sales are based on historical experience and the specific terms in the individual agreements. Chargebacks and rebates are the largest components of sales reserves and allowances. Provisions for chargebacks are determined using historical chargeback experience and expected chargeback levels and wholesaler sales information for products, which are compared to externally obtained distribution channel reports for reasonableness. Rebates are recognized based on contractual obligations in place at the time of sales with consideration given to relevant factors that may affect the payment as well as historical experience for estimated market activity. Shelf-stock adjustments are granted to customers based on the existing inventory of a customer following decreases in the invoice or contract price of the related product and are estimated based on expected market performance. Teva records a reserve for estimated sales returns by applying historical experience of customer returns to the amounts invoiced and the amount of returned products to be destroyed versus products that can be placed back in inventory for resale.

Revenue resulting from the achievement of milestone events stipulated in agreements is recognized when the milestone is achieved. Milestones are based on the occurrence of a substantive element specified in the contract or as a measure of substantive progress toward completion under the contract

Revenues from licensees, sales of licensed products and technology are recorded in accordance with the contract terms, when third-party sales can be reliably measured and collection of the funds is reasonably assured.

Royalty revenue is recognized as a component of net revenues in accordance with the terms of their respective contractual agreements when collectability is reasonably assured and when revenue can be reasonably measured.

*The Company's revenue recognition accounting policy from January 1, 2018, following the adoption of the new revenue standard*

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

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

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

The amount of consideration to which Teva expects to be entitled varies as a result of rebates, chargebacks, returns and other sales reserves and allowances ( SR&A ) that the Company offers to its customers and their customers, as well as the occurrence or nonoccurrence of future events, including milestone events. A minimum amount of variable consideration is recorded by the Company concurrently with the satisfaction of performance



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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

obligations to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimates of variable consideration are based on historical experience and the specific terms in the individual agreements (which the Company believes approximates expected value). Rebates and chargebacks are the largest components of SR&A. If a minimum can not be reasonably estimated, such revenue may be deferred to a future period when better information is available. For further description of SR&A components and how they are estimated, see Variable Consideration, in note 9.

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

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

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

**t. Research and development:**

Research and development expenses are charged to income as incurred. Participations and grants in respect of research and development expenses are recognized as a reduction of research and development expenses as the related costs are incurred, or as the related milestone is met. Upfront fees received in connection with cooperation agreements are deferred and recognized over the period of the applicable agreements as a reduction of research and development expenses.

Advance payments for goods or services that will be used or rendered for future research and development activities are deferred. Such amounts are recognized as an expense as the related goods are delivered or the services are performed.

Research and development in-process acquired as part of an asset purchase, which has not reached technological feasibility and has no alternative future use, is expensed as incurred.

**u. Shipping and handling costs:**

Shipping and handling costs, which are included in S&M expenses, were \$159 million, \$164 million and \$134 million for the years ended December 31, 2018, 2017 and 2016, respectively.

**v. Advertising costs:**

Advertising costs are expensed as incurred. Advertising costs for the years ended December 31, 2018, 2017 and 2016 were \$256 million, \$318 million and \$312 million, respectively.

**w. Restructuring:**

Restructuring provisions are recognized for the direct expenditures arising from restructuring initiatives, where the plans are sufficiently detailed and where appropriate communication to those affected has been made.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

Contractual termination benefits are provided to employees when employment is terminated due to an event specified in the provisions of an existing plan or agreement. A liability is recorded and the expense is recognized when it is probable that employees will be entitled to the benefits and the amount is reasonably estimable.

Special termination benefits arise when the Company offers, for a short period of time, to provide certain additional benefits to employees electing voluntary termination. A liability is recorded and the expense is recognized in the period the employees irrevocably accept the offer and the amount of the termination liability is reasonably estimable.

**x. Segment reporting:**

The Company's business includes three reporting segments based on three geographical areas:

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

Each business segment manages the entire product portfolio in its region, including generics, specialty and over-the-counter ( OTC ) products.

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.

**y. Earnings per share:**

Basic earnings per share are computed by dividing the net income attributable to ordinary shareholders by the weighted average number of ordinary shares (including fully vested RSUs and PSUs) outstanding during the year, net of treasury shares.

In computing diluted earnings per share, basic earnings per share are adjusted to take into account the potential dilution that could occur upon: (i) the exercise of options and non-vested RSUs and PSUs granted under employee

stock compensation plans and one series of convertible senior debentures, using the treasury stock method; (ii) the conversion of the remaining convertible senior debentures using the if-converted method, by adding to net income interest expense on the debentures and amortization of issuance costs, net of tax benefits, and by adding the weighted average number of shares issuable upon assumed conversion of the debentures; and (iii) until December 17, 2018, the conversion of the mandatory convertible preferred shares ( MCPS ) using the if-converted method by adding to net income attributable to ordinary shareholders the dividends on the preferred shares and by adding the weighted average number of shares issuable upon assumed conversion of the mandatory convertible preferred shares.

On December 17, 2018, the mandatory convertible preferred shares automatically converted into ordinary shares. As a result of this conversion, Teva issued 70.6 million ADSs. See note 14.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**z. Securitization**

Teva accounts for transfers of certain of its trade receivable as sales when it has surrendered control over the related assets in accordance with ASC Topic 860 Transfer and Servicing of Financial Assets. Whether control has been relinquished requires, among other things, an evaluation of relevant legal considerations and an assessment of the nature and extent of the Company's continuing involvement with the assets transferred. Assets obtained and liabilities incurred in connection with transfers reported as sales are initially recognized in the balance sheet at fair value. Refer to note 16d.

**aa. Divestitures:**

The Company nets the proceeds on the divestitures of products with the carrying amount of the related assets and records gain or loss on sale within other income. Any contingent payments that are potentially due to the Company as a result of these divestitures are recorded when realizable. For divestitures of businesses, including divestitures of products that qualify as a business, the Company reflects the relative fair value of goodwill associated with the businesses in the determination of gain or loss on sale.

**bb. Reclassifications:**

During the fourth quarter of 2018, the Company changed its accounting policy for the presentation of royalty payments to third parties that are not involved in the production of products. Teva previously accounted for royalty payments to such third parties in S&M expenses. Royalties paid to a party that is involved in the production process are classified as cost of sales. The Company believes this change in accounting policy is preferable in order to be aligned with industry practice of classifying all royalty payments related to currently marketed products in cost of sales. The Company now reports all royalty payments as cost of sales. The Company has retrospectively adjusted prior periods to reflect this change and the impact was a \$210 million and \$206 million increase in cost of sales with an offsetting decrease in S&M for the years ended December 31, 2017 and 2016, respectively. The impact of the change in accounting policy for the year ended December 31, 2018 was an increase in cost of sales of \$142 million with an offsetting decrease in S&M.

Certain other comparative figures have been reclassified to conform to the current year presentation.

**cc. Debt instruments**

Debt instruments are initially recognized at the fair value of the consideration received. Debt issuance costs are recorded on the consolidated balance sheet as a reduction of liability. They are subsequently recognized at amortized cost using the effective interest method. Debt may be considered extinguished when it has been modified and the terms of the new debt instruments and old debt instruments are substantially different (as defined in the debt modification guidance in ASC 470-50 Debt Modifications and Extinguishments). The Company classifies the current portion of long term debt as non-current liabilities on the balance sheet when it has the intent and ability to refinance

the obligation on a long-term basis, in accordance with ASC 470-50 Debt .

**NOTE 2 CERTAIN TRANSACTIONS:**

**a. Business acquisitions:**

**Actavis Generics and Anda acquisitions**

On August 2, 2016, Teva consummated its acquisition of Allergan plc s ( Allergan ) worldwide generic pharmaceuticals business ( Actavis Generics ). At closing, Teva transferred to Allergan consideration of approximately \$33.4 billion in cash and approximately 100.3 million Teva shares.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

On October 3, 2016, Teva consummated the acquisition of Anda Inc. ( Anda ), a medicines distribution business in the United States, from Allergan, for cash consideration of \$500 million. This transaction was related to the Actavis Generics acquisition and, as such, the purchase price accounting and related disclosures were treated on a combined basis.

The final cash consideration for the Actavis Generics acquisition was subject to certain net working capital adjustments. On January 31, 2018, Teva and Allergan entered into a settlement agreement and mutual releases for which Allergan made a one-time payment of \$703 million to Teva to settle the working capital adjustments under the Master Purchase Agreement, dated July 26, 2015. As the measurement period has ended, this amount was recorded as a gain under legal settlements and loss contingencies in the first quarter of 2018.

**Rimsa**

On March 3, 2016, Teva completed the acquisition of Representaciones e Investigaciones Médicas, S.A. de C.V. ( Rimsa ), a pharmaceutical manufacturing and distribution company in Mexico, for \$2.3 billion, in a cash free, debt free set of transactions. Teva financed the transaction using cash on hand.

Following the closing of the acquisition, Teva identified issues concerning Rimsa s pre-acquisition quality, manufacturing and other practices, at which point Teva began an assessment of the extent and cost of remediation required to return its products to the market. In September 2016, two lawsuits were filed: a pre-emptive suit by the Rimsa sellers against Teva and Teva s lawsuit alleging fraud and breach of contract against the Rimsa sellers. The Rimsa sellers subsequently dismissed their lawsuit and the dismissal was approved by court order on December 20, 2016.

On February 15, 2018, Teva and the Rimsa sellers entered into a settlement agreement and mutual releases with respect to Teva s breach of contract claim, pursuant to which the Rimsa sellers made a one-time payment to Teva. Teva s breach of contract claim was subsequently dismissed by the court. As the measurement period has ended, this payment was recorded as a gain under legal settlements and loss contingencies in the first quarter of 2018.

**b. Assets and Liabilities Held For Sale:  
Certain Women s Health and Other Specialty Products**

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

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

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



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

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

	<b>December 31, 2018</b>	<b>December 31, 2017</b>
	<b>(U.S. \$ in millions)</b>	
Inventories	\$	\$ 39
Property, plant and equipment, net (*)	72	16
Identifiable intangible assets, net		236
Goodwill (*)	20	275
<b>Total assets of the disposal group classified as held for sale in the consolidated balance sheets</b>	<b>\$ 92</b>	<b>\$ 566</b>
 Other taxes and long-term liabilities		38
<b>Total liabilities of the disposal group classified as held for sale in the consolidated balance sheets</b>	<b>\$</b>	<b>\$ 38</b>

(\*) Mainly comprised of certain facilities in Israel.

**c. Other significant agreements:**

The Company has entered into alliances and other arrangements with third parties to acquire rights to products it does not have, to access markets it does not operate in and to otherwise share development costs or business risks. The Company's most significant agreements of this nature are summarized below.

**Eli Lilly and Alder BioPharmaceuticals**

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

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

### **PGT Healthcare Partnership**

In April 2018, Teva signed a separation agreement with the Procter & Gamble Company ( P&G ), to terminate Teva s joint venture with P&G, PGT Healthcare partnership ( PGT ), which the two companies established in 2011 to market OTC medicines. Teva will continue to maintain its OTC business on an independent basis.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

The separation became effective on July 1, 2018. As part of the separation, Teva transferred to P&G the shares it held in New Chapter Inc. and ownership rights in an OTC plant located in India. Teva provides certain services to P&G after the separation for a transition period.

During the first quarter of 2018, Teva classified the plant in India as an asset held for sale and recorded an impairment of \$64 million under other asset impairments, restructuring and other items. In addition, Teva recorded a write-down of \$94 million of its investment in New Chapter Inc. under share in losses of associated companies.

During September 2018, Teva and P&G completed the final net asset distribution as part of the dissolution and Teva recorded a gain of \$50 million to reflect the cash payment received from P&G under the dissolution agreement.

**AUSTEDO**

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

**Otsuka**

On May 12, 2017, Teva entered into a license and collaboration agreement with Otsuka Pharmaceutical Co. Ltd. ( Otsuka ), providing Otsuka with an exclusive license to conduct phase 2 and 3 clinical trials for AJOVY in Japan and, if approved, to commercialize the product in Japan. Otsuka paid Teva an upfront payment of \$50 million in consideration for the transaction. Teva may receive additional milestone payments upon filing with Japanese regulatory authorities, receipt of regulatory approval and achievement of certain revenue targets. Otsuka will also pay Teva royalties on AJOVY sales in Japan.

**Attenukine™**

In December 2016, Teva entered into a license agreement for research, development, manufacture and commercializing of Attenukine technology with a subsidiary of Takeda Pharmaceutical Company Ltd. ( Takeda ). Teva received a \$30 million upfront payment. The agreement stipulates additional milestone payments to Teva of up to \$280 million, as well as future royalties.

**Ninlaro®**

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

2017, Teva received payments in the amount of \$150 million, which were recognized as revenue for the period.

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**Notes to Consolidated Financial Statements (Continued)**

**Celltrion**

In October 2016, Teva and Celltrion, Inc. ( Celltrion ) entered into a collaborative agreement to commercialize Truxima and Herzuma, two biosimilar products in development for the U.S. and Canadian markets. Teva paid Celltrion \$160 million, of which up to \$60 million is refundable or creditable under certain circumstances. Teva and Celltrion will share the profit from the commercialization of these products.

**Regeneron**

In September 2016, Teva and Regeneron Pharmaceuticals, Inc. ( Regeneron ) entered into a collaborative agreement to develop and commercialize Regeneron's pain medication product, fasinumab. Teva and Regeneron share equally in the global commercial rights to this product, as well as ongoing associated R&D costs of approximately \$1 billion. Teva made an upfront payment of \$250 million to Regeneron in the third quarter of 2016 as part of the agreement. Milestone payments of \$25 million, \$35 million and \$60 million were paid in the second quarter of 2017, the first quarter of 2018 and the fourth quarter of 2018, respectively.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****NOTE 3 FAIR VALUE MEASUREMENT:**

Financial items carried at fair value as of December 31, 2018 and 2017 are classified in the tables below in one of the three categories described in note 1f:

	Level 1	December 31, 2018 Level 2    Level 3 (U.S. \$ in millions)		Total
Cash and cash equivalents:				
Money markets	\$ 203	\$	\$	\$ 203
Cash, deposits and other	1,579			1,579
Investment in securities:				
Equity securities	51			51
Other, mainly debt securities	2		10	12
Derivatives:				
Asset derivatives options and forward contracts		18		18
Asset derivatives cross-currency swaps		58		58
Liabilities derivatives options and forward contracts		(26)		(26)
Liabilities derivatives interest rate and cross-currency swaps		(50)		(50)
Contingent consideration*			(507)	(507)
Total	\$ 1,835	\$	\$ (497)	\$ 1,338

	Level 1	December 31, 2017 Level 2    Level 3 (U.S. \$ in millions)		Total
Cash and cash equivalents:				
Money markets	\$ 5	\$	\$	\$ 5
Cash, deposits and other	958			958
Investment in securities:				
Equity securities	65			65
Other, mainly debt securities	14		18	32
Derivatives:				
Asset derivatives options and forward contracts		17		17
Asset derivatives cross-currency swaps		25		25
Liability derivatives options and forward contracts		(15)		(15)
Liabilities derivatives interest rate and cross-currency swaps		(98)		(98)
Contingent consideration*			(735)	(735)

Total	\$ 1,042	\$ (71)	\$ (717)	\$ 254
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\* Contingent consideration represents liabilities recorded at fair value in connection with acquisitions. Teva determined the fair value of 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 for product candidates including risks associated with uncertainty regarding achievement and payment of milestone events; the time and resources needed to complete the development and approval of product candidates; the life of the potential commercialized products and associated risks of obtaining regulatory approvals in the U.S. and Europe and the discount rate for fair value measurement.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)**

The contingent consideration is evaluated quarterly or more frequently if circumstances dictate. Changes in the fair value of contingent consideration are recorded in earnings under other asset impairments, restructuring and other items.

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

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

	<b>December 31, 2018</b>	<b>December 31, 2017</b>
	<b>(U.S. \$ in millions)</b>	
Fair value at the beginning of the period	\$ (717)	\$ (811)
Investment in debt securities	(8)	
Translation differences		(17)
Adjustments to provisions for contingent consideration:		
Actavis Generics transaction		(35)
Labrys acquisition	(17)	(40)
Eagle transaction	(40)	(178)
MicroDose acquisition		89
Cephalon acquisition		10
Settlement of contingent consideration:		
Labrys acquisition	151	100
Eagle transaction	134	165
Fair value at the end of the period	\$ (497)	\$ (717)

Teva's financial instruments consist mainly of cash and cash equivalents, investments in securities, current and non-current receivables, short-term credit, accounts payable and accruals, loans and senior notes, convertible senior debentures and derivatives.

The fair value of the financial instruments included in working capital and non-current receivables approximates their carrying value. The fair value of long-term bank loans mostly approximates their carrying value, since they bear interest at rates close to the prevailing market rates.



Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****Financial instruments not measured at fair value**

Financial instruments measured on a basis other than fair value consist of senior notes and convertible senior debentures (see note 11), and are presented in the below table in terms of fair value:

	<b>Estimated fair value*</b>	
	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(U.S. \$ in millions)</b>	
Senior notes included under long-term liabilities	\$ 23,560	\$ 23,459
Senior notes and convertible senior debentures included under short-term liabilities	2,140	2,713
Fair value at the end of the period	\$ 25,700	\$ 26,172

\* The fair value was estimated based on quoted market prices, where available.

**NOTE 4 INVESTMENT IN SECURITIES:**

Available-for-sale securities are comprised mainly of debt securities. Investments in securities are classified based on the initial maturity as well as the intended time of realization.

In January 2016, the FASB issued guidance which requires entities to recognize changes in fair value in net income rather than in accumulated other comprehensive income. Teva adopted this update in the first quarter of 2018.

At December 31, 2018 and 2017, the fair value, amortized cost and gross unrealized holding gains and losses of such securities were as follows:

	<b>Fair value</b>	<b>Amortized cost</b>	<b>Gross unrealized holding gains</b>	<b>Gross unrealized holding losses</b>
	<b>(U.S. \$ in millions)</b>			
December 31, 2018	\$ 266	\$	\$	\$
December 31, 2017	\$ 102	\$ 103	\$ 19	\$ 20

During 2018, Teva sold and settled certain investments for cash consideration of approximately \$11 million; Consequently, Teva recorded a \$2 million net gain under financial expenses-net. Additionally the company recorded a

revaluation to its remaining securities, resulting in approximately \$10 million loss recorded under financial expenses-net.

In the first quarter of 2017, Teva settled the remaining balance of approximately 17 million Mylan shares for an average price of \$40.2 per share for an aggregate cash consideration of approximately \$702 million. Consequently, Teva recorded a \$36 million net gain under financial expenses-net. See note 17.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)**

Investments in securities are presented in the balance sheet as follows:

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(U.S. \$ in millions)</b>	
Other current assets	\$ 2	\$ 14
Other non-current assets	61	83
Money market funds	203	5
	\$ 266	\$ 102

**NOTE 5 INVENTORIES:**

Inventories, net of reserves, consisted of the following:

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(U.S. \$ in millions)</b>	
Finished products	\$ 2,665	\$ 2,689
Raw and packaging materials	1,328	1,454
Products in process	590	597
Materials in transit and payments on account	148	184
	\$ 4,731	\$ 4,924

**NOTE 6 PROPERTY, PLANT AND EQUIPMENT:**

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

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(U.S. \$ in millions)</b>	
Machinery and equipment	\$ 5,691	\$ 5,809
Buildings	3,143	3,329
Computer equipment and other assets	2,097	2,016
Payments on account	514	634

Land*	351	390
	11,796	12,178
Less accumulated depreciation	(4,928)	(4,505)
	\$ 6,868	\$ 7,673

\* Land includes long-term leasehold rights in various locations, with lease term of between 30 and 99 years. Depreciation expenses were \$676 million, \$632 million and \$501 million in the years ended December 31, 2018, 2017 and 2016, respectively. During the years ended December 31, 2018, 2017 and 2016, Teva had impairments of property, plant and equipment in the amount of \$500 million, \$544 million and \$157 million, respectively. See note 18.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****NOTE 7 GOODWILL:**

The changes in the carrying amount of goodwill for the years ended December 31, 2018 and 2017 were as follows:

	Generics	Specialty (U.S. \$ in millions)	Other	Total	North America	International Europe Market	Other	Total
Balance as of January 1, 2017 (1)	32,863	9,323	2,223	44,409				
Changes during the year:								
Goodwill adjustments (2)	1,480		(560)	920				
Goodwill disposal (3)	(7)	(690)		(697)				
Goodwill impairment (4)	(16,500)		(600)	(17,100)				
Goodwill reclassified as assets to held for sale (5)		(275)		(275)				
Translation differences	1,028	106	23	1,157				
Balance as of December 31, 2017 (1)	\$ 18,864	\$ 8,464	\$ 1,086	\$ 28,414	\$	\$	\$	\$
Relative fair value allocation	(18,864)	(8,464)	(1,086)	(28,414)	11,144	9,001	5,404	28,414
Balance as of January 1, 2018					11,144	9,001	5,404	28,414
Changes during the year:								
Goodwill impairment (6)						(2,834)	(193)	(3,027)
Goodwill disposal (7)						(65)	(14)	(79)
Goodwill reclassified as assets to held for sale						(3)	(17)	(20)
Translation differences and Other					(46)	(280)	(77)	(371)
Balance as of December 31, 2018 (1)	\$	\$	\$	\$	\$ 11,098	\$ 8,653	\$ 2,479	\$ 24,917

(1) Accumulated goodwill impairment as of December 31, 2018, December 31, 2017 and as of January 1, 2017 was approximately \$21.0 billion, \$18.0 billion and \$900 million, respectively.

(2) Measurement period adjustments on goodwill acquired in 2016.

- (3) Goodwill on the divestiture of certain Teva generic products, as part of the Actavis Generics acquisition, and the U.S. women's health business.
  - (4) Goodwill impairment is mainly attributable to the U.S. generics reporting unit.
  - (5) Represent amounts related to the anticipated divestitures of the non-U.S women's health products.
  - (6) Goodwill impairment mainly attributable to the International Markets, Mexico and Medis.
  - (7) Mainly due to the divestment of the women's health business, the sale of Actavis Brazil and other activities.
- In November 2017, Teva announced a new organizational structure and leadership changes to enable strategic alignment across its portfolios, regions and functions. Teva now operates its business through three segments: North America, Europe and International Markets. The purpose of the new structure is to enable stronger alignment and integration between operations, commercial regions, R&D and Teva's global marketing and portfolio function, in order to optimize its product lifecycle across the therapeutic areas. Teva began reporting its financial results under this structure in the first quarter of 2018.

In addition to these three segments, Teva has other sources of revenues, primarily the sale of APIs to third parties, certain contract manufacturing services and an out-licensing platform offering a portfolio of products to other pharmaceutical companies through its affiliate Medis. See note 20.

Following the announcement of its new organizational structure and leadership changes in November 2017, Teva conducted an analysis of its business segments, which led to changes in Teva's identified reporting units, operating and reporting segments. As a result, on January 1, 2018, Teva reallocated its goodwill to the adjusted reporting units using a relative fair value allocation. In conjunction with the goodwill reallocation, Teva

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**Notes to Consolidated Financial Statements (Continued)**

performed a goodwill impairment test for the balances in its adjusted reporting units, utilizing the same annual operating plan ( AOP ) and long range plan ( LRP ) model that were used in its 2017 annual impairment test; the Company concluded that the fair value of each reporting unit was in excess of its carrying value.

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

Based on its revised analysis, Teva recorded a goodwill impairment of \$180 million related to its Rimsa reporting unit in the first quarter of 2018. The remaining goodwill allocated to this reporting unit was \$706 million as of March 31, 2018. This impairment was driven by the change in fair value, as a result of the updated WACC noted above, and the change in allocated net assets to the reporting unit. See note 2.

In the second quarter of 2018, the Company completed its LRP process. The LRP is part of Teva's internal financial planning and budgeting processes and is discussed and reviewed by Teva's management and its board of directors. Certain events and changes in circumstances, reflected in the LRP, indicated that it was more likely than not that the carrying value of certain reporting units exceeded their fair value:

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

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

Additionally, the Company identified further developments with respect to legislation proposed by the Russian Ministry of Health. The draft legislation includes, among other items, amendments in the mechanism of regulating prices for vital and essential medicines. The suggested amendments triggered a public discussion between authorities and pharmaceutical companies, which ended in the second quarter of 2018, followed by an internal discussion by the relevant authorities. The estimated impact of developments and uncertainties with respect to the final legislation in Russia were reflected in the LRP and triggered an impairment test for the International Markets reporting unit and related intangible assets, significantly

decreasing the difference between the estimated fair value and estimated carrying value of the reporting unit, from 6% to 2%; however no impairment was recorded.

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

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

During the third quarter of 2018, Teva identified an increase in the risk free interest rate, which was the main cause of an increase in the WACC. In addition, certain currencies in countries included in Teva's



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**Notes to Consolidated Financial Statements (Continued)**

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

Pursuant to the Company's policy, Teva conducted its annual goodwill impairment test during the fourth quarter of 2018, in conjunction with the update of its 2019 AOP. The updated AOP was used as a base for an update of the 2019-2023 LRP, incorporating the 2019 changes for future years in the fair value model. Teva conducted its annual impairment test with the assistance of an independent valuation expert.

Teva recorded a goodwill impairment of \$2,530 million in the fourth quarter of 2018 attributable to goodwill associated with its International Markets reporting unit and \$170 million attributable to goodwill associated with its Medis reporting unit, which is reported under other activities.

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 that was used is the discounted cash flow method. Teva started with a forecast of all the expected net cash flows associated with the reporting unit, which includes the application of a terminal value, and then applied a discount rate to arrive at a net present value amount. Cash flow projections are based on Teva's estimates of revenue growth rates and operating margins, taking into consideration industry and market conditions. The discount rate used is based on the WACC, adjusted for the relevant risk associated with country-specific and business-specific characteristics. If any of these expectations were to vary materially from Teva's assumptions, Teva could face impairment of goodwill allocated to these reporting units in the future.

**Impaired Reporting Units**

***International Markets***

In the fourth quarter of 2018, Teva noted a decrease in the fair value of its International Markets reporting unit, mainly due to changes to certain discount rate parameters and the selected Terminal Growth Rate ( TGR ), negative effect of currency fluctuations and decreased projections in its Japanese market, partially offset by lower tax expense.

Decreased projections in the Japanese market were mainly due to price reductions caused by price regulation and generic competition to off-patented products, which are expected to continue to negatively affect the Company's sales in Japan.

Due to the above factors, Teva recorded a goodwill impairment of \$2,530 million related to its International Markets reporting unit in the fourth quarter of 2018.

If Teva holds all other assumptions constant, a reduction in the terminal value growth rate of 0.1% or an increase in discount rate of 0.1% would result in an additional impairment of approximately \$48 million and \$68 million related to its International Markets reporting unit, respectively.

***Medis***

Teva's other activities include its Medis business. In the fourth quarter of 2018, Teva noted a decrease in the fair value of its Medis reporting unit, mainly due to updated projections as a result of a revised strategy for the business. Consequently, Teva recorded a goodwill impairment of \$170 million related to its Medis reporting unit.

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If Teva holds all other assumptions constant, a reduction in the terminal value growth rate of 0.1% or an increase in discount rate of 0.1% would, in both cases, result in an additional immaterial impairment related to its Medis reporting unit. The remaining goodwill balance assigned to the Medis reporting unit is approximately \$300 million.

**Non-Impaired Reporting Units*****Europe***

Teva noted a decrease in its Europe reporting unit profit projections mainly due to projected currency translation effect and increased generics competition to COPAXONE.

The percentage difference between estimated fair value and estimated carrying value for the Europe reporting unit is 6%.

If Teva holds all other assumptions constant, a reduction in the terminal value growth rate of 0.1% or an increase in discount rate of 0.1% would result in a reduction in fair value of approximately \$121 million and \$171 million related to its Europe reporting unit, respectively.

***North America and TAPI***

The percentage difference between estimated fair value and estimated carrying value for the North America and TAPI reporting units is 28% and 47%, respectively.

**Market Capitalization**

Teva analyzed the aggregate fair value of its reporting units as compared to its market capitalization in order to assess the reasonableness of the results of its cash flow projections used for its goodwill impairment analysis. In light of the volatility in the stock markets during the month of December 2018 and the subsequent positive correction, Teva used an average share price, as it believes that it is more indicative of the fair value than the December 31, 2018 share price. Management believes that its fair value assessment is reasonably supported by the market capitalization.

Management will continue to monitor business conditions and will also consider future developments in its market capitalization when assessing whether additional goodwill impairment is required in future periods.

**NOTE 8 IDENTIFIABLE INTANGIBLE ASSETS:**

Identifiable intangible assets consisted of the following:

Gross carrying amount net of impairment	Accumulated amortization	Net carrying amount
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			<b>December 31,</b>			
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
			<b>(U.S. \$ in millions)</b>			
Product rights	\$ 20,361	\$ 21,011	\$ 9,565	\$ 8,276	\$ 10,796	\$ 12,735
Trade names	606	617	91	55	515	562
In-process research and development (IPR&D)	2,694	4,343			2,694	4,343
Total	\$ 23,661	\$ 25,971	\$ 9,656	\$ 8,331	\$ 14,005	\$ 17,640

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**Product rights and trade names**

Product rights and trade names are assets presented at amortized cost. Product rights and trade names represent a portfolio of pharmaceutical products from various categories with a weighted average life of approximately 12 years. Amortization of intangible assets amounted to \$1,166 million, \$1,444 million and \$993 million in the years ended December 31, 2018, 2017 and 2016, respectively.

As of December 31, 2018, the estimated aggregate amortization of intangible assets for the years 2019 to 2023 is as follows: 2019 \$1,034 million; 2020 \$1,019 million; 2021 \$889 million; 2022 \$930 million and 2023 \$896 million. These estimates do not include the impact of IPR&D that is expected to be successfully completed and reclassified to product rights.

**IPR&D**

Teva's IPR&D are assets that have not yet been approved in major markets. Teva's IPR&D is comprised mainly of the following acquisitions and related assets: various generic products (Actavis Generics) \$2,433 million; various generic products (Rimsa) \$50 million and Austedo \$211 million. IPR&D carry intrinsic risks that the asset might not succeed in advanced phases and may be impaired in future periods.

In 2018, Teva reclassified approximately \$723 million relating to certain products from IPR&D to product rights following regulatory approval, mainly \$444 million in connection with AJOVY and \$103 million in connection with mesalamine and various other generic products.

**Intangible assets impairment**

Impairment of identifiable intangible assets amounted to \$1,991 million, \$3,238 million and \$589 million in the years ended December 31, 2018, 2017 and 2016, respectively, and are recorded in earnings under intangible assets impairment.

Impairments of long-lived intangible assets in 2018 were \$1,991 million, mainly consisting of:

1. Identifiable product rights of \$1,068 million, mainly due to: (a) \$412 million in connection with updated market assumptions regarding price and volume of products acquired from Actavis Generics currently marketed in the United States and supply constraints; (b) \$290 million in certain international markets, due to a loss of several tenders and termination of products manufacturing lines; and (c) \$222 million in Japan in connection with ongoing regulatory pricing reductions and generic competition.
2. IPR&D assets of \$923 million, mainly related to revaluation of generic products acquired from Actavis Generics due to development progress and changes in other key valuation indications (e.g., market size, legal

landscape, launch date or discount rate).

**NOTE 9 REVENUE FROM CONTRACTS WITH CUSTOMERS:**

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

**Revenue recognition prior to the adoption of the new revenue standard**

See note 1 for a summary of the significant accounting policies.

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**Notes to Consolidated Financial Statements (Continued)**

**Revenue recognition following the adoption of the new revenue standard**

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

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

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

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

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

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

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****Disaggregation of revenue**

The following table disaggregates Teva's revenues by major revenue streams. For additional information on disaggregation of revenues, see note 20.

	<b>Year ended December 31, 2018</b>				
	<b>North America</b>	<b>Europe</b>	<b>International Markets</b>	<b>Other activities</b>	<b>Total</b>
	<b>(U.S.\$ in millions)</b>				
Sale of goods	7,838	5,153	2,151	739	15,881
Licensing arrangements	111	23	22	9	165
Distribution	1,347	7	602		1,956
Other	1	3	230	618	852
	<b>\$ 9,297</b>	<b>\$ 5,186</b>	<b>\$ 3,005</b>	<b>\$ 1,366</b>	<b>\$ 18,854</b>

	<b>Year ended December 31, 2017</b>				
	<b>North America</b>	<b>Europe</b>	<b>International Markets</b>	<b>Other activities</b>	<b>Total</b>
	<b>(U.S.\$ in millions)</b>				
Sale of goods	10,706	5,244	2,558	748	19,256
Licensing arrangements	281	3	38	5	327
Distribution	1,153	214	549		1,916
Other	1	5	250	630	886
	<b>\$ 12,141</b>	<b>\$ 5,466</b>	<b>\$ 3,395</b>	<b>\$ 1,383</b>	<b>\$ 22,385</b>

	<b>Year ended December 31, 2016</b>				
	<b>North America</b>	<b>Europe</b>	<b>International Markets</b>	<b>Other activities</b>	<b>Total</b>
	<b>(U.S.\$ in millions)</b>				
Sale of goods	11,186	4,751	3,286	766	19,989
Licensing arrangements	291	7	8	8	314
Distribution	301	204	458		963
Other		7	263	367	637



\$ 11,778	\$ 4,969	\$ 4,015	\$ 1,141	\$ 21,903
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### Nature of revenue streams

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

Licensing arrangements performance obligations generally include intellectual property ( IP ) rights, certain R&D and contract manufacturing services. The Company accounts for IP rights and services separately if they are distinct i.e. if they are separately identifiable from other items in the arrangement and if the customer can benefit from them on their own or with other resources that are readily available to the customer. The consideration is allocated between IP rights and services based on their relative stand-alone selling prices.

Revenue for distinct IP rights is accounted for based on the nature of the promise to grant the license. In determining whether the Company's promise is to provide a right to access its IP or a right to use its IP, the

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

Company considers the nature of the IP to which the customer will have rights. IP is either functional IP which has significant standalone functionality or symbolic IP which does not have significant standalone functionality. Revenue from functional IP is recognized at the point in time when control of the distinct license is transferred to the customer, the Company has a present right to payment and risks and rewards of ownership are transferred to the customer. Revenue from symbolic IP is recognized over the access period to the Company's IP.

Revenue from sales based milestones and royalties promised in exchange for a license of IP is recognized only when, or as, the later of subsequent sale or the performance obligation to which some or all of the sales-based royalty has been allocated, is satisfied. Revenues from licensing arrangements included royalty income of \$165 million, \$327 million and \$314 million for the years ended December 31, 2018, 2017 and 2016, respectively. The amounts recognized in 2017 include royalty income resulting from the Ninlaro® transaction.

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

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

**Contract assets and liabilities**

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

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

**Variable consideration**

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

The Company recognizes these provisions at the time of sale and adjusts them if the actual amounts differ from the estimated provisions. The following describes the nature of each deduction and how provisions are estimated:

**Rebates**

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

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**Medicaid and Other Governmental Rebates**

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

**Chargebacks**

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

**Other Promotional Arrangements**

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

**Shelf Stock Adjustments**

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

## **Returns**

Returns primarily relate to customer returns of expired products which, the customer has the right to return up to one year following the expiration date. Such returned products are destroyed and credits and/or refunds are

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

**Prompt Pay Discounts**

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

SR&A to U.S. customers comprised approximately 85% of the Company's total SR&A as of December 31, 2018, with the remaining balance primarily in Canada and Germany. The changes in SR&A for third-party sales for the period ended December 31, 2018 were as follows:

<b>Sales Reserves and Allowances</b>							<b>Total reserves included in Sales Reserves and Allowances</b>	
	<b>Reserves included in Accounts Receivable, net</b>	<b>Rebates</b>	<b>Medicaid and other governmental allowances</b>	<b>Chargebacks</b>	<b>Returns</b>	<b>Other</b>	<b>Allowances</b>	<b>Total</b>
<b>(U.S.\$ in millions)</b>								
Balance at January 1, 2018	\$ 196	\$ 3,077	\$ 1,908	\$ 1,849	\$ 780	\$ 267	\$ 7,881	\$ 8,077
Provisions related to sales made in current year period	514	6,572	1,284	10,206	442	417	18,899	\$ 19,413
Provisions related to sales made in prior periods	3	(14)	24		28	(30)	(62)	\$ (59)
Credits and payments	(538)	(6,596)	(1,850)	(10,519)	(606)	(463)	(19,942)	\$ (20,480)
Translation differences		(33)	(5)	(6)	(6)	(15)	(65)	\$ (65)
	\$ 175	3,006	\$ 1,361	\$ 1,530	\$ 638	\$ 176	\$ 6,711	\$ 6,886

Balance at  
December 31, 2018

**NOTE 10 LONG-TERM EMPLOYEE-RELATED OBLIGATIONS:**

**a. Long-term employee-related obligations consisted of the following**

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(U.S. \$ in millions)</b>	
Accrued severance obligations	\$ 75	\$ 91
Defined benefit plans	146	182
<b>Total</b>	<b>\$ 221</b>	<b>\$ 273</b>

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

As of December 31, 2018 and 2017, the Group had \$137 million and \$149 million, respectively, deposited in funds managed by financial institutions that are earmarked by management to cover severance pay liability mainly in respect of Israeli employees. Such deposits are not considered to be plan assets and are therefore included in long-term investments and receivables.

Most of the change resulted from actuarial updates, as well as from exiting from several defined benefit plans in several countries.

The Company expects to expense an approximate contribution of \$106 million in 2019 to the pension funds and insurance companies in respect of its severance and pension pay obligations.

The main terms of the different arrangements with employees are described in below.

**b. Terms of arrangements:**

*Israel*

Israeli law generally requires payment of severance pay upon dismissal of an employee or upon termination of employment in certain other circumstances. The Parent Company and its Israeli subsidiaries make ongoing deposits into employee pension plans to fund their severance liabilities. According to the general collective pension agreement in Israel, Company deposits with respect to employees who were employed by the Company after the agreement took effect are made in lieu of the Company's severance liability; therefore no obligation is provided for in the financial statements. Severance pay liabilities with respect to employees who were employed by the Parent Company and its Israeli subsidiaries prior to the collective pension agreement effective date, as well as employees who have special contractual arrangements, are provided for in the financial statements based upon the number of years of service and the latest monthly salary.

*Europe*

Many of the employees in the Company's European subsidiaries are entitled to a retirement grant when they leave the Company. In the consolidated financial statements, the liability of the European subsidiaries is accrued, based on the length of service and remuneration of each employee at the balance sheet date. Other employees in Europe are entitled to a pension according to a defined benefit scheme providing benefits based on final or average pensionable pay or according to a hybrid pension scheme that provides retirement benefits on a defined benefit and a defined contribution basis. Independent certified actuaries value these schemes and determine the rates of contribution payable. Pension costs for the defined benefit section of the scheme are accounted for on the basis of charging the expected cost of providing pensions over the period during which the subsidiaries benefit from the employees' services. The Company uses December 31 as the measurement date for defined benefit plans.

*North America*



The Company's North American subsidiaries mainly provide various defined contribution plans for the benefit of their employees. Under these plans, contributions are based on specified percentages of pay. Additionally, a multi-employer plan is maintained in accordance with various union agreements.

*Latin America*

The majority of the employees in Latin America are entitled to severance under local law. The severance payments are calculated based on service term and employee remuneration, and accruals are maintained to reflect

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these amounts. In some Latin American countries it is Teva's practice to offer retirement health benefits to qualifying employees. Based on the specific plan requirements, benefits accruals are maintained to reflect the estimated amounts or adjusted if future plans are modified.

The Company expects to pay the following future minimum benefits to its employees: \$6 million in 2019; \$6 million in 2020; \$7 million in 2021; \$8 million in 2022; \$8 million in 2023 and \$42 million between 2024 to 2028. These amounts do not include amounts that may be paid to employees who cease working with the Company before their normal retirement age.

**NOTE 11 DEBT OBLIGATIONS:****a. Short-term debt:**

	Weighted average interest rate as of December 31, 2018	Maturity	December 31, 2018      2017 (U.S. \$ in millions)	
Term loan JPY 28.3 billion	JPY LIBOR+0.25%	2018	\$	251
Bank and financial institutions	6.79%		2	1
Convertible debentures	0.25%	2026	514	514
Current maturities of long-term liabilities			1,700	2,880
Total short term debt			\$ 2,216	\$ 3,646

***Line of credit:***

In November 2015, the Company entered into a \$3 billion five-year unsecured syndicated credit facility (which was increased to \$4.5 billion upon closing of the Actavis Generics acquisition, see note 2). In February 2018, the facility was decreased to \$3 billion. This revolving line of credit was not utilized as of December 31, 2018.

***Convertible senior debentures***

Teva 0.25% convertible senior debentures, due 2026, principal amount as of December 31, 2018 and 2017 were \$514 million. These convertible senior debentures include a net share settlement feature according to which the principal amount will be paid in cash and in case of conversion, only the residual conversion value above the principal amount will be paid in Teva shares. Due to the net share settlement feature, exercisable at any time, these convertible senior debentures are classified in the balance sheet under short-term debt. Holders of the convertible debentures will be able to cause Teva to redeem the debentures on February 1, 2021.



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	Weighted average interest rate as of December 31, 2018 %	Maturity	December 31, 2018 (U.S. \$ in millions)	December 31, 2017
Senior notes EUR 1,660 million (8)	0.38%	2020	\$ 1,897	\$ 2,095
Senior notes EUR 1,500 million	1.13%	2024	1,707	1,788
Senior notes EUR 1,300 million	1.25%	2023	1,480	1,550
Senior notes EUR 1,000 million (3)	2.88%	2019		1,199
Senior notes EUR 900 million (1)	4.50%	2025	1,029	
Senior notes EUR 750 million	1.63%	2028	850	891
Senior notes EUR 700 million (1)	3.25%	2022	801	
Senior notes EUR 700 million	1.88%	2027	798	837
Senior notes USD 3,500 million	3.15%	2026	3,493	3,492
Senior notes USD 3,000 million	2.20%	2021	2,997	2,996
Senior notes USD 3,000 million	2.80%	2023	2,993	2,992
Senior notes USD 1,700 million (8)	1.70%	2019	1,700	2,000
Senior notes USD 2,000 million	4.10%	2046	1,985	1,984
Senior notes USD 1,500 million (3)	1.40%	2018		1,500
Senior notes USD 1,250 million (2)	6.00%	2024	1,250	
Senior notes USD 1,250 million (2)	6.75%	2028	1,250	
Senior notes USD 844 million	2.95%	2022	860	864
Senior notes USD 789 million	6.15%	2036	782	781
Senior notes USD 700 million	2.25%	2020	700	700
Senior notes USD 613 million	3.65%	2021	621	624
Senior notes USD 588 million	3.65%	2021	587	587
Senior notes CHF 450 million (10)	1.50%	2018		461
Senior notes CHF 350 million	0.50%	2022	356	360
Senior notes CHF 350 million	1.00%	2025	356	360
Senior notes CHF 300 million (9)	0.13%	2018		308
Fair value hedge accounting adjustments			(9)	(2)
Total senior notes			28,483	28,367
Term loan USD 2.5 billion (4)	LIBOR +1.1375%	2018		285
Term loan USD 2.5 billion (4)	LIBOR +1.50%	2017-2020		2,000
Term loan JPY 58.5 billion (5)	JPY LIBOR +0.55%	2022		519
Term loan JPY 35 billion (6)	1.42%	2019		311
Term loan JPY 35 billion (6)	JPY LIBOR +0.3%	2018		311
Total loans				3,426

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Debentures USD 15 million (7)	7.20%	2018		15
Other	4.79%	2026	12	5
Total debentures and others			12	20
Less current maturities			(1,700)	(2,880)
Derivative instruments			9	2
Less debt issuance costs			(104)	(106)
Total senior notes and loans			\$ 26,700	\$ 28,829

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

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**Notes to Consolidated Financial Statements (Continued)**

- (4) During the first quarter of 2018, Teva prepaid approximately \$2.3 billion principal amount of the remaining term loan facilities.
- (5) During the first quarter of 2018, Teva prepaid in full JPY 86.8 billion principal amount of the outstanding term loan facilities of which JPY 28.3 billion were in short-term debt as of December 31, 2017.
- (6) During the first quarter of 2018, Teva prepaid in full JPY 70 billion of its 1.42% and JPY LIBOR+0.3% outstanding term loans.
- (7) During the first quarter of 2018, Teva prepaid in full \$15 million of its outstanding debentures.
- (8) In September 2018, Teva consummated a cash tender offer for certain of its outstanding senior notes. As a result of the offer, Teva redeemed \$300 million aggregate principal amount of its 1.7% senior notes and 90 million principal amount of its 0.38% senior notes.
- (9) In July 2018, Teva repaid at maturity CHF 300 million of its 0.13% senior notes.
- (10) In October 2018, Teva repaid at maturity CHF 450 million of its 1.5% senior notes.

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

Long term debt as of December 31, 2018 is effectively denominated (taking into consideration cross currency swap agreements) in the following currencies: U.S. dollar 63%, euro 34% and Swiss franc 3%.

Teva's principal sources of short-term liquidity are its existing cash investments, liquid securities and available credit facilities, primarily its \$3 billion syndicated revolving credit facility ( RCF ), which was not utilized as of December 31, 2018, as well as internally generated funds.

In connection with the requirements of the RCF, the Company entered into negative pledge agreements with certain banks and institutional investors. Under the agreements, the Company and its subsidiaries have undertaken not to register floating charges on assets in favor of any third parties without the prior consent of the banks, to maintain certain financial ratios, including the requirement to maintain compliance with a net debt to EBITDA ratio, which becomes more restrictive over time, and to fulfill other restrictions, as stipulated by the agreements. As of December 31, 2018, the Company did not have any outstanding debt under the RCF, which is its only debt subject to the net debt to EBITDA covenant, and met all financial covenants thereunder.

Teva expects that it will continue to have sufficient cash resources to support its debt service payments and all other financial obligations for at least twelve months from the date of this report, without utilizing the RCF.

If Teva experiences lower than required cash flows to support its debt service payments, it may need to draw additional debt under the RCF. Under such circumstances, Teva will need to maintain compliance with its net debt to EBITDA ratio covenant. If such covenant will not be met, Teva believes it will be able to renegotiate and amend the covenants, or refinance the debt with different repayment terms to address such situation as circumstances warrant.

Assuming utilization of the RCF, and under specified circumstances, including non-compliance with such covenants and the unavailability of any waiver, amendment or other modification thereto and the expiration of any applicable grace period thereto, substantially all of the Company's debt could be negatively impacted by non-compliance with

such covenants.

Although Teva has been successful in the past in obtaining financing and renegotiating debt covenants at commercially acceptable terms, there are no guarantees it will be able to do so in the future. If such efforts could not be successfully completed on commercially acceptable terms, Teva may curtail additional planned spending or divest additional assets in order to generate enough cash to meet its debt requirements and all other financial obligations.

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The required annual principal payments of long-term debt, excluding debt issuance cost as of December 31, 2018, starting with the year 2020, are as follows:

	<b>December 31, 2018</b>
	<b>(U.S. \$ in millions)</b>
2020	\$ 2,596
2021	4,205
2022	2,017
2023	4,473
2024 and thereafter	13,513
	\$ 26,804

**NOTE 12 OTHER INCOME:**

	<b>Year ended December 31, 2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S. \$ in millions)</b>		
Gain on divestitures, net of divestitures related costs (1)	\$ 67	1,083	720
Section 8 and similar payments (2)	195	83	20
Gain on sale of assets	9	11	10
Other, net	20	22	19
Total other income	\$ 291	\$ 1,199	\$ 769

(1) Mainly related to the divestment of the women's health business. See note 2.

(2) Section 8 of the Patented Medicines (Notice of Compliance) Regulation relates to recoveries of lost revenue related to patent infringement proceedings in Canada.

**NOTE 13 COMMITMENTS AND CONTINGENCIES:****a. Commitments:**

*Operating leases:*



As of December 31, 2018, minimum future rentals under operating leases of buildings, machinery and equipment for periods in excess of one year were as follows: 2019 \$193 million; 2020 \$154 million; 2021 \$118 million; 2022 \$91 million; 2023 \$66 million; 2024 and thereafter \$283 million.

The lease fees expensed in each of the years ended December 31, 2018, 2017 and 2016 were \$175 million, \$200 million and \$164 million, respectively.

*Royalty commitments:*

The Company is committed to pay royalties to owners of know-how, partners in alliances and other certain arrangements and to parties that financed research and development, at a wide range of rates as a percentage of sales or of the gross margin of certain products, as defined in the underlying agreements.

Until September 30, 2018, royalty expenses were reported in cost of goods sold if related to the acquisition of a product, and if not, such expenses are included in S&M expenses. Commencing October 1, 2018, royalty

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**Notes to Consolidated Financial Statements (Continued)**

expenses are retroactively reported entirely under cost of goods sold. Royalty expenses in each of the years ended December 31, 2018, 2017 and 2016 were \$536 million, \$956 million and \$814 million, respectively. See note 1bb.

*Milestone commitments:*

Teva has committed to make potential future milestone payments to third parties under various agreements. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, Teva may be required to pay such amounts. As of December 31, 2018, if all milestones and targets, for compounds in phase 2 and more advanced stages of development, are achieved, the total contingent payments could reach an aggregate amount of up to \$420 million.

**b. Contingencies:**

**General**

From time to time, Teva and/or its subsidiaries are subject to claims for damages and/or equitable relief arising in the ordinary course of business. In addition, as described below, in large part as a result of the nature of its business, Teva is frequently subject to litigation. Teva generally believes that it has meritorious defenses to the actions brought against it and vigorously pursues the defense or settlement of each such action. Except as described below, Teva does not currently have a reasonable basis to estimate the loss, or range of loss, that is reasonably possible with respect to matters disclosed in this note.

Teva records a provision in its financial statements to the extent that it concludes that a contingent liability is probable and the amount thereof is estimable. Based upon the status of the cases described below, management's assessments of the likelihood of damages, and the advice of counsel, no provisions have been made regarding the matters disclosed in this note, except as noted below. Litigation outcomes and contingencies are unpredictable, and excessive verdicts can occur. Accordingly, management's assessments involve complex judgments about future events and often rely heavily on estimates and assumptions. Teva continuously reviews the matters described below and may, from time to time, remove previously disclosed matters that the Company has determined no longer meet the materiality threshold for disclosure.

If one or more of such proceedings described below were to result in final judgments against Teva, such judgments could be material to its results of operations and cash flows in a given period. In addition, Teva incurs significant legal fees and related expenses in the course of defending its positions even if the facts and circumstances of a particular litigation do not give rise to a provision in the financial statements.

In connection with third-party agreements, Teva may under certain circumstances be required to indemnify, and may be indemnified by, in unspecified amounts, the parties to such agreements against third-party claims. Among other things, Teva's agreements with third parties may require Teva to indemnify them, or require them to indemnify Teva, for the costs and damages incurred in connection with product liability claims, in specified or unspecified amounts.

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Except as otherwise noted, all of the litigation matters disclosed below involve claims arising in the United States. Except as otherwise noted, all third party sales figures given below are based on IQVIA (formerly IMS Health Inc.) data.

For income tax contingencies, see note 15 to our consolidated financial statements.

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

**Intellectual Property Litigation**

From time to time, Teva seeks to develop generic versions of patent-protected pharmaceuticals for sale prior to patent expiration in various markets. In the United States, to obtain approval for most generics prior to the expiration of the originator's patents, Teva must challenge the patents under the procedures set forth in the Hatch-Waxman Act of 1984, as amended. To the extent that Teva seeks to utilize such patent challenge procedures, Teva is and expects to be involved in patent litigation regarding the validity, enforceability or infringement of the originator's patents. Teva may also be involved in patent litigation involving the extent to which its product or manufacturing process techniques may infringe other originator or third-party patents.

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

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

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

In July 2014, GlaxoSmithKline (GSK) sued Teva in Delaware federal court for infringement of a patent expiring in June 2015 directed to using carvedilol in a specified manner to decrease the risk of mortality in patients with congestive heart failure. Teva and eight other generic producers began selling their carvedilol tablets (the generic version of GSK's Coreg®) in September 2007. A jury trial was held and the jury returned a verdict in GSK's favor finding Teva liable for induced infringement, including willful infringement, and assessing damages of \$235.5 million, not including pre- or post-judgment interest. Following post-trial motions filed by the parties, on March 28, 2018, the district court issued an opinion overturning the jury verdict and instead found no induced infringement by Teva, thereby finding that Teva did not owe any damages; the district court also denied Teva's motion seeking to overturn the jury verdict with respect to invalidity. On May 25, 2018, both parties filed an appeal. If the appeal of the district court's decision is decided against Teva, the case would be remanded to the district court for it to consider Teva's other legal and equitable defenses that have not yet been considered by the district court. The provision that was included in the financial statements for this matter was reversed as the exposure is no longer considered probable.

In 2014, Teva Canada succeeded in its challenge of the bortezomib (the generic equivalent of Velcade®) product and mannitol ester patents under the Patented Medicines (Notice Of Compliance) Regulations ( PM(NOC) ). At the time of Teva's launch in 2015, annual sales of Velcade were approximately 94 million Canadian dollars. Additionally, Teva commenced an action under Section 8 of PM(NOC) to recover damages for being kept off of the market during the PM(NOC) proceedings. Janssen and Millennium filed a counterclaim for infringement of the same two patents as well as a patent covering a process to prepare bortezomib. The product patent expired in October 2015; the other patents expire in January 2022 and March 2025. In 2017, Teva entered

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**Notes to Consolidated Financial Statements (Continued)**

into an agreement with Janssen and Millennium which limits the damages payable by either party depending on the outcome of the infringement/impeachment action. As a result, the most Janssen and Millennium could recover is 200 million Canadian dollars plus post-judgment interest. In June 2018, the court ruled that Janssen and Millennium pay Teva 5 million Canadian dollars in Section 8 damages. Janssen and Millennium filed an appeal that is currently pending. If the decision is overturned on appeal, Teva could owe the capped damages set forth above. In addition to the potential damages that could be awarded, Teva could be ordered to cease sales of its bortezomib product.

On July 8, 2011, Helsinn sued Teva over its filing of an ANDA to market a generic version of palonosetron IV solution (the generic equivalent of Aloxi®) and in November 2015, the District Court of New Jersey ruled against Teva. Teva appealed this decision and in May 2017, the Federal Circuit Court of Appeals reversed the district court's ruling and found the asserted patents invalid. In January 2018, full appellate review of that decision was denied. Helsinn filed an appeal with the US Supreme Court, which was granted. On January 22, 2019, the Supreme Court affirmed the appellate court's decision finding the asserted patent invalid. Helsinn has no further opportunity to appeal this patent decision. Separately, in October 2014, Helsinn filed an additional claim on later-acquired patents. On January 30, 2018, the District Court of New Jersey denied Helsinn's request for a preliminary injunction based on these later acquired patents. Teva launched its generic palonosetron IV solution after obtaining final regulatory approval on March 23, 2018. If Teva ultimately loses the case on the later-acquired patents discussed above, Teva may be ordered to cease sales of its generic product and/or pay damages to Helsinn. Aloxi® annual U.S. sales as of November 2017 were \$459 million.

In July 2015, Janssen sued Actavis and Teva (along with 10 other filers) over their filing of an ANDA to market their abiraterone acetate tablets, 250mg (generic versions of Zytiga®). In August 2017, Janssen sued Teva over its ANDA filing to market a 500mg generic version of Zytiga. In both cases, Janssen asserted a method of treatment patent. In January 2018, following a petition for *inter partes* review, the Patent Trials and Appeals Board (PTAB) found the patent to be invalid. In October 2018, the New Jersey District Court also found the patent to be invalid. Both the District Court and PTAB decisions are currently on appeal. Teva launched its generic 250mg product in November 2018. If Teva ultimately loses this case, Teva may be ordered by the court to cease sales of its generic product and/or pay damages to Janssen. Annual U.S. sales of Zytiga at the time of generic entry were about \$1.3B.

**Product Liability Litigation**

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

**Competition Matters**

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

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

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

In June 2013, the United States Supreme Court held, in *Federal Trade Commission v. Actavis, Inc.* (the *AndroGel* case), that a rule of reason test should be applied in analyzing whether such settlements potentially violate the federal antitrust laws. The Supreme Court held that a trial court must analyze each agreement in its entirety in order to determine whether it violates the antitrust laws. This new test has resulted in increased scrutiny of Teva's patent settlements, additional action by the FTC and state and local authorities, and an increased risk of liability in Teva's currently pending antitrust litigations.

In April 2006, certain subsidiaries of Teva were named in a class action lawsuit filed in the U.S. District Court for the Eastern District of Pennsylvania. The case alleges that the settlement agreements entered into between Cephalon, Inc., now a Teva subsidiary (Cephalon), and various generic pharmaceutical companies in late 2005 and early 2006 to resolve patent litigation involving certain finished modafinil products (marketed as PROVIGIL®) were unlawful because they had the effect of excluding generic competition. The case also alleges that Cephalon improperly asserted its PROVIGIL patent against the generic pharmaceutical companies. The first lawsuit was filed by a purported class of direct purchasers. Similar complaints were also filed by a purported class of indirect purchasers, certain chain pharmacies and by Apotex, Inc. (collectively, these cases are referred to as the *Philadelphia Modafinil Action*). Separately, Apotex challenged Cephalon's PROVIGIL patent and, in October 2011, the court found the patent to be invalid and unenforceable based on inequitable conduct. Teva has either settled or reached agreements in principle to settle with all of the plaintiffs in the *Philadelphia Modafinil Action*. Additionally, Cephalon and Teva have reached a settlement with 48 state attorneys general, which was approved by the court on November 7, 2016. Certain other claimants, including the State of California, have given notices of potential claims related to these settlement agreements. Teva has produced documents and information in response to discovery requests issued by the California Attorney General's office as part of its ongoing investigation of generic competition to PROVIGIL.

In May 2015, Cephalon entered into a consent decree with the FTC under which the FTC dismissed its claims against Cephalon in the *FTC Modafinil Action* in exchange for payment of \$1.2 billion (less set-offs for prior settlements) by Cephalon and Teva into a settlement fund. Under the consent decree, Teva also agreed to certain injunctive relief with



respect to the types of settlement agreements Teva may enter into to resolve patent litigation in the United States for a period of ten years. The settlement fund does not cover any judgments or settlements outside the United States.

Additionally, following an investigation initiated by the European Commission in April 2011 regarding a modafinil patent settlement in Europe, the Commission issued a Statement of Objections in July 2017 against

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both Cephalon and Teva alleging that the 2005 settlement agreement between the parties had the object and effect of hindering the entry of generic modafinil. No final decision regarding infringement has yet been taken by the Commission. The sales of modafinil in the European Economic Area during the last full year of the alleged infringement amounted to EUR 46.5 million.

In January 2009, the FTC and the State of California filed a complaint for injunctive relief in California federal court alleging that a September 2006 patent lawsuit settlement between Watson Pharmaceuticals, Inc. ( Watson ), now a Teva subsidiary, and Solvay Pharmaceuticals, Inc. ( Solvay ) relating to AndroGel® (testosterone gel) violated the antitrust laws. Additional lawsuits alleging similar claims were later filed by private plaintiffs (including plaintiffs purporting to represent classes of similarly situated claimants as well as direct purchaser plaintiffs filing separately) and the various actions were consolidated in a multidistrict litigation in Georgia federal court. On July 16, 2018, the direct-purchaser plaintiffs' motion for class certification was denied. As a result, the three direct purchasers that had sought class certification can proceed as individual plaintiffs, but any other member of the proposed direct purchaser class will need to file a separate, individual lawsuit if it wishes to participate in the litigation. The court has ordered a bench trial on the FTC's claims to commence on March 4, 2019, with a jury trial on the private plaintiffs' claims to be scheduled thereafter. Annual sales of AndroGel® 1% were approximately \$350 million at the time of the settlement and approximately \$140 million at the time Actavis launched its generic version of AndroGel® 1% in November 2015.

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

In February 2012, two purported classes of direct-purchaser plaintiffs sued GSK and Teva in New Jersey federal court for alleged violations of the antitrust laws in connection with their settlement of patent litigation involving lamotrigine (generic Lamictal®) entered into in February 2005. The plaintiffs claim that the settlement agreement unlawfully delayed generic entry and seek unspecified damages. In December 2012, the court dismissed the case, but in June 2015, the Third Circuit reversed and remanded for further proceedings. In December 2018, the court granted the direct-purchaser plaintiffs' motion for class certification. GSK and Teva filed a petition with the Third Circuit, seeking immediate appellate review of the district court's class certification ruling. That petition 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 purchaser class and, in December 2018, both the direct-purchaser class plaintiffs and indirect-purchaser class plaintiffs filed motions for class certification, which remain pending. In October 2016, the District Attorney for Orange County, California, filed a similar complaint, which has since been amended, in California state court,

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alleging violations of state law. Defendants moved to strike the District Attorney's claims for restitution and civil penalties to the extent not limited to alleged activity occurring in Orange County. The Superior Court denied that motion. The Court of Appeal subsequently reversed the decision and review of the Appellate Court decision is now pending before the California Supreme Court. Annual sales of Niaspan® were approximately \$416 million at the time of the settlement and approximately \$1.1 billion at the time Teva launched its generic version of Niaspan® in September 2013.

In November 2013, a putative class action was filed in Pennsylvania federal court against Actavis, Inc. and certain of its affiliates, alleging that Watson's 2012 patent lawsuit settlement with Endo Pharmaceuticals Inc. relating to Lidoderm® (lidocaine transdermal patches) violated the antitrust laws. Additional lawsuits containing similar allegations followed on behalf of other classes of putative direct purchaser and end-payer plaintiffs, as well as retailers acting in their individual capacities, and those cases were consolidated as a multidistrict litigation in federal court in California. On February 21, 2017, the court granted both the indirect purchaser plaintiffs' and the direct purchaser plaintiffs' motions for class certification. Teva settled the multidistrict litigation with the various plaintiff groups in the first quarter of 2018 and a provision was included in the financial statements. The FTC has also filed suit to challenge the Lidoderm® settlement, initially bringing antitrust claims against Watson, Endo and Allergan in Pennsylvania federal court in March 2016. The FTC later voluntarily dismissed those claims and refiled them (along with a stipulated order for permanent injunction to settle its claims against Endo) in the same California federal court in which the private multidistrict litigation referenced above was pending. On February 3, 2017, the State of California filed its own complaint against Allergan and Watson, and that complaint was also assigned to the California federal court presiding over the multidistrict litigation. The California federal court stayed the claims brought by the FTC and the State of California pending resolution of a related declaratory judgment action in Pennsylvania federal court. That declaratory judgment action has since been dismissed, but the stay remains in place. Annual sales of Lidoderm® at the time of the settlement were approximately \$1.2 billion and approximately \$1.4 billion at the time Actavis launched its generic version in September 2013.

Since November 2013, numerous lawsuits have been filed in various federal courts by purported classes of end payers for, and direct purchasers of, Aggrenox® (dipyridamole/aspirin tablets) against Boehringer Ingelheim (BI), the innovator, and several Teva subsidiaries. The lawsuits allege, among other things, that the settlement agreement between BI and Barr entered into in August 2008 violated the antitrust laws. A multidistrict litigation has been established in the U.S. District Court for the District of Connecticut. On April 11, 2017, the Orange County District Attorney filed a complaint for violations of California's Unfair Competition Law based on the Aggrenox® patent litigation settlement. Teva has settled with the putative classes of direct purchasers and end payers, as well as with the opt-out direct purchaser plaintiffs, and with two of the opt-out end payer plaintiffs. A provision with respect to the settlements was included in the financial statements. The district court overruled certain objections to the end payer settlement, including objections made by the Orange County District Attorney, and approved the settlement. The District Attorney subsequently appealed the court's approval to the Second Circuit. Opt-outs from the end payer class have also appealed certain aspects of the court's approval order to the Second Circuit. Those appeals remain pending. Annual sales of Aggrenox® were approximately \$340 million at the time of the settlement and approximately \$455 million at the time Teva launched its authorized generic version of Aggrenox® in July 2015.

Since January 2014, numerous lawsuits have been filed in the U.S. District Court for the Southern District of New York by purported classes of end payers for, and direct purchasers of, Actos® and Actoplus Met (pioglitazone and pioglitazone plus metformin) against Takeda, the innovator, and several generic manufacturers, including Teva, Actavis and Watson. The lawsuits allege, among other things, that the settlement agreements between Takeda and the generic manufacturers violated the antitrust laws. The court dismissed the end payer lawsuits against all defendants in September 2015. On February 8, 2017, the Court of Appeals for the Second

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Circuit affirmed the dismissal in part and vacated and remanded the dismissal in part with respect to the claims against Takeda. The direct purchasers' case had been stayed pending resolution of the appeal in the end payer matter and the direct purchasers amended their complaint for a second time following the Second Circuit's decision. Defendants moved to dismiss the direct purchasers' complaint, and that motion remains pending. At the time of the settlement, annual sales of Actos® and Actoplus Met were approximately \$3.7 billion and approximately \$500 million, respectively. At the time Teva launched its authorized generic version of Actos® and Actoplus Met in August 2012, annual sales of Actos® and Actoplus Met were approximately \$2.8 billion and approximately \$430 million, respectively.

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

In May 2015, a purported class of end payers for Namenda IR® (memantine hydrochloride) filed a lawsuit against Forest Laboratories, LLC ( Forest ), the innovator, and several generic manufacturers, including Teva. The lawsuit alleges, among other things, that settlement agreements between Forest and the generic manufacturers to resolve patent litigation over Namenda IR® violated the antitrust laws. The court has denied defendants' motions to dismiss and in September 2018 referred the parties to mediation. Annual sales of Namenda IR® at the time of the settlement were approximately \$1.1 billion and approximately \$550 million at the time other manufacturers first launched generic versions of Namenda IR® in July 2015.

On December 16, 2016, the U.K. Competition and Markets Authority ( CMA ) issued a statement of objections (a provisional finding of infringement of the Competition Act) in respect of certain allegations against Allergan, Actavis UK and certain Auden Mckenzie entities alleging competition law breaches in connection with the supply of 10mg and 20mg hydrocortisone tablets in the U.K. On December 18, 2017, the CMA issued a Statement of Draft Penalty Calculation. No final decision regarding infringement of competition law has yet been issued. On March 3, 2017, the CMA issued a second statement of objections in respect of certain additional allegations (relating to the same products and covering part of the same time period as in the first statement of objections) against Actavis UK, Allergan and certain Auden Mckenzie entities. On January 9, 2017, Teva completed the sale of Actavis UK to Accord Healthcare Limited, pursuant to which Teva will indemnify Accord Healthcare for potential fines imposed by the CMA and/or damages awarded by a court against Actavis UK as a result of the conduct prior to the closing date of the sale. In addition, Teva agreed to indemnify Allergan against losses arising from this matter, pursuant to the agreement the parties entered into on January 31, 2018. See note 3. In the event of any such fines or damages, Teva expects to assert claims, including claims for breach of warranty, against the sellers of Auden Mckenzie. The terms of the purchase

agreement may preclude a full recovery by Teva. A liability for this matter has been recorded in purchase accounting related to the acquisition of Actavis Generics.

Since November 2016, several putative indirect purchaser and direct purchaser class actions were filed in federal courts in Wisconsin, Massachusetts and Florida against Shire U.S., Inc. and Shire LLC (collectively,

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Shire ), Actavis and Teva, alleging that Shire's 2013 patent litigation settlement with Actavis related to the ADHD drug Intuniv® (guanfacine) violated various state consumer protection and antitrust laws. All cases are now in Massachusetts federal court. Annual sales of Intuniv® were approximately \$335 million at the time of the settlement and approximately \$327 million at the time Actavis launched its generic version of Intuniv® in 2014.

**Government Investigations and Litigation Relating to Pricing and Marketing**

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

A number of state attorneys general have filed various actions against Teva and/or certain of its subsidiaries relating to reimbursements or drug price reporting under Medicaid or other programs. Such price reporting is alleged to have caused states and others to pay inflated reimbursements for covered drugs. Teva and its subsidiaries have reached settlements in most of these cases. On October 4, 2018, Teva settled longstanding litigation filed by the State of Illinois against subsidiaries of Teva and Watson for a total settlement amount of \$135 million, the majority of which was paid in December of 2018. Teva accepted the settlement while denying any liability with respect to the claims made by the state. Pending the final settlement payment, the Illinois litigation is stayed. In August 2013, judgment was entered in a separate case brought by the State of Mississippi against Watson, pursuant to which Watson was ordered to pay compensatory damages amounting to \$12.4 million. In March 2014, the Mississippi court amended the judgment to also include punitive damages in the amount of \$17.9 million. The judgment was affirmed in all respects by the Mississippi Supreme Court in January 2018 and has since been satisfied in full. Certain Actavis subsidiaries remain parties to active litigation in Utah where previously dismissed claims against Watson are now on appeal. A provision for these cases has been included in the financial statements.

Several *qui tam* complaints have been unsealed in recent years as a result of government decisions not to participate in the cases. The following is a summary of certain government investigations, *qui tam* actions and related matters.

In January 2014, Teva received a civil investigative demand from the U.S. Attorney for the Southern District of New York seeking documents and information from January 1, 2006 related to sales, marketing and promotion of COPAXONE and AZILECT®, focusing on educational and speaker programs. The demand states that the government is investigating possible civil violations of the federal False Claims Act. In March 2015, the docket in this matter and a False Claims Act civil *qui tam* complaint concerning this matter were unsealed by the court after the government declined to intervene. In February 2016, the court denied Teva's motions to dismiss the False Claims Act claims and instructed the relators to amend their complaint with additional information. In March 2016, the relators filed an amended complaint. In August 2018, Teva filed a motion for summary judgment on all claims, which is now pending before the court.



In January 2014, a *qui tam* complaint was filed in Rhode Island federal court alleging that Teva and several other defendants, including manufacturers of MS drugs and pharmacy benefit managers, violated the False Claims Act. The *qui tam* action was unsealed on April 4, 2018 after the government declined to intervene. The

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relator alleges that Teva and the other defendants induced fraudulent overpayments for illegitimate Bona Fide Service Fees in excess of fair market value to inflate prices for the Medicare Part D program. Teva moved to dismiss the complaint. The DOJ also moved to dismiss the complaint, arguing that it lacked merit and was not in the government's interest to continue. Both motions are pending.

In May 2017, a *qui tam* action was filed against a number of Teva subsidiaries. The *qui tam* action was unsealed on June 13, 2018 after the government declined to intervene. The relator in the case alleges that Teva violated the False Claims Act by devising and engaging in promotional schemes that violate the Anti-Kickback Statute ( AKS ), resulting in false certifications of compliance with the AKS. Specifically, the relator alleges that Teva paid in-kind remuneration to physicians through reimbursement support and nursing services in order to increase the number of COPAXONE prescriptions. An amended complaint was filed on October 15, 2018. Teva and the DOJ moved to dismiss the case. These motions are pending.

Since May 2014, approximately 1,500 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 and private plaintiffs in both state and federal courts. Most of the federal cases have been consolidated into a multidistrict litigation in the Northern District of Ohio ( MDL Opioid Proceeding ) and many of the cases filed in state court have been removed to federal court and consolidated into the MDL Opioid Proceeding. Complaints asserting claims under similar provisions of different state law, generally contend that the defendants allegedly engaged in improper marketing and distribution of opioids, including ACTIQ® and FENTORA®. The complaints also assert claims related to Teva's generic opioid products. In addition, several dozen complaints filed by cities, counties and the State of Delaware have named Anda, Inc. (and other distributors and manufacturers) alleging that Anda failed to develop and implement systems sufficient to identify suspicious orders of opioid products and prevent the abuse and diversion of such products to individuals who used them for other than legitimate medical purposes. Plaintiffs seek a variety of remedies, including restitution, civil penalties, disgorgement of profits, treble damages, attorneys' fees and injunctive relief. Certain plaintiffs assert that the measure of damages is the entirety of the costs associated with addressing the abuse of opioids and opioid addiction. None of the complaints specify the exact amount of damages at issue; however, an adverse resolution of any of these lawsuits or investigations may involve large monetary penalties and could have a material and adverse effect on Teva's reputation, business, results of operations and cash flows. Teva and its affiliates that are defendants in the various lawsuits deny all allegations asserted in these complaints and have filed or will file motions to dismiss where possible. On October 5, 2018, the magistrate judge in the MDL Opioid Proceeding issued a Report & Recommendation rejecting the first motion to dismiss, except for the common law public nuisance claim, which was dismissed. On December 19, 2018, the District Court judge overruled defendants' objections to the Report & Recommendation. Motions to dismiss in eight additional similar cases remain pending. Discovery in the MDL Opioid Proceeding for the first track of cases is proceeding with a trial scheduled for October 2019. Other cases remain pending in various state courts, including Oklahoma, where a trial is scheduled to begin in May 2019, and where the plaintiffs are seeking joint and several damages among all defendants. In some jurisdictions, such as Illinois, New York, Pennsylvania, South Carolina and Texas, certain state court cases have been transferred to a single court within their respective state court systems for coordinated pretrial proceedings. On April 27, 2018, Teva received subpoena requests from the DOJ seeking documents relating to the manufacture, marketing and sale of opioids. Teva is complying with this subpoena. In addition, a number of state attorneys general, including a coordinated multistate effort, have initiated investigations into sales and marketing

practices of Teva and its affiliates with respect to opioids. Other states are conducting their own investigations outside of the multistate group. Teva is cooperating with these ongoing investigations and cannot predict the outcome at this time.

On June 21, 2016, Teva USA received a subpoena from the DOJ Antitrust Division seeking documents and other information relating to the marketing and pricing of certain Teva USA generic products and

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communications with competitors about such products. Actavis received a similar subpoena in June 2015. Teva and Actavis are cooperating with the DOJ subpoena requests. On July 12, 2016, Teva USA received a subpoena from the Connecticut Attorney General seeking documents and other information relating to potential state antitrust law violations. In 2015, Actavis received a similar subpoena from the Connecticut Attorney General.

On December 15, 2016, a civil action was brought by the attorneys general of twenty states against Teva USA and several other companies asserting claims under federal antitrust law alleging price fixing of generic products in the United States. An amended complaint was filed on March 1, 2017 adding twenty additional states to the named plaintiffs and adding supplemental state law claims. The states seek a finding that the defendants' actions violated federal antitrust law and state antitrust and consumer protection laws, as well as injunctive relief, disgorgement, damages on behalf of various state and governmental entities and consumers, civil penalties and costs. On August 3, 2017, the action was transferred to the generic drug multidistrict litigation in the Eastern District of Pennsylvania ( Pennsylvania MDL ). On July 17, 2017, a new complaint was filed in the District Court of Connecticut on behalf of four additional states with the same factual allegations and claims that are at issue in the Pennsylvania MDL case. The complaint was subsequently transferred to the Pennsylvania MDL. On October 31, 2017, the attorneys general of 45 states plus Puerto Rico and the District of Columbia filed a motion for leave to file an amended complaint in this action. The proposed amended complaint names Actavis and Teva as defendants, and adds new allegations and claims to those appearing in the prior complaints. Defendants have opposed the motion. On June 5, 2018, the District Court for the Eastern District of Pennsylvania granted the attorneys general's motion to amend.

Beginning on March 2, 2016, numerous complaints have been filed in the United States on behalf of putative classes of direct and indirect purchasers of several generic drug products, as well as several individual direct purchaser opt-out plaintiffs. These complaints, which allege that the defendants engaged in conspiracies to fix prices and/or allocate market share of generic products have been brought against various manufacturer defendants, including Teva and Actavis. The plaintiffs generally seek injunctive relief and damages under federal antitrust law, and damages under various state laws. On April 6, 2017, these cases were transferred to the Pennsylvania MDL. Additional cases were transferred to that court and the plaintiffs filed consolidated amended complaints on August 15, 2017. On October 16, 2018, the court denied certain of the defendants' motions to dismiss. Teva and Actavis deny having engaged in any conduct that would give rise to liability with respect to the above-mentioned complaints.

In May 2018, Teva received a civil investigative demand from the DOJ Civil Division, pursuant to the federal False Claims Act, seeking documents and information produced since January 1, 2009 relevant to the Civil Division's investigation concerning allegations that generic pharmaceutical manufacturers, including Teva, engaged in market allocation and price-fixing agreements, paid illegal remuneration, and caused false claims to be submitted in violation of the False Claims Act. Teva is cooperating with this subpoena.

On March 21, 2017, Teva received a subpoena from the U.S. Attorney's office in Boston, Massachusetts requesting documents related to Teva's donations to patient assistance programs. Teva is cooperating in responding to the subpoena.

In December 2016, Teva resolved certain claims under the U.S. Foreign Corrupt Practices Act ( FCPA ) with the SEC and the DOJ, as more fully described in Teva's 2017 Annual Report. The settlement included a fine, disgorgement and

prejudgment interest; a three-year deferred prosecution agreement ( DPA ) for Teva and the retention of an independent compliance monitor for a period of three years. If, during the term of the DPA (approximately three years unless extended), the DOJ determines that Teva has committed a felony under federal law, provided deliberately false or misleading information or otherwise breached the DPA, Teva could be subject to prosecution and additional fines or penalties, including the deferred charges. Following the above resolution

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**Notes to Consolidated Financial Statements (Continued)**

with the SEC and DOJ, Teva has had requests for documents and information from various Russian government entities. In addition, on January 14, 2018, Teva entered into an arrangement for the Contingent Cessation of Proceedings pursuant to the Israeli Securities Law with the Government of Israel that ended the investigation of the Israeli government into the conduct that was subject to the FCPA investigation, and provided a payment of approximately \$22 million.

**Shareholder Litigation**

On November 6, 2016 and December 27, 2016, two putative securities class actions were filed in the U.S. District Court for the Central District of California against Teva and certain of its current and former officers and directors. After those two lawsuits were consolidated and transferred to the U.S. District Court for the District of Connecticut, the court appointed the Ontario Teachers Pension Plan Board as lead plaintiff (the Ontario Teachers Securities Litigation). The lead plaintiff then filed a consolidated amended complaint. On April 3, 2018, the court dismissed the case without prejudice. Lead plaintiff filed a second amended complaint on June 22, 2018, purportedly on behalf of purchasers of Teva's securities between February 6, 2014 and August 3, 2017. The second complaint asserts that Teva and certain of its current and former officers and directors violated federal securities laws in connection with Teva's alleged failure to disclose pricing strategies for various drugs in its generic drug portfolio and by making allegedly false or misleading statements in certain offering materials issued during the class period. The second complaint seeks unspecified damages, legal fees, interest, and costs. Teva and the current and former officer and director defendants filed motions to dismiss the second complaint on September 14, 2018. Those motions are pending before the court.

On July 17, 2017, a lawsuit was filed in the U.S. District Court for the Southern District of Ohio derivatively on behalf of the Teva Employee Stock Purchase Plan, and alternatively as a putative class action lawsuit on behalf of individuals who purchased Teva stock through that plan. That lawsuit seeks unspecified damages, legal fees, interest and costs. The complaint alleges that Teva failed to maintain adequate financial controls based on the facts underpinning Teva's FCPA DPA and also based on allegations substantially similar to those in the Ontario Teachers Securities Litigation. On November 29, 2017, the court granted Teva's motion to transfer the litigation to the U.S. District Court for the District of Connecticut where the Ontario Teachers Securities Litigation is pending. On February 12, 2018, the district court stayed the case pending resolution of the motions to dismiss filed in the consolidated putative securities class action described above.

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

On August 21 and 30, 2017, Elliot Grodtko and Barry Baker filed putative securities class actions in the U.S. District Court for the Eastern District of Pennsylvania purportedly on behalf of purchasers of Teva's securities between November 15, 2016 and August 2, 2017 seeking unspecified damages, legal fees, interest, and costs. The complaints allege that Teva and certain of its current and former officers violated the federal securities laws and Israeli securities

laws by making false and misleading statements in connection with Teva's acquisition and integration of Actavis Generics. On November 1, 2017, the court consolidated the Baker and Grodsko cases. On April 10, 2018, the court granted Teva's motion to transfer the consolidated action to the District of Connecticut where the Ontario Teachers Securities Litigation is currently pending.

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Between August 2018 and February 2019, nine complaints were filed against Teva and current and former officer and director defendants seeking unspecified compensatory and rescissory damages, legal fees, costs and expenses. The allegations in these complaints are substantially similar to the allegations in the Ontario Teachers Securities Litigation, but have been brought on behalf of plaintiffs that have opted out of the putative class in the Ontario Teachers Securities Litigation. The plaintiffs in these opt-out cases filed their complaints in the Court of Common Pleas of Montgomery County, Pennsylvania, the U.S. District Court for the Eastern District of Pennsylvania and the U.S. District Court for the District of Connecticut. Teva and the current and former officer and director defendants filed or will file motions to transfer the cases filed in Pennsylvania to the U.S. District Court for the District of Connecticut, where the Ontario Teachers Securities Litigation is pending. The cases filed in Connecticut have been or will request to be stayed pending resolution of the motions to dismiss filed in the consolidated putative securities class action described above.

Motions to approve derivative actions against certain past and present directors and officers have been filed in Israel alleging negligence and recklessness with respect to the acquisition of the Rimsa business and the acquisition of Actavis Generics. Motions for document disclosure prior to initiating derivative actions were filed with respect to dividend distribution, executive compensation, several patent settlement agreements and the U.S. price-fixing investigations. Motions to approve securities class actions against Teva and certain of its current and former directors and officers were filed in Israel based on allegations of improper disclosure of the above-mentioned pricing investigation, as well as lack of disclosure of negative developments in the generic sector, including price erosion with respect to Teva's products. Other motions were filed in Israel to approve a derivative action, discovery and a class action related to claims regarding Teva's above-mentioned FCPA resolution with the SEC and DOJ.

**Environmental Matters**

Teva or its subsidiaries are party to a number of environmental proceedings, or have received claims, including under the federal Superfund law or other federal, provincial or state and local laws, imposing liability for alleged noncompliance, or for the investigation and remediation of releases of hazardous substances and for natural resource damages. Many of these proceedings and claims seek to require the generators of hazardous wastes disposed of at a third party-owned site, or the party responsible for a release of hazardous substances that impacted a site, to investigate and clean the site or to pay or reimburse others for such activities, including for oversight by governmental authorities and any related damages to natural resources. Teva or its subsidiaries have received claims, or been made a party to these proceedings, along with others, as an alleged generator of wastes that were disposed of or treated at third-party waste disposal sites, or as a result of an alleged release from one of Teva's facilities or former facilities.

Although liability among the responsible parties, under certain circumstances, may be joint and several, these proceedings are frequently resolved so that the allocation of clean-up and other costs among the parties reflects the relative contributions of the parties to the site conditions and takes into account other pertinent factors. Teva's potential liability varies greatly at each of the sites; for some sites the costs of the investigation, clean-up and natural resource damages have not yet been determined, and for others Teva's allocable share of liability has not been determined. At other sites, Teva has taken an active role in identifying those costs, to the extent they are identifiable and estimable, which do not include reductions for potential recoveries of clean-up costs from insurers, indemnitors, former site owners or operators or other potentially responsible parties. In addition, enforcement proceedings relating to alleged



violations of federal, state, commonwealth or local requirements at some of Teva's facilities may result in the imposition of significant penalties (in amounts not expected to materially adversely affect Teva's results of operations) and the recovery of certain costs and natural resource damages, and may require that corrective actions and enhanced compliance measures be implemented.

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**Notes to Consolidated Financial Statements (Continued)**

**Other Matters**

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

**NOTE 14 EQUITY:**

**a. Ordinary shares and ADSs**

As of December 31, 2018 and 2017, Teva had approximately 1.2 billion and 1.1 billion ordinary shares issued, respectively. Teva ordinary shares are traded on the Tel-Aviv Stock Exchange and on the New York Stock Exchange, in the form of American Depositary Shares (ADSs), each of which represents one ordinary share.

On December 8, 2015, Teva completed an offering of 54 million ADSs at \$62.50 per share. On January 6, 2016, Teva sold an additional 5.4 million ADSs, pursuant to the underwriters' exercise in full of their overallotment option. As a result, Teva received an additional \$329 million in net proceeds, for an aggregate of approximately \$3.62 billion, including the initial closing.

On August 2, 2016, Teva issued approximately 100.3 million Teva shares to Allergan in connection with the closing of the Actavis Generics acquisition.

On December 17, 2018, the mandatory convertible preferred shares automatically converted into ordinary shares. As a result of this conversion, Teva issued 70.6 million ADSs.

**b. Mandatory convertible preferred shares**

On December 8, 2015, Teva completed an offering of 3,375,000 of its 7% mandatory convertible preferred shares. The mandatory convertible preferred shares had no voting rights and ranked senior to Teva's ordinary shares with respect to dividends and distributions upon liquidation, winding-up or dissolution.

On January 6, 2016, Teva sold an additional 337,500 mandatory convertible preferred shares pursuant to the underwriters' exercise in full of their overallotment option. As a result, Teva received an additional \$329 million in net

proceeds, for an aggregate of approximately \$3.62 billion including the initial closing.

On December 17, 2018, the mandatory convertible preferred shares automatically converted into ordinary shares at a ratio of 1 mandatory convertible preferred share to 16 ADSs, and all of the accumulated and unpaid dividends on the mandatory convertible preferred shares were paid in ADSs, at a ratio of 3.0262 ADSs per mandatory convertible preferred share, all in accordance with the conversion mechanism set forth in the terms of the mandatory convertible preferred shares.

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**Notes to Consolidated Financial Statements (Continued)**

***Share repurchase program***

In December 2011, Teva's Board of Directors authorized it to repurchase up to an aggregate amount of \$3.0 billion of its ordinary shares/ADSs, of which \$1.3 billion remained available for purchase. In October 2014, the Board of Directors authorized Teva to increase its share repurchase program by \$1.7 billion to \$3.0 billion, of which \$2.1 billion remained available as of December 31, 2018. Teva did not repurchase any of its shares during 2018 and currently cannot do so due to its accumulated deficit. The repurchase program has no time limit. Repurchases may be commenced or suspended at any time, subject to applicable law.

**c. Stock-based compensation plans:**

Stock-based compensation plans are comprised of employee stock options, RSUs, PSUs, and other equity-based awards to employees, officers and directors. The purpose of the plans is to enable the Company to attract and retain qualified personnel and to motivate such persons by providing them with equity participation in the Company.

On June 29, 2010, the Teva 2010 Long-Term Equity-Based Incentive Plan was approved by Teva's shareholders, under which 70 million equivalent share units, including options exercisable into ordinary shares, RSUs and PSUs, were approved for grant. The 2010 Plan expired on June 28, 2015 (except with respect to awards outstanding on that date), and no additional awards under the 2010 Plan may be made.

On September 3, 2015, the Teva 2015 Long-Term Equity-Based Incentive Plan was approved by Teva's shareholders, under which 43.7 million equivalent share units, including options exercisable into ordinary shares, RSUs and PSUs, were approved for grant.

On April 18, 2016, Teva's shareholders approved an increase of an additional 33.3 million equivalent share units to the share reserve of Teva's 2015 Long-Term Equity-Based Incentive Plan, so that 77 million equivalent share units, including options exercisable into ordinary shares, RSUs and PSUs, are approved for grant.

On July 13, 2017, Teva's shareholders approved an increase of an additional 65 million equivalent share units to the share reserve of Teva's 2015 Long-Term Equity-Based Incentive Plan, so that 142 million equivalent share units, including options exercisable into ordinary shares, RSUs and PSUs, are approved for grant.

As of December 31, 2018, 76.6 million equivalent share units remain available for future awards.

In the past, Teva had various employee stock and incentive plans under which stock options and other share-based awards were granted. Stock options and other share-based awards granted under such prior plans continue in accordance with the terms of the respective plans.

The vesting period of the outstanding options, RSUs and PSUs is generally from 1 to 4 years from the date of grant. The rights of the ordinary shares obtained from the exercise of options, RSUs or PSUs are identical to those of the other ordinary shares of the Company. The contractual term of these options is primarily for seven years in prior plans

and ten years for options granted under the 2010 and 2015 plans described above.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)***Status of options*

A summary of the status of the options as of December 31, 2018, 2017 and 2016, and changes during the years ended on those dates, is presented below (the number of options represents ordinary shares exercisable in respect thereof).

	Year ended December 31,					
	2018	Weighted	2017	Weighted	2016	Weighted
	Number	average	Number	average	Number	average
	(in thousands)	exercise price	(in thousands)	exercise price	(in thousands)	exercise price
Balance outstanding at beginning of year	43,121	\$ 44.32	32,789	\$ 50.71	25,233	\$ 49.69
Changes during the year:						
Granted	12,401	19.12	15,467	32.08	10,895	53.21
Exercised	(84)	17.01	(7)	17.44	(766)	44.24
Forfeited	(7,040)	39.38	(4,953)	47.92	(1,382)	54.09
Expired	(5)	50.65	(175)	59.81	(1,191)	52.79
Balance outstanding at end of year	48,393	38.62	43,121	44.32	32,789	50.71
Balance exercisable at end of year	24,086	46.89	19,129	47.94	14,468	46.06

The weighted average fair value of options granted during the years was generally estimated by using the Black-Scholes option-pricing model as follows:

	Year ended December 31,		
	2018	2017	2016
Weighted average fair value	\$ 7.4	\$ 5.7	\$ 9.4

The fair value of these options was estimated on the date of grant, based on the following weighted average assumptions:

	Year ended December 31,		
	2018	2017	2016
Dividend yield	0%	3.7%	2.6%

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Expected volatility	40%	29%	25%
Risk-free interest rate	2.6%	2.1%	1.4%
Expected term	5 years	5 years	5 years

The expected term was estimated based on the weighted average period for which the options granted are expected to be outstanding, taking into consideration the current vesting of options and the historical exercise patterns of existing options. The expected volatility assumption used is based on a blend of the historical and implied volatility of the Company's stock. The risk-free interest rate used is based on the yield of U.S. Treasuries with a maturity closest to the expected term of the options granted. The dividend yield assumption reflects the expected dividend yield based on historical dividends and expected dividend growth.

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The following tables summarize information at December 31, 2018 regarding the number of ordinary shares issuable upon (1) outstanding options and (2) vested options:

**(1) Number of ordinary shares issuable upon exercise of outstanding options**

Range of exercise prices	Balance at end of period (in thousands) Number of shares	Weighted average	Weighted average	Aggregate intrinsic
		exercise	remaining	value (in
		price	life	millions)
		\$	Years	\$
Lower than \$15.01	593	11.40	8.85	2.4
\$15.01 - \$25.00	12,398	18.92	9.13	*
\$25.01 - \$35.00	9,615	34.63	8.17	
\$35.01 - \$45.00	6,703	40.57	3.58	
\$45.01 - \$55.00	12,908	50.84	5.64	
\$55.01 - \$65.00	6,167	59.34	6.30	
\$65.01 - \$70.00	9	66.85	0.03	
Total	48,393	38.62	6.87	2.4

**(2) Number of ordinary shares issuable upon exercise of vested options**

Range of exercise prices	Balance at end of period (in thousands) Number of shares	Weighted average	Weighted average	Aggregate intrinsic
		exercise	remaining	value (in
		price	life	millions)
		\$	Years	\$
\$15.01 - \$25.00	548	16.99	8.68	*
\$25.01 - \$35.00	2,464	34.60	8.18	
\$35.01 - \$45.00	6,655	40.59	3.55	
\$45.01 - \$55.00	10,041	50.17	5.17	
\$55.01 - \$65.00	4,369	59.58	6.25	
\$65.01 - \$70.00	9	66.85	0.03	
Total	24,086	46.89	5.30	*

\* Represents an amount less than 0.5 million.



The aggregate intrinsic value in the above tables represents the total pre-tax intrinsic value, based on the Company's closing stock price of \$15.42 on December 31, 2018, less the weighted average exercise price in each range. This represents the potential amount receivable by the option holders had all option holders exercised their options as of such date. As of December 31, 2018, there was an immaterial amount of options exercisable that were in-the-money.

The total intrinsic value of options exercised during the years ended December 31, 2018 and 2017 were immaterial, based on the Company's average stock price of \$20.92 and \$25.62, for the years then ended, respectively.

The total intrinsic value of options exercised during the year ended December 31, 2016 was \$5 million based on the Company's average stock price of \$50.96.

*Status of non-vested RSUs*

The fair value of RSUs and PSUs is estimated based on the market value of the Company's stock on the date of award grant, less an estimate of dividends that will not accrue to RSU and PSU holders prior to vesting.

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The following table summarizes information about the number of RSUs and PSUs issued and outstanding:

	Year ended December 31,					
	2018		2017		2016	
	Number	Weighted average grant date fair value	Number	Weighted average grant date fair value	Number	Weighted average grant date fair value
	(in thousands)		(in thousands)		(in thousands)	
Balance outstanding at beginning of year	7,468	\$ 27.95	4,636	\$ 45.15	2,551	\$ 51.43
Granted	5,900	18.80	5,461	20.10	3,193	40.78
Vested	(1,638)	37.30	(1,884)	39.63	(830)	45.79
Forfeited	(1,327)	32.5	(745)	42.84	(278)	46.08
Balance outstanding at end of year	10,403	20.93	7,468	27.95	4,636	45.15

The Company expenses compensation costs based on the grant-date fair value. For the years ended December 31, 2018, 2017 and 2016, the Company recorded stock-based compensation costs as follows:

	Year ended December 31,		
	2018	2017	2016
	(U.S. \$ in millions)		
Employee stock options	\$ 74	\$ 64	\$ 56
RSUs and PSUs	81	69	66
Total stock-based compensation expense	155	133	122
Tax effect on stock-based compensation expense	18	24	26
Net effect	\$ 137	\$ 109	\$ 96

At December 31, 2018, the total unrecognized compensation cost before tax on employee stock options and RSU/PSUs amounted to \$112 million and \$138 million, respectively, and is expected to be recognized over a weighted average period of approximately 2.5 years.

**d. Dividends:**

Commencing in April 2015, dividends on Teva's ordinary shares were declared in U.S. dollars. Dividends paid per share in the years ended December 31, 2018, 2017 and 2016 were \$0, \$0.85 and \$1.36, respectively.

In addition, dividends paid on Teva's mandatory convertible preferred shares per share in the years ended December 31, 2018 and 2017 were \$0 and \$70 million, respectively.

In December 2017, Teva announced an immediate suspension of dividends on its ordinary shares and ADSs.

Teva suspended cash dividends on its mandatory convertible preferred shares in the fourth quarter of 2017, due to its accumulated deficit. The mandatory conversion date of the mandatory convertible preferred shares was in December 2018. All of the accumulated and unpaid dividends on the mandatory convertible preferred shares were paid in ADSs, at a ratio of 3.0262 ADSs per mandatory convertible preferred share, according to the conversion mechanism set forth in the terms of the mandatory convertible preferred shares.

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The components of accumulated other comprehensive loss attributable to Teva are presented in the table below:

	Net Unrealized Gains/(Losses)			Benefit Plans Actuarial gains/(losses) and prior service (costs)/credits	Total
	Foreign currency translation adjustments	Available-for-sale securities	Derivative financial instruments		
Balance, January 1, 2016	(2,384)	312	175	(58)	(1,955)
Other comprehensive loss before reclassifications	(355)	(456)	(491)	(26)	(1,328)
Amounts reclassified to the statements of income	3	140	14	(6)	151
Net other comprehensive loss before tax	(352)	(316)	(477)	(32)	(1,177)
Corresponding income tax	(33)	(3)		9	(27)
Net other comprehensive loss after tax*	(385)	(319)	(477)	(23)	(1,204)
Balance, December 31, 2016	(2,769)	(7)	(302)	(81)	(3,159)
Other comprehensive income/(loss) before reclassifications	1,075	64	(167)	(3)	969
Amounts reclassified to the statements of income	378	(66)	27	(5)	334
Net other comprehensive income/(loss) before tax	1,453	(2)	(140)	(8)	1,303
Corresponding income tax		5		(2)	3
Net other comprehensive income/(loss) after tax*	1,453	3	(140)	(10)	1,306
Balance, December 31, 2017	(1,316)	(4)	(442)	(91)	(1,853)
Cumulative effect of new accounting standard (See Note 1)		5			5
	(739)	(1)	87	4	(649)

Other comprehensive income/(loss) before reclassifications					
Amounts reclassified to the statements of income		1	28	13	42
Net other comprehensive income/(loss) before tax	(739)		115	17	(607)
Corresponding income tax				(4)	(4)
Net other comprehensive income/(loss) after tax*	(739)		115	13	(611)
Balance, December 31, 2018	(2,055)	1	(327)	(78)	(2,459)

\* Amounts do not include foreign currency translation adjustments attributable to non-controlling interests of \$26 million gain in 2018, \$63 million loss in 2017 and \$60 million loss in 2016

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****NOTE 15 INCOME TAXES:****a. Income before income taxes:**

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S. \$ in millions)</b>		
Parent Company and its Israeli subsidiaries	\$ 1,022	\$ 1,451	\$ 1,516
Non-Israeli subsidiaries	(3,618)	(19,830)	(692)
	\$ (2,596)	\$ (18,379)	\$ 824

**b. Income taxes:**

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S. \$ in millions)</b>		
In Israel	\$ 131	\$ 96	\$ 209
Outside Israel	(326)	(2,029)	312
	\$ (195)	\$ (1,933)	\$ 521
Current	\$ 700	\$ 373	\$ 481
Deferred	(895)	(2,306)	40
	\$ (195)	\$ (1,933)	\$ 521

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S. \$ in millions)</b>		
Income (loss) before income taxes	\$ (2,596)	\$ (18,379)	\$ 824
Statutory tax rate in Israel	23.0%	24.0%	25.0%

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Theoretical provision for income taxes	\$ (597)	\$ (4,411)	\$ 206
Increase (decrease) in effective tax rate due to:			
The Parent Company and its Israeli subsidiaries			
Mainly tax benefits arising from reduced tax rates under benefit programs	(134)	(253)	(212)
Non-Israeli subsidiaries, including impairments (*)	381	3,817	546
U.S. Tax Cuts and Jobs Act effect	97	(1,061)	
Increase (decrease) in other uncertain tax positions net	58	(25)	(19)
Effective consolidated income taxes	\$ (195)	\$ (1,933)	\$ 521

\* Income before income taxes includes goodwill impairment in non-Israeli subsidiaries that did not have a corresponding tax effect.

The effective tax rate is the result of a variety of factors, including the geographic mix and type of products sold during the year, different effective tax rates applicable to non-Israeli subsidiaries that have tax rates above Teva's average tax rates, the impact of impairment, restructuring and legal settlement charges and adjustments to valuation allowances on deferred tax assets on such subsidiaries.

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	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(U.S. \$ in millions)</b>	
Long-term deferred tax assets (liabilities) net:		
Inventory related	\$ 113	\$ 40
Sales reserves and allowances	199	201
Provision for legal settlements	42	171
Intangible assets (*)	(2,282)	(3,132)
Carryforward losses and deductions and credits (**)	1,340	1,485
Property, plant and equipment	(167)	(231)
Deferred interest (***)	391	
Provisions for employee related obligations	102	142
Other	123	125
	(139)	(1,199)
Valuation allowance in respect of carryforward losses and deductions that may not be utilized (**)	(1,633)	(1,504)
	\$ (1,772)	\$ (2,703)

\* The decrease in deferred tax liability is mainly due to impairment and amortization.

\*\* The amounts are shown after reduction for unrecognized tax benefits of \$35 million and \$26 million as of December 31, 2018 and 2017, respectively.

This amount represents the tax effect of gross carryforward losses and deductions with the following expirations: 2019-2021 \$206 million; 2022-2028 \$448 million; 2029 and thereafter \$280 million. The remaining balance \$441 million can be utilized with no expiration date.

\*\*\* The increase in deferred tax asset is mainly due to the interest expense limitation following the enactment of the Tax Cuts and Jobs Act.

The deferred income taxes are reflected in the balance sheets among:

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(U.S. \$ in millions)</b>	
Long-term assets deferred income taxes	368	574



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Long-term liabilities	deferred income taxes	(2,140)	(3,277)
		\$ (1,772)	\$ (2,703)

Balances are presented under long term deferred taxes, due to the implementation of ASU 2015-17.

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The following table summarizes the activity of Teva's gross unrecognized tax benefits:

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S. \$ in millions)</b>		
Balance at the beginning of the year	\$ 1,034	\$ 734	\$ 648
Increase related to prior year tax positions, net	76	56	23
Increase related to current year tax positions	11	26	71
Decrease related to settlements with tax authorities and lapse of applicable statutes of limitations	(49)	(56)	(103)
Liabilities assumed in acquisitions		273	101
Other		1	(6)
Balance at the end of the year	\$ 1,072	\$ 1,034	\$ 734

Uncertain tax positions, mainly of a long-term nature, included accrued potential penalties and interest of \$131 million, \$112 million and \$83 million as of December 31, 2018, 2017 and 2016, respectively. The total amount of interest and penalties reflected in the consolidated statements of income was a net increase of \$19 million for the year ended December 31, 2018, a net increase of \$29 million for the year ended December 31, 2017 and a net decrease of \$18 million for the year ended December 31, 2016. Substantially all the above uncertain tax benefits, if recognized, would reduce Teva's annual effective tax rate. Teva does not expect uncertain tax positions to change significantly over the next 12 months, except in the case of settlements with tax authorities, the likelihood and timing of which is difficult to estimate.

**e. Tax assessments:**

Teva files income tax returns in various jurisdictions with varying statutes of limitations. The Parent Company and its subsidiaries in Israel have received final tax assessments through tax year 2007.

In 2013, Teva settled the 2005-2007 income tax assessment with the Israeli tax authorities, paying \$213 million. No further taxes are due in relation to these years. Certain guidelines which were set pursuant to the agreement reached in relation to the 2005-2007 assessment have been implemented in the audit of tax years 2008-2011, and are reflected in the provisions.

The Israeli tax authorities issued tax assessment decrees for 2008-2012 and a tax assessment for 2013-2016, challenging the Company's positions on several issues. Teva has protested the 2008-2012 decrees before the Central District Court in Israel and intends to challenge the tax assessment for 2013-2016 as well. The Company believes it has adequately provided for these items and that any adverse results would have an immaterial impact on Teva's

financial statements.

The Company's subsidiaries in North America and Europe have received final tax assessments mainly through tax year 2008.

**f. Basis of taxation:**

The Company and its subsidiaries are subject to tax in many jurisdictions, and a certain degree of estimation is required in recording the assets and liabilities related to income taxes. The Company believes that its accruals for tax liabilities are adequate for all open years. The Company considers various factors in making these

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**Notes to Consolidated Financial Statements (Continued)**

assessments, including past history, recent interpretations of tax law, and the specifics of each matter. Because tax regulations are subject to interpretation and tax litigation is inherently uncertain, these assessments can involve a series of complex judgments regarding future events.

***Incentives Applicable until 2013***

Under the incentives regime applicable to the Company until 2013, industrial projects of Teva and certain of its Israeli subsidiaries were eligible for Approved Enterprise status.

Most of the projects in Israel have been granted Approved Enterprise status under the alternative tax benefit track which offered tax exemption on undistributed income for a period of two to ten years, depending on the location of the enterprise. Upon distribution of such exempt income, the distributing company is subject to corporate tax at the rate ordinarily applicable to the Approved Enterprise's income.

***Amendment 69 to the Investment Law***

Pursuant to Amendment 69 to the Investment Law (Amendment 69), a company that elected by November 11, 2013 to pay a corporate tax rate as set forth in that amendment (rather than the tax rate applicable to Approved Enterprise income) with respect to undistributed exempt income accumulated by the company up until December 31, 2011 is entitled to distribute a dividend from such income without being required to pay additional corporate tax with respect to such dividend. A company that has so elected must make certain qualified investments in Israel over the five-year period commencing in 2013. Teva invested the entire required amount in 2013.

During 2013, Teva applied the provisions of Amendment 69 to certain exempt profits Teva accrued prior to 2012. Consequently, Teva paid \$577 million in corporate tax on exempt income of \$9.4 billion. Part of this income was distributed as dividends during 2013-2018, while the remainder is available to be distributed as dividends in future years with no additional corporate tax liability.

***Incentives Applicable starting 2014: The Incentives Regime Amendment 68 to the Investment Law***

Under Amendment 68 to the Investment Law, which Teva started applying in 2014, upon an irrevocable election made by a company, a uniform corporate tax rate will apply to all qualifying industrial income of such company (Preferred Enterprise), as opposed to the previous law's incentives, which were limited to income from Approved Enterprises during the benefits period. Under the law, when the election is made, the uniform tax rate for 2014 until 2016 was 9% in areas in Israel designated as Development Zone A and 16% elsewhere in Israel. The uniform tax rate for Development Zone A, as of January 1, 2017, is 7.5% (as part of changes enacted in Amendment 73, as described below). The profits of these Preferred Enterprise will be freely distributable as dividends, subject to a 20% or lower withholding tax, under an applicable tax treaty. Certain Special Preferred Enterprises that meet more stringent criteria (significant investment, R&D or employment thresholds) will enjoy further reduced tax rates of 5% in Zone A and 8% elsewhere. In order to be classified as a Special Preferred Enterprises, the approval of three governmental authorities in Israel is required.

***The New Technological Enterprise Incentives Regime Amendment 73 to the Investment Law***

Starting 2017, part of the Company taxable income in Israel is entitled to a preferred 6% tax rate under Amendment 73 to the Investment Law.

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**Notes to Consolidated Financial Statements (Continued)**

The new incentives regime applies to Preferred Technological Enterprises or Special Preferred Technological Enterprises. A Preferred Technological Enterprise is an enterprise that meet certain conditions, including, inter alia:

1. Investment of at least 7% of income, or at least NIS 75 million (approximately \$19 million) in R&D activities; and
2. One of the following:
  - a. At least 20% of the workforce (or at least 200 employees) are employed in R&D;
  - b. A venture capital investment approximately equivalent to at least \$2 million was previously made in the company; or
  - c. Growth in sales or workforce by an average of 25% over the three years preceding the tax year.

A Special Preferred Technological Enterprise is an enterprise that meets, inter alia conditions 1 and 2 above, and in addition has total annual consolidated revenues above NIS 10 billion (approximately \$2.8 billion).

Preferred Technological Enterprises are subject to a corporate tax rate of 7.5% on their income derived from intellectual property in areas in Israel designated as Zone A and 12% elsewhere, while Special Preferred Technological Enterprises are subject to 6% on such income. The withholding tax on dividends from these enterprises is 4% to foreign companies (or a lower rate under a tax treaty, if applicable).

Income not eligible for Preferred Technological Enterprise benefits is taxed at the regular corporate tax rate, which is 23%, or the preferred tax rate, as the case may be.

The Parent Company and its Israeli subsidiaries elected to compute their taxable income in accordance with Income Tax Regulations (Rules for Accounting for Foreign Investors Companies and Certain Partnerships and Setting their Taxable Income), 1986. Accordingly, the taxable income or loss is calculated in U.S. dollars. Applying these regulations reduces the effect of U.S. dollar NIS exchange rate on the Company's Israeli taxable income.

Non-Israeli subsidiaries are taxed according to the tax laws in their respective country of residence. Certain manufacturing subsidiaries operate in several jurisdictions outside Israel, some of which benefit from tax incentives such as reduced tax rates, investment tax credits and accelerated deductions.

***U.S. Tax reform***

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (the "Act"), which among other provisions, reduced the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018, and imposed a one-time deemed repatriation tax based on the post-1986 earnings and profits of the Company's U.S. owned foreign subsidiaries.

The year ended December 31, 2017 includes a one-time benefit of \$1.2 billion recorded to re-measure certain of the Company's U.S. deferred tax assets and liabilities, based on the rates at which they are expected to reverse in the future.

The one-time deemed repatriation tax is based on the post-1986 earnings and profits for which the Company has previously deferred from U.S. income taxes and is payable over 8 years. The year ended December 31, 2017 included a \$112 million provisional estimate for Teva's one-time deemed repatriation taxes liability. During

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**Notes to Consolidated Financial Statements (Continued)**

2018, Teva completed its analysis of the impacts of the Act and recorded an additional expense of \$97 million, pursuant to guidance issued by the U.S. Department of Treasury and revisions to the Company's estimates since the assessment date. Other provisions of the Act did not have a material effect on our effective tax rate for 2018.

**NOTE 16 DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES:**

**a. Foreign exchange risk management:**

In 2018, approximately 48% of Teva's revenues were denominated in currencies other than the U.S. dollar. As a result, Teva is subject to significant foreign currency risks.

The Company enters into forward exchange contracts, purchases and writes options in order to hedge the currency exposure on balance sheet items. In addition, the Company takes measures to reduce exposure by using natural hedging. The Company also acts to offset risks in opposite directions among the companies in the Group. The currency hedged items are usually denominated in the following main currencies: the new Israeli shekel (NIS), the euro (EUR), the Swiss franc (CHF), the Japanese yen (JPY), the British pound (GBP), Canadian dollar (CAD), the Polish zloty (PLN), the Indian rupee (INR) and other European and Latin American currencies.

Depending on market conditions, foreign currency risk also is managed through the use of foreign currency debt.

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

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

**b. Interest risk management:**

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

**c. Derivative instrument disclosure:**

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



	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(U.S. \$ in millions)</b>	
Cross-currency swap cash flow hedge	\$ 588	\$ 588
Interest rate swap fair value hedge	500	500
Cross-currency swap net investment hedge	1,000	1,000

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

	<b>Fair value</b>			
	<b>Designated as hedging instruments</b>		<b>Not designated as hedging instruments</b>	
	<b>December 31, 2018</b>	<b>December 31, 2017</b>	<b>December 31, 2018</b>	<b>December 31, 2017</b>
	<b>(U.S. \$ in millions)</b>			
<b>Reported under</b>				
<b>Asset derivatives:</b>				
<b>Other current assets:</b>				
Option and forward contracts	\$	\$	\$ 18	\$ 17
<b>Other non-current assets:</b>				
Cross-currency swaps cash flow hedge	58	25		
<b>Liability derivatives:</b>				
<b>Other current liabilities:</b>				
Option and forward contracts			(26)	(15)
<b>Other taxes and long-term liabilities:</b>				
Cross currency swaps net investment hedge	(41)	(96)		
<b>Senior notes and loans:</b>				
Interest rate swaps fair value hedge	(9)	(2)		

Teva uses foreign exchange contracts (mainly option and forward contracts) to hedge balance sheet items from currency exposure. These foreign exchange contracts are not designated as hedging instruments for accounting purposes. In connection with these foreign exchange contracts, Teva recognized a gain of \$12 million, a loss of \$82 million and \$7 million under financial expenses net for the years ended December 31, 2018, 2017 and 2016, respectively. Such losses and gains offset the revaluation of the balance sheet items also recorded under financial expenses net.

With respect to the interest rate and cross-currency swap agreements, Teva recognized gains of \$2 million, \$6 million and \$15 million under financial expenses net for the years ended December 31, 2018, 2017 and 2016, respectively. Such gains mainly reflect the differences between the fixed interest rate and the floating interest rate.

Commencing in the third quarter of 2015, Teva entered into forward starting interest rate swap and treasury lock agreements designated as cash flow hedges of the U.S. dollar debt issuance in July 2016, with respect to \$3.75 billion and \$1.5 billion notional amounts, respectively. These agreements hedged the variability in anticipated future interest payments due to possible changes in the benchmark interest rate between the date the agreements were entered into and the actual date of the U.S. dollar debt issuance in July 2016 (in connection with the closing of the Actavis Generics acquisition). See note 11.

Certain of the forward starting interest rate swaps and treasury lock agreements matured during the first half of 2016. In July 2016, in connection with the debt issuances, Teva terminated the remaining forward starting interest rate swaps and treasury lock agreements. The termination of these transactions resulted in a loss position of \$493 million, of which \$242 million were settled on October 7, 2016 and the remaining amount was settled in January 2017. The change in fair value of these instruments recorded in other comprehensive income (loss) will be amortized under financial expenses-net over the life of the debt. Such losses mainly reflect the changes in the benchmark interest rate between the date the agreements were entered into and the actual date of the U.S. debt issuance in July 2016.

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**Notes to Consolidated Financial Statements (Continued)**

With respect to the forward starting interest rate swaps and treasury lock agreements, losses of \$28 million, \$27 million and \$12 million were recognized under financial expenses-net for the years ended December 31, 2018, 2017 and 2016, respectively.

In the third quarter of 2016, Teva terminated interest rate swap agreements designated as fair value hedge relating to its 2.95% senior notes due 2022 with respect to \$844 million notional amount and its 3.65% senior notes due 2021 with respect to \$450 million notional amount. Settlement of these transactions resulted in a gain position of \$41 million. The fair value hedge accounting adjustments of these instruments, which 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 agreements, gains of \$6 million, \$7 million and \$2 million were recognized under financial expenses-net for the years ended December 31, 2018, 2017 and 2016, respectively.

In the fourth quarter of 2016, Teva entered into interest rate swap agreement designated as fair value hedge relating to its 2.8% senior notes due 2023 with respect to \$500 million notional amount of outstanding debt.

In each of the first and second quarters of 2017, Teva entered into a cross currency swap agreement with a notional amount of \$500 million maturing in 2020. These cross currency swaps were designated as a net investment hedge of Teva's foreign subsidiaries euro denominated net assets, in order to reduce the risk of adverse exchange rate fluctuations.

With respect to these cross currency swap agreements, Teva recognized gains of \$31 million under financial expenses-net for the year ended December 31, 2018.

**d. Securitization:**

In April 2011, Teva established a trade receivables securitization program to sell trade receivables to BNP Paribas Bank (BNP). Under the program Teva (on a consolidated basis) receives, as purchase price for the receivables sold by it, an initial cash purchase price and the right to receive a deferred purchase price (DPP).

On an individual seller basis, each Teva subsidiary sells receivables to BNP for an amount equal to their nominal amount. BNP then immediately on-sells such receivables to a bankruptcy-remote special-purpose entity (SPE), for an amount equal to the nominal amount of such trade receivables. The SPE then on-sells such receivables to a conduit sponsored by BNP (the conduit) for an initial cash purchase price (equal to the nominal amount of such receivables less a discount) and the right to receive a DPP.

The SPE is a VIE for which Teva is considered to be the primary beneficiary. The SPE's sole business consists of the purchase of receivables from Teva subsidiaries and the subsequent transfer of such receivables to the conduit.

Although the SPE is included in Teva's consolidated financial statements, it is a separate legal entity with separate creditors. The conduit and other designated creditors of the SPE are entitled, both before and upon the SPE's

liquidation, to be paid out of the SPE's assets prior to the DPP payable to Teva. The assets of the SPE are not available to pay creditors of Teva or its subsidiaries.

This program expires on August 23, 2019 but can be renewed with consent from the parties to the program up to August 31, 2021 or any other date agreed between the parties.

Once sold to BNP, the relevant Teva subsidiary as seller has no retained interests in the receivables sold and they are unavailable to the relevant seller should the relevant seller become insolvent. The conduit has all the

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rights in the securitized trade receivables, including the right to pledge or dispose of such receivables. Consequently, receivables sold under this agreement are de-recognized from Teva's consolidated balance sheet.

The portion of the purchase price for the receivables which is not paid in cash by the conduit is a DPP asset. The conduit pays the SPE the DPP from collections received by the conduit from the securitized trade receivables (after paying senior costs and expenses, including the conduit's debt service obligations), which the SPE then pays to Teva. The DPP asset represents a beneficial interest in the transferred financial assets and is recognized at fair value as part of the sale transaction. The DPP asset is included in other current assets on Teva's consolidated balance sheet.

Teva has collection and administrative responsibilities for the sold receivables. The fair value of these servicing arrangements as well as the fees earned was immaterial.

DPP asset as of December 31, 2018 and 2017 was \$231 million and \$261 million, respectively.

As of December 31, 2018 and 2017, the balance of Teva's securitized assets sold were \$686 million and \$799 million, respectively.

The following table summarizes the sold receivables outstanding balance net of DPP asset under the outstanding securitization program:

	<b>As of and for the year ended December 31, 2018                      2017 (U.S. \$ in millions)</b>	
Sold receivables at the beginning of the year	\$ 799	\$ 621
Proceeds from sale of receivables	5,071	4,944
Cash collections (remitted to the owner of the receivables)	(5,151)	(4,863)
Effect of currency exchange rate changes	(33)	97
Sold receivables at the end of the year	\$ 686	\$ 799

**NOTE 17 FINANCIAL EXPENSES NET:**

	<b>Year ended December, 31 2018                      2017                      2016 (U.S. \$ in millions)</b>		
Venezuela devaluation (1)	\$	\$ 42	\$ 746

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Interest expenses and other bank charges	920	875	546
Income from investments	(39)	(84)	(51)
Foreign exchange (gains) losses net	13	65	(49)
Other, net (2)	65	(3)	2
Other-than-temporary impairment (3)			136
Total finance expense net	\$ 959	\$ 895	\$ 1,330

- (1) For further information regarding the Venezuela devaluation, refer to note 1a.
- (2) Other, net comprised mainly of a make-whole payment of \$46 million following early redemption of senior notes during 2018.
- (3) Other-than-temporary impairment relates mainly to equity securities.

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	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S. \$ in millions)</b>		
Impairment of long-lived tangible assets (1)	\$ 500	\$ 544	\$ 157
Contingent consideration (see note 3)	57	154	83
Acquisition, integration and related costs	13	105	261
Restructuring	488	535	245
Venezuela deconsolidation charge (see note 1)		396	
Other	(71)	102	84
<b>Total</b>	<b>\$ 987</b>	<b>\$ 1,836</b>	<b>\$ 830</b>

(1) Including impairments related to exit and disposal activities

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

*Impairments*

Impairments of property, plant and equipment for the year ended 2018 were \$500 million, mainly consisting of:

- a) \$245 million mainly due to: (a) \$180 million machinery and equipment impairment in Japan in connection with ongoing regulatory pricing reductions and generic competition; and (b) \$28 million impairment related to a plant in China;
- b) \$155 million related to the restructuring plan, including:

\$113 million related to site closures in Israel; and



\$42 million related to the consolidation of headquarters and distribution sites in the United States.

- c) Other impairment costs, mainly \$64 million related to a plant located in India in connection with the P&G separation agreement. See note 2.

*Contingent consideration*

In 2018, Teva recorded \$57 million of contingent consideration expenses, compared to \$154 million in 2017. The expenses in 2018 consisted mainly of \$40 million related to an increase in the expected future royalty payments to Eagle Pharmaceuticals due to the orphan drug status granted to BENDEKA.

*Restructuring*

In 2018, Teva recorded \$488 million of restructuring expenses, compared to \$535 million in 2017. The expenses in 2018 were primarily related to headcount reductions across all functions, as part of the restructuring plan announced in 2017.

In December 2017, Teva announced a comprehensive restructuring plan intended to significantly reduce its cost base, unify and simplify its organization and improve business performance, profitability, cash flow generation and productivity.

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Since the announcement of its restructuring plan, Teva reduced its global headcount by approximately 10,300 full-time-equivalent employees.

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

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S. \$ in millions)</b>		
Restructuring			
Employee termination	\$ 410	\$ 443	\$ 211
Other	78	92	34
Total	\$ 488	\$ 535	\$ 245

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

	<b>Employee termination costs</b>	<b>Other</b>	<b>Total</b>
	<b>(U.S. \$ in millions)</b>		
Balance as of January 1, 2017	\$ (144)	\$ (9)	\$ (153)
Provision	(443)	(92)	(535)
Utilization and other*	293	84	377
Balance as of December 31, 2017	\$ (294)	\$ (17)	\$ (311)
Provision	(410)	(78)	(488)
Utilization and other*	500	66	566
Balance as of December 31, 2018	\$ (204)	\$ (29)	\$ (233)

\* Includes adjustments for foreign currency translation.  
*Significant regulatory events*

In July 2018, the FDA completed an inspection of Teva's manufacturing plant in Davie, Florida in the United States, and issued a Form FDA-483 to the site. In October 2018, the FDA notified Teva that the inspection of the site is classified as official action indicated (OAI). On February 5, 2019, Teva received a warning letter from the FDA that contains four enumerated concerns related to production, quality control, and investigations at this site. Teva is working diligently to investigate the FDA's concerns in a manner consistent with current good manufacturing practice (CGMP) requirements, and to address those concerns as quickly and as thoroughly as possible. If Teva is unable to remediate the warning letter findings to the FDA's satisfaction, it may face additional consequences, including delays in FDA approval for future products from the site, financial implications due to loss of revenues, impairments, inventory write offs, customer penalties, idle capacity charges, costs of additional remediation and possible FDA enforcement action. Teva expects to generate approximately \$255 million in revenues from this site in 2019, assuming remediation or enforcement does not cause any unscheduled slowdown or stoppage at the facility.

In July 2018, Teva announced the voluntary recall of valsartan and certain combination valsartan medicines in various countries due to the detection of trace amounts of a previously unknown impurity called NDMA found in valsartan API supplied to Teva by Zhejiang Huahai Pharmaceutical. Since July 2018, Teva has been actively engaged with regulatory agencies around the world in reviewing its valsartan and other sartan products for

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**Notes to Consolidated Financial Statements (Continued)**

NDMA and other related impurities and, where necessary, has initiated additional voluntary recalls. The impact of this recall on Teva's 2018 financial statements was \$51 million, primarily related to inventory reserves. Teva expects to continue to experience loss of revenues and profits in connection with this matter. In addition, multiple lawsuits have been filed in connection with this matter, for which litigation costs are currently being incurred. Teva may also incur customer penalties, impairments and litigation costs going forward.

**NOTE 19 LEGAL SETTLEMENTS AND LOSS CONTINGENCIES:**

Legal settlements and loss contingencies for 2018 amounted to an income of \$1,208 million, compared to a loss of \$500 million and \$899 million in 2017 and 2016, respectively. The 2018 income primarily consisted of the working capital adjustment with Allergan, the Rimsa settlement and reversal of the reserve recorded in the second quarter of 2017 with respect to the carvedilol patent litigation.

The expenses in 2017 primarily consisted of the reserve recorded in the second quarter of 2017 following the jury trial loss in connection with the carvedilol patent litigation. As of December 31, 2018 and 2017, accrued amounts for legal settlements and loss contingencies of \$562 million and \$1,232 million, respectively, are recorded in accrued expenses.

**NOTE 20 SEGMENTS:**

In November 2017, Teva announced a new organizational structure and leadership changes to enable strategic alignment across its portfolios, regions and functions. Teva now operates its business through three segments: North America, Europe and International Markets.

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

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

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

The purpose of the new structure is to enable stronger alignment and integration between operations, commercial regions, R&D and Teva's global marketing and portfolio function, in order to optimize its product lifecycle across all therapeutic areas. The Company began reporting its financial results under this structure in the first quarter of 2018.

In addition to these three segments, Teva has other 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.

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

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.

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

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

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

**a. Segment information:**

	<b>North America</b>	<b>Europe</b>	<b>International Markets</b>
	<b>Year ended December 31, 2018</b>		
	<b>(U.S. \$ in millions)</b>		
Revenues	\$ 9,297	\$ 5,186	\$ 3,005
Gross profit	4,979	2,884	1,254
R&D expenses	713	283	96
S&M expenses	1,154	1,003	518
G&A expenses	484	325	153
Other income (loss)	(209)		(11)
Segment profit	\$ 2,837	\$ 1,273	\$ 498

	<b>North America</b>	<b>Europe</b>	<b>International Markets</b>
	<b>Year ended December 31, 2017</b>		
	<b>(U.S. \$ in millions)</b>		
Revenues	\$ 12,141	\$ 5,466	\$ 3,395
Gross profit	7,322	2,887	1,433
R&D expenses	969	390	154
S&M expenses	1,288	1,130	672
G&A expenses	533	354	189

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Other income (loss)	(92)	(16)	(8)
Segment profit	\$ 4,624	\$ 1,029	\$ 426

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**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)**

	North America	Europe	International Markets
	Year ended December 31, 2016		
	(U.S. \$ in millions)		
Revenues	\$ 11,778	\$ 4,969	\$ 4,015
Gross profit	8,404	2,685	1,811
R&D expenses	1,040	383	205
S&M expenses	1,362	1,267	754
G&A expenses	496	377	226
Other income (loss)	(30)	(9)	(10)
Segment profit	\$ 5,536	\$ 667	\$ 636

	Year ended December 31,		
	2018	2017	2016
	(U.S.\$ in millions)		
North America profit	\$ 2,837	\$ 4,624	\$ 5,536
Europe profit	1,273	1,029	667
International Markets profit	498	426	636
Total segment profit	4,608	6,079	6,839
Profit (loss) of other activities	115	(6)	8
	4,723	6,073	6,847
Amounts not allocated to segments:			
Amortization	1,166	1,444	993
Other asset impairments, restructuring and other items	987	1,836	830
Goodwill impairment	3,027	17,100	900
Intangible asset impairments	1,991	3,238	589
Gain on divestitures, net of divestitures related costs	(66)	(1,083)	(720)
Inventory step-up		67	383
Other R&D expenses	83	221	426
Costs related to regulatory actions taken in facilities	14	47	153
Legal settlements and loss contingencies	(1,208)	500	899
Other unallocated amounts	366	187	240
Consolidated operating income (loss)	(1,637)	(17,484)	2,154
Financial expenses, net	959	895	1,330



Consolidated income (loss) before income taxes	\$ (2,596)	\$ (18,379)	\$ 824
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**b. Segment revenues by major products and activities:**

The following tables present revenues by major products and activities for each segment for the year ended December 31, 2018, 2017 and 2016:

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****North America segment:**

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S.\$ in millions)</b>		
Generic products	\$ 4,056	\$ 5,203	\$ 4,654
COPAXONE	1,759	3,116	3,543
BENDEKA / TREANDA	642	656	661
ProAir	397	501	565
QVAR	182	313	409
AUSTEDO	204	24	
Anda	1,347	1,153	301

The table above does not include revenues from other products and activities amounting to \$710 million, \$1,175 million and \$1,645 million for the years ended December 31, 2018, 2017 and 2016, respectively.

**Europe segment:**

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S.\$ in millions)</b>		
Generic products	\$ 3,593	\$ 3,471	\$ 3,155
COPAXONE	535	595	585
Respiratory products	402	368	239

The table above does not include revenues from other products and activities amounting to \$656 million, \$1,032 million and \$990 million for the years 2018, 2017 and 2016, respectively.

**International Markets segment:**

	<b>Year ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S.\$ in millions)</b>		
Generic products	\$ 2,022	\$ 2,370	\$ 3,129
COPAXONE	72	91	95
Distribution	602	550	458

The table above does not include revenues from other products and activities amounting to \$309 million, \$384 million and \$333 million for the years 2018, 2017 and 2016, respectively.

Teva revenues from external customers attributed to Israel were less than 5% of the consolidated revenues in the years ended December 31, 2018, 2017 and 2016, respectively.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****c. Supplemental data major customers:**

The following table represents the percentage of consolidated third party net sales to Teva's major customers during the years ended December 31, 2018, 2017 and 2016.

	<b>Percentage of Third Party Net Sales</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
McKesson Corporation	12%	16%	15%
AmerisourceBergen Corporation	14%	15%	19%

Most of Teva's revenues from these customers were in the United States.

**d. Property, plant and equipment by geographical location were as follows:**

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(U.S. \$ in millions)</b>	
Israel	\$ 1,987	\$ 2,180
United States	950	1,109
Croatia	538	561
Germany	518	423
Czech republic	352	347
Hungary	343	368
Japan	188	376
Other	1,992	2,309
<b>Total property, plant and equipment</b>	<b>\$ 6,868</b>	<b>\$ 7,673</b>

**NOTE 21 EARNINGS (LOSS) PER SHARE:**

The net income attributable to Teva and the weighted average number of ordinary shares used in computation of basic and diluted earnings per share for the years ended December 31, 2018, 2017 and 2016 are as follows:

	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>(U.S. \$ in millions, except share data)</b>		
Net income (loss) used for the computation of diluted earnings per share	\$ (2,399)	\$ (16,525)	\$ 68

Weighted average number of shares used in the computation of basic earnings per share	1,021	1,016	955
Add:			
Additional shares from the assumed exercise of employee stock options and unvested RSUs			3
Weighted average number of additional shares issued upon the assumed conversion of convertible senior debentures			3
Weighted average number of shares used in the computation of diluted earnings per share	1,021	1,016	961

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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

**Notes to Consolidated Financial Statements (Continued)**

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

In computing dilutive loss per share for the years ended December 31, 2018 and 2017, no account was taken of the potential dilution of the assumed exercise of employee stock options, RSUs and PSUs, amounting to 51 million and 38 million weighted average shares, respectively, and convertible senior debentures, since they had an anti-dilutive effect on earnings per share.

Diluted earnings per share for the year ended 2016, take into account the potential dilution that could occur upon the exercise of options and non-vested RSUs granted under employee stock compensation plans, amounting to 4 million weighted average shares, using the treasury stock method since they had a dilutive effect on earnings per share.

Additionally, in computing dilutive earnings per share for the period between January 1, 2018 and December 17, 2018 and for the years ended December 31, 2017 and 2016, no account was taken of the potential dilution of the mandatory convertible preferred shares amounting to 74 million, 59 million and 59 million weighted average shares, respectively, since they had an anti-dilutive effect on earnings (loss) per share.

On December 17, 2018, the mandatory convertible preferred shares automatically converted into ordinary shares at a ratio of 1 mandatory convertible preferred share to 16 ADSs, and all of the accumulated and unpaid dividends on the mandatory convertible preferred shares were paid in ADSs, at a ratio of 3.0262 ADSs per mandatory convertible preferred share, all in accordance with the conversion mechanism set forth in the terms of the mandatory convertible preferred shares. As a result of this conversion, Teva issued 70.6 million ADSs.

**Table of Contents****TEVA PHARMACEUTICAL INDUSTRIES LIMITED****Notes to Consolidated Financial Statements (Continued)****NOTE 22 SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED):**

The following table presents selected unaudited quarterly financial data for 2018 and 2017:

	<b>2018*</b>			
	<b>4th quarter**</b>	<b>3rd quarter**</b>	<b>2nd quarter**</b>	<b>1st quarter**</b>
	<b>(U.S. \$ in millions, except per share amounts)</b>			
Net revenues	4,559	4,529	4,701	5,065
Gross profit	1,971	1,977	2,033	2,315
Net income (loss)	(3,243)	(197)	(166)	1,134
Net income (loss) attributable to Teva	(2,886)	(208)	(176)	1,120
Net income (loss) attributable to ordinary shareholders	(2,940)	(273)	(241)	1,055
Earnings per share attributable to ordinary shareholders:				
Basic	(2.85)	(0.27)	(0.24)	1.04
Diluted	(2.85)	(0.27)	(0.24)	1.03
	<b>2017*</b>			
	<b>4th quarter**</b>	<b>3rd quarter**</b>	<b>2nd quarter**</b>	<b>1st quarter**</b>
	<b>(U.S. \$ in millions, except per share amounts)</b>			
Net revenues	5,398	5,617	5,720	5,650
Gross profit	2,444	2,599	2,802	2,770
Net income (loss)	(11,730)	610	(5,970)	641
Net income (loss) attributable to Teva	(11,535)	595	(5,970)	645
Net income (loss) attributable to ordinary shareholders	(11,600)	530	(6,035)	580
Earnings per share attributable to ordinary shareholders:				
Basic	(11.41)	0.52	(5.94)	0.57
Diluted	(11.41)	0.52	(5.94)	0.57

\* Certain comparative figures have been reclassified to conform to the fourth quarter presentation.

\*\* Losses in the second and fourth quarters of 2017 were primarily due to goodwill impairments of \$6.1 billion and \$11 billion, respectively.

During the fourth quarter of 2018, the Company changed its accounting policy for the presentation of royalty payments to third parties (see note 1 bb). The impact of the change in accounting policy for the first, second, third and fourth quarters of 2018 was an increase in cost of sales of \$33 million, \$28 million, \$44 million and \$37 million, respectively, with a corresponding decrease in S&M expenses. The Company has retrospectively adjusted prior periods to reflect this change in the first, second, third and fourth quarters of 2017, increasing cost of sales by \$69 million, \$53 million, \$51 million and \$37 million, respectively, with a corresponding decrease in S&M expenses.



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**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**  
**SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**

**Three Years Ended December 31, 2018**

(U.S. \$ in millions)

Column A	Column B	Column C		Column D	Column E
	Balance at beginning of period	Charged to costs and expenses	Charged to other accounts	Deductions	Balance at end of period
Allowance for doubtful accounts:					
Year ended December 31, 2018	\$ 232	\$ 13	\$ (9)	\$ (4)	\$ 232
Year ended December 31, 2017	\$ 191	\$ 12	\$ 51	\$ (22)	\$ 232
Year ended December 31, 2016	\$ 146	\$ 5	\$ 61	\$ (21)	\$ 191
Allowance in respect of carryforward tax losses:					
Year ended December 31, 2018	\$ 1,504	\$ 407	\$ 5	\$ (283)	\$ 1,633
Year ended December 31, 2017	\$ 1,690	\$ 173	\$ 390	\$ (749)	\$ 1,504
Year ended December 31, 2016	\$ 760	\$ 135	\$ 1,137	\$ (342)	\$ 1,690

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### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not Applicable.

### **ITEM 9A. 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 December 31, 2018, 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.

#### **Report of Teva Management on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as amended. Our internal control over financial reporting is a process designed 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of Teva's internal control over financial reporting as of December 31, 2018. In making this assessment, it used the criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such assessment, management has concluded that, as of December 31, 2018, Teva's internal control over financial reporting was effective.

Our internal control over financial reporting as of December 31, 2018 has been audited by Kesselman & Kesselman, an independent registered public accounting firm in Israel and a member of PricewaterhouseCoopers International Limited (PwC), as stated in their report which is included under Item 8 Financial Statements.

#### **Remediation of Prior Material Weakness in Internal Control Over Financial Reporting**

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial

statements will not be prevented or detected on a timely basis.

Management previously identified and disclosed a material weakness in Teva's internal control over financial reporting with respect to our interim goodwill impairment testing. Specifically, our control designed to

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validate the allocation of businesses between the International Markets and Rimsa reporting units did not operate effectively. This control deficiency did not result in a material misstatement of our annual or interim consolidated financial statements, account balances or disclosures. However, this control deficiency could have resulted in a misstatement of the goodwill balances and disclosures, which would have resulted in a material misstatement of the consolidated financial statements that would not have been prevented or detected.

In response to this material weakness, changes were made to Teva's internal control over financial reporting, including enhancing the precision of controls and the timing of internal processes relating to the performance of interim and annual goodwill impairment testing, in order to ensure controls are designed and reviewed properly within the financial reporting close process. Management has completed the documentation and testing of the corrective actions described above and, based on the evidence obtained in validating the design and operating effectiveness of the controls, has concluded that the previously disclosed material weakness has been remediated as of December 31, 2018.

## **Changes in Internal Control over Financial Reporting**

During the quarter ended December 31, 2018, 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.

## **ITEM 9B. OTHER INFORMATION**

None.

## **PART III**

## **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Reference is made to Teva's 2019 Proxy Statement, which will be filed no later than 120 days after the close of the registrant's fiscal year ended December 31, 2018, with respect to Teva's directors, executive officers and corporate governance, which is incorporated herein by reference and made a part hereof in response to the information required by Item 10.

## **ITEM 11. EXECUTIVE COMPENSATION**

Reference is made to Teva's 2019 Proxy Statement, which will be filed no later than 120 days after the close of Teva's fiscal year ended December 31, 2018, with respect to Teva's executive compensation, which is incorporated herein by reference and made a part hereof in response to the information required by Item 11.

## **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Reference is made to Teva's 2019 Proxy Statement, which will be filed no later than 120 days after the close of Teva's fiscal year ended December 31, 2018, with respect to the security ownership of certain beneficial owners and management and related stockholder matters of Teva, which is incorporated herein by reference and made a part hereof in response to the information required by Item 12.

## **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Reference is made to Teva's 2019 Proxy Statement, which will be filed no later than 120 days after the close of Teva's fiscal year ended December 31, 2018, with respect to certain relationships and related transactions, and director independence of Teva, which is incorporated herein by reference and made a part hereof in response to the information required by Item 13.

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**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Reference is made to Teva's 2019 Proxy Statement, which will be filed no later than 120 days after the close of Teva's fiscal year ended December 31, 2018, with respect to principal accountant fees and services provided to Teva, which is incorporated herein by reference and made a part hereof in response to the information required by Item 14.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(a) The following financial statements are filed as part of this Annual Report on Form 10-K:

<u>Report of Independent Registered Public Accounting Firm</u>	<b>page</b> 96
<b>Consolidated Financial Statements:</b>	
<u>Balance sheets</u>	98
<u>Statements of income (loss)</u>	99
<u>Statements of comprehensive income (loss)</u>	100
<u>Statements of changes in equity</u>	101
<u>Statements of cash flows</u>	102
<u>Notes to consolidated financial statements</u>	104
<b>Financial Statement Schedule:</b>	
<u>Schedule II Valuation and Qualifying Accounts</u>	178
<b>Exhibits</b>	

The information called for by this Item is incorporated herein by reference to the Exhibit Index in this Form 10-K.

- 3.1 Memorandum of Association (1)(2)
- 3.2 Amendment to Memorandum of Association (1)(3)
- 3.3 Articles of Association (1)(4)
- 4.1 Second Amended and Restated Deposit Agreement, dated as of December 4, 2018, among Teva Pharmaceutical Industries Limited, Citibank, N.A., as depositary, and the holders from time to time of shares (5)
- 4.2 Senior Indenture, dated as of January 31, 2006, by and among Teva Pharmaceutical Finance Company LLC, Teva Pharmaceutical Industries Limited and The Bank of New York, as trustee (6)
- 4.3 First Supplemental Senior Indenture, dated as of January 31, 2006, by and among Teva Pharmaceutical Finance Company LLC, Teva Pharmaceutical Industries Limited and The Bank of New York, as trustee, including the form of 0.25% Convertible Senior Debentures due 2026 (7)
- 4.4 Second Supplemental Senior Indenture, dated as of January 31, 2006, by and among Teva Pharmaceutical

Finance Company LLC, Teva Pharmaceutical Industries Limited and The Bank of New York, as trustee, including the form of 6.150% Senior Notes due 2036 (8)

- 4.5 Third Supplemental Senior Indenture, dated as of March 16, 2010, by and among Teva Pharmaceutical Finance Company LLC, Teva Pharmaceutical Industries Limited and The Bank of New York, as trustee, relating to Teva's 0.25% Convertible Senior Debentures due 2026 (9)
- 4.6 Senior Indenture, dated as of November 10, 2011, by and among Teva Pharmaceutical Finance IV, LLC, Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee (10)

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- 4.7 Second Supplemental Senior Indenture, dated as of December 18, 2012, by and among Teva Pharmaceutical Finance IV, LLC, Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee, including the form of 2.950% Senior Notes due 2022 (11)
- 4.8 Senior Indenture, dated as of November 10, 2011, by and among Teva Pharmaceutical Finance Company B.V., Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee (12)
- 4.9 First Supplemental Senior Indenture, dated as of November 10, 2011, by and among Teva Pharmaceutical Finance Company B.V., Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee, including the form of 3.650% Senior Notes due 2021 (13)
- 4.10 Second Supplemental Senior Indenture, dated as of December 18, 2012, by and among Teva Pharmaceutical Finance Company B.V., Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee, including the form of 2.250% Senior Notes due 2020 (14)
- 4.11 Senior Indenture, dated as of November 10, 2011, by and among Teva Pharmaceutical Finance IV B.V., Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee (15)
- 4.12 First Supplemental Senior Indenture, dated as of November 10, 2011, by and among Teva Pharmaceutical Finance IV B.V., Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee, including the form of 3.650% Senior Notes due 2021(16)
- 4.13 Second Supplemental Senior Indenture, dated as of April 4, 2012, by and among Teva Pharmaceutical Finance IV B.V., Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee, including the form of 2.875% Senior Notes due 2019 (17)
- 4.14 Permanent Global Certificate, dated as of April 25, 2012, and the Terms of the CHF 450,000,000 1.5 per cent Notes due 2018 (18)
- 4.15 Guarantee, dated as of April 25, 2012, by Teva Pharmaceutical Industries Limited (19)
- 4.16 Senior Indenture, dated as of March 31, 2015, by and among Teva Pharmaceutical Industries Limited, Teva Pharmaceutical Finance Netherlands II B.V. and The Bank of New York Mellon, as trustee (20)
- 4.17 Supplemental Senior Indenture, dated as of March 31, 2015, by and among Teva Pharmaceutical Industries Limited, Teva Pharmaceutical Finance Netherlands II B.V., The Bank of New York Mellon, as trustee, and The Bank of New York Mellon, London branch, as principal paying agent, including the form of 1.250% Senior Notes due 2023 and the form of 1.875% Senior Notes due 2027 (21)
- 4.18 Second Supplemental Senior Indenture, dated as of July 25, 2016, by and among Teva Pharmaceutical Industries Limited, Teva Pharmaceutical Finance Netherlands II B.V., The Bank of New York Mellon, as trustee, and The Bank of New York Mellon, London branch, as principal paying agent, including the form of 0.375% Senior Notes due 2020, the form of 1.125% Senior Notes due 2024 and the form of 1.625% Senior Notes due 2028 (22)
- 4.19 Senior Indenture, dated as of July 21, 2016, by and among Teva Pharmaceutical Finance Netherlands III B.V., Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee (23)
- 4.20 First Supplemental Senior Indenture, dated as of July 21, 2016, by and among Teva Pharmaceutical Finance Netherlands III B.V., Teva Pharmaceutical Industries Limited and The Bank of New York Mellon, as trustee, including the form of 1.400% Senior Notes due 2018, the form of 1.700% Senior Notes due 2019, the form of 2.200% Senior Notes due 2021, the form of 2.800% Senior Notes due 2023, the form of 3.150% Senior Notes due 2026 and the form of 4.100% Senior Notes due 2046 (24)
- 4.21



Permanent Global Certificate, dated as of July 28, 2016, and the Terms of the CHF 300,000,000 0.125 per cent Notes due 2018 (25)

4.22 Permanent Global Certificate, dated as of July 28, 2016, and the Terms of the CHF 350,000,000 0.500 per cent Notes due 2022 (26)

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4.23	<u>Permanent Global Certificate, dated as of July 28, 2016, and the Terms of the CHF 350,000,000 1.000 per cent Notes due 2025 (27)</u>
4.24	<u>Guarantee, dated as of July 28, 2016, by Teva Pharmaceutical Industries Limited (relating to the 2018 Notes) (28)</u>
4.25	<u>Guarantee, dated as of July 28, 2016, by Teva Pharmaceutical Industries Limited (relating to the 2022 Notes) (29)</u>
4.26	<u>Guarantee, dated as of July 28, 2016, by Teva Pharmaceutical Industries Limited (relating to the 2025 Notes) (30)</u>
4.27	<u>Senior Indenture, dated as of March 14, 2018, by and among Teva Pharmaceutical Finance Netherlands III B.V., Teva Pharmaceutical Industries Limited and the Bank of New York Mellon, as trustee (31)</u>
4.28	<u>First Supplemental Senior Indenture, dated as of March 14, 2018, by and among Teva Pharmaceutical Finance Netherlands III B.V., Teva Pharmaceutical Industries Limited and the Bank of New York Mellon, as trustee, including the form of 6.000% Senior Notes due 2024 and the form of 6.750% Senior Notes due 2028 (32)</u>
4.29	<u>Registration Rights Agreement, dated as of March 14, 2018, by and among Teva Pharmaceutical Finance Netherlands III B.V., Teva Pharmaceutical Industries Limited and the initial purchasers listed therein (33)</u>
4.30	<u>Senior Indenture, dated as of March 14, 2018, by and among Teva Pharmaceutical Finance Netherlands II B.V., Teva Pharmaceutical Industries Limited and the Bank of New York Mellon, as trustee (34)</u>
4.31	<u>First Supplemental Senior Indenture, dated as of March 14, 2018, by and among Teva Pharmaceutical Finance Netherlands II B.V., Teva Pharmaceutical Industries Limited and the Bank of New York Mellon, as trustee, including the form of 3.250% Senior Notes due 2022 and the form of 4.500% Senior Notes due 2025 (35)</u>
4.32	<u>Registration Rights Agreement, dated as of March 14, 2018, by and among Teva Pharmaceutical Finance Netherlands II B.V., Teva Pharmaceutical Industries Limited and the initial purchasers listed therein (36)</u>
4.33	Other long-term debt instruments: The registrant hereby undertakes to provide the Securities and Exchange Commission with copies upon request.
10.1	<u>Senior Unsecured Fixed Rate Japanese Yen Term Loan Credit Agreement, dated as of March 28, 2012, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings GK, as initial borrower, Sumitomo Mitsui Banking Corporation, as administrative agent, and the lenders party thereto (37)</u>
10.2	<u>Senior Unsecured Japanese Yen Term Loan Credit Agreement, dated as of December 17, 2013, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings GK, as initial borrower, Mizuho Bank LTD., as administrative agent, and the lenders party thereto (38)</u>
10.3	<u>Term Loan Credit Agreement, dated as of November 16, 2015, by and among Teva Pharmaceutical Industries Limited, as guarantor, Teva Pharmaceuticals USA, Inc., Teva Capital Services Switzerland GmbH, Teva Finance Services B.V., Teva Finance Services II B.V., Teva Pharmaceutical Finance Netherlands III B.V., as borrowers, Citibank, N.A., as administrative agent, and the lenders party thereto (39)</u>

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- 10.4 Senior Unsecured Revolving Credit Agreement, dated as of November 16, 2015, by and among Teva Pharmaceutical Industries Limited, as guarantor, Teva Pharmaceuticals USA, Inc., Teva Capital Services Switzerland GmbH, Teva Finance Services B.V., Teva Finance Services II B.V., Teva Pharmaceutical Finance Netherlands III B.V., as borrowers, Citibank, N.A., as administrative agent, and the lenders party thereto (40)
- 10.5 Senior Unsecured Japanese Yen Term Loan Credit Agreement, dated as of March 22, 2017, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings K.K., as borrower, the lenders party thereto, Sumitomo Mitsui Banking Corporation, as administrative agent, Mizuho Bank Ltd. and Sumitomo Mitsui Banking Corporation, Brussels Branch, as mandated lead arrangers and as bookrunners (41)
- 10.6 Amendment, dated as of September 24, 2015, to the Senior Unsecured Fixed Rate Japanese Yen Term Loan Credit Agreement, dated as of March 28, 2012, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings K.K. (f/k/a Teva Holdings GK), as initial borrower, Sumitomo Mitsui Banking Corporation, as administrative agent, and the lenders party thereto (42)
- 10.7 Amendment, dated as of September 24, 2015, to the Senior Unsecured Japanese Yen Term Loan Credit Agreement, dated as of December 17, 2013, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings K.K., as initial borrower, Mizuho Bank LTD., as administrative agent, and the lenders party thereto (43)
- 10.8 Amendment, dated as of July 21, 2016, to the Senior Unsecured Revolving Credit Agreement, dated as of November 16, 2015, by and among Teva Pharmaceutical Industries Limited, as guarantor, Teva Pharmaceuticals USA, Inc., Teva Capital Services Switzerland GmbH, Teva Finance Services B.V., Teva Finance Services II B.V., Teva Pharmaceutical Finance Netherlands III B.V., as borrowers, Citibank, N.A., as administrative agent, and the lenders party thereto (44)
- 10.9 Amendment, dated as of September 18, 2017, to the Senior Unsecured Revolving Credit Agreement, dated as of November 16, 2015, by and among Teva Pharmaceutical Industries Limited, as guarantor, Teva Pharmaceuticals USA, Inc., Teva Capital Services Switzerland GmbH, Teva Finance Services B.V., Teva Finance Services II B.V., Teva Pharmaceutical Finance Netherlands III B.V., as borrowers, Citibank, N.A., as administrative agent, and the lenders party thereto (45)
- 10.10 Amendment, dated as of September 18, 2017, to the Term Loan Credit Agreement, dated as of November 16, 2015, by and among Teva Pharmaceutical Industries Limited, as guarantor, Teva Pharmaceuticals USA, Inc., Teva Capital Services Switzerland GmbH, Teva Finance Services B.V., Teva Finance Services II B.V., Teva Pharmaceutical Finance Netherlands III B.V., as borrowers, Citibank, N.A., as administrative agent, and the lenders party thereto (46)
- 10.11 Amendment, dated as of September 19, 2017, to the Senior Unsecured Fixed Rate Japanese Yen Term Loan Credit Agreement, dated as of March 28, 2012, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings K.K. (f/k/a Teva Holdings GK), as initial borrower, Sumitomo Mitsui Banking Corporation, as administrative agent, and the lenders party thereto (47)
- 10.12 Amendment, dated as of September 19, 2017, to the Senior Unsecured Japanese Yen Term Loan Credit Agreement, dated as of December 17, 2013, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings K.K., as initial borrower, Mizuho Bank LTD., as administrative agent, and the lenders party thereto (48)
- 10.13 Amendment, dated as of September 19, 2017, to the Senior Unsecured Japanese Yen Term Loan Credit Agreement, dated as of March 22, 2017, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings K.K., as borrower, the lenders party thereto and Sumitomo Mitsui Banking Corporation, as



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- 10.14 Amendment, dated as of February 1, 2018, to the Senior Unsecured Revolving Credit Agreement, dated as of November 16, 2015, by and among Teva Pharmaceutical Industries Limited, as guarantor, Teva Pharmaceuticals USA, Inc., Teva Capital Services Switzerland GmbH, Teva Finance Services B.V., Teva Finance Services II B.V., Teva Pharmaceutical Finance Netherlands III B.V., as borrowers, Citibank, N.A., as administrative agent, and the lenders party thereto (50)
- 10.15 Amendment, dated as of February 1, 2018, to the Term Loan Credit Agreement, dated as of November 16, 2015, by and among Teva Pharmaceutical Industries Limited, as guarantor, Teva Pharmaceuticals USA, Inc., Teva Capital Services Switzerland GmbH, Teva Finance Services B.V., Teva Finance Services II B.V., Teva Pharmaceutical Finance Netherlands III B.V., as borrowers, Citibank, N.A., as administrative agent, and the lenders party thereto (51)
- 10.16 Amendment, dated as of February 1, 2018, to the Senior Unsecured Fixed Rate Japanese Yen Term Loan Credit Agreement, dated as of March 28, 2012, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings K.K. (f/k/a Teva Holdings GK), as initial borrower, Sumitomo Mitsui Banking Corporation, as administrative agent, and the lenders party thereto (52)
- 10.17 Amendment, dated as of February 1, 2018, to the Senior Unsecured Japanese Yen Term Loan Credit Agreement, dated as of December 17, 2013, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings K.K., as initial borrower, Mizuho Bank LTD., as administrative agent, and the lenders party thereto (53)
- 10.18 Amendment, dated as of February 1, 2018, to the Senior Unsecured Japanese Yen Term Loan Credit Agreement, dated as of March 22, 2017, among Teva Pharmaceutical Industries Limited, as guarantor, Teva Holdings K.K., as borrower, the lenders party thereto and Sumitomo Mitsui Banking Corporation, as administrative agent (54)
- 10.19 Employment Agreement, dated September 7, 2017, between Teva Pharmaceutical Industries Limited and Kåre Schultz (55)
- 10.20 Employment Agreement, dated as of February 8, 2018, between Teva Pharmaceuticals USA, Inc. and Michael McClellan (56)
- 10.21 Letter Agreement, dated as of July 19, 2017, between Teva Pharmaceuticals USA, Inc. and Michael McClellan (57)
- 10.22 Letter Agreement, dated as of September 19, 2017, between Teva Pharmaceuticals USA, Inc. and Michael McClellan (58)
- 10.23 Letter Agreement, dated as of April 26, 2017, between Teva Pharmaceuticals USA, Inc. and Michael McClellan (59)
- 10.24 Amended and Restated Employment Agreement, dated as of February 7, 2018, between Teva Pharmaceuticals USA, Inc. and Carlo de Notaristefani (60)
- 10.25 Employment Agreement, dated as of June 18, 2017, between Teva Pharmaceuticals USA, Inc. and Hafrun Fridriksdottir (61)
- 10.26 Amendment to Employment Agreement between Teva Pharmaceuticals USA, Inc. and Hafrun Fridriksdottir, dated as of January 4, 2019 \*
- 10.27 Letter Agreement, dated as of February 21, 2016, between Teva Pharmaceuticals USA, Inc. and Hafrun Fridriksdottir (62)
- 10.28

Letter Agreement, dated as of December 1, 2016, between Teva Pharmaceuticals USA, Inc. and Hafrun Fridriksdottir (63)

10.29 Letter Agreement, dated as of November 7, 2016, between Teva Pharmaceuticals USA, Inc. and Hafrun Fridriksdottir (64)

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10.30	<u>Letter Agreement, dated as of July 28, 2015, between Teva Pharmaceutical Industries Limited and Hafrun Fridriksdottir (65)</u>
10.31	<u>Employment Agreement, dated as of December 22, 2013, between Teva Pharmaceutical Industries Limited and Mark Sabag (66)</u>
10.32	<u>Letter Agreement, dated as of June 2017, between Teva Pharmaceutical Industries Limited and Mark Sabag (67)</u>
10.33	<u>Long-Term Assignment Letter, dated as of August 9, 2018, between Teva Pharmaceutical Industries Limited and Michael McClellan (68)</u>
10.34	<u>2017 Form Bonus Letter Agreement, applicable to Hafrun Fridriksdottir, Carlo de Notaristefani and Mark Sabag (69)</u>
10.35	<u>Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan (70)</u>
10.36	<u>Teva Pharmaceutical Industries Limited 2017 Executive Incentive Compensation Plan (71)</u>
10.37	<u>Teva Pharmaceuticals USA, Inc. Supplemental Deferred Compensation Plan (72)</u>
10.38	<u>Teva Pharmaceuticals USA, Inc. Defined Contribution Supplemental Executive Retirement Plan (73)</u>
10.39	<u>Form of Indemnification and Release Agreement (74)</u>
10.40	<u>Form Director Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to selected 2015, 2016 and 2017 grants (75)</u>
10.41	<u>Hafrun Fridriksdottir Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to selected 2016 grants (76)</u>
10.42	<u>Kåre Schultz Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to November 3, 2017 grant (77)</u>
10.43	<u>Carlo de Notaristefani Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to May 18, 2017 grant (78)</u>
10.44	<u>Form Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to selected 2016 grants made to Michael McClellan and Hafrun Fridriksdottir and selected 2017 grants made to Michael McClellan (79)</u>
10.45	<u>Hafrun Fridriksdottir Substitute Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to August 2, 2016 stock option grant (80)</u>
10.46	<u>Hafrun Fridriksdottir Substitute Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to August 2, 2016 restricted stock unit grant (81)</u>
10.47	<u>Form Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to selected 2015 grants made to Michael McClellan (82)</u>
10.48	<u>Form Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to selected 2017 grants made to Mark Sabag, Carlo de Notaristefani, Hafrun Fridriksdottir and Kåre Schultz (83)</u>
10.49	<u>Form Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to selected 2016 grants made to Mark Sabag and Carlo de Notaristefani (84)</u>

10.50	<u>Form Award Agreement under the Teva Pharmaceutical Industries Limited 2010 Long-Term Equity-Based Incentive Plan applicable to selected 2015 grants made to Mark Sabag and Carlo de Notaristefani (85)</u>
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10.51	<u>Form Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to selected 2018 grants made to Kåre Schultz, Michael McClellan, Mark Sabag, Carlo de Notaristefani and Hafrun Fridriksdottir (86)</u>
10.52	<u>2018 Form Bonus Letter Agreement (87)</u>
10.53	<u>Michael McClellan Award Agreement under the Teva Pharmaceutical Industries Limited 2015 Long-Term Equity-Based Incentive Plan applicable to September 18, 2017 grant (88)</u>
10.54	<u>Settlement Agreement and Mutual Releases Agreement, dated as of January 31, 2018, by and between Teva Pharmaceutical Industries Ltd. and Allergan plc (89)</u>
18	<u>Kesselman &amp; Kesselman Preferability Letter *</u>
21	<u>Subsidiaries of the Registrant *</u>
23	<u>Consent of Kesselman &amp; Kesselman, independent registered public accountants *</u>
31.1	<u>Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *</u>
31.2	<u>Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *</u>
32	<u>Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 *</u>
101	The following financial information from Teva Pharmaceutical Industries Limited's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Statements of Income for the years ended December 31, 2018, 2017 and 2016; (ii) Consolidated Balance Sheets at December 31, 2018 and 2017; (iii) Consolidated Statements of Changes in Equity for the years ended December 31, 2018, 2017 and 2016; (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016; and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

\* Filed herewith.

1. English translation or summary from Hebrew original, which is the official version.
2. Incorporated by reference to Exhibit 3.1 to Registration Statement on Form F-1(Reg. No. 33-15736).
3. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed on December 14, 2018.
4. Incorporated by reference to Exhibit 3.3 to Current Report on Form 8-K filed on December 14, 2018.
5. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed on December 4, 2018.
6. Incorporated by reference to Exhibit 4.1 to Form 6-K filed on January 31, 2006.
7. Incorporated by reference to Exhibit 4.2 to Form 6-K filed on January 31, 2006.
8. Incorporated by reference to Exhibit 4.3 to Form 6-K filed on January 31, 2006.
9. Incorporated by reference to Exhibit 4.1 to Form 6-K filed on May 4, 2010.
10. Incorporated by reference to Exhibit 4.1 to Form 6-K filed on November 10, 2011.
11. Incorporated by reference to Exhibit 4.2 to Form 6-K filed on December 18, 2012.
12. Incorporated by reference to Exhibit 4.3 to Form 6-K filed on November 10, 2011.
13. Incorporated by reference to Exhibit 4.4 to Form 6-K filed on November 10, 2011.
14. Incorporated by reference to Exhibit 4.4 to Form 6-K filed on December 18, 2012.
15. Incorporated by reference to Exhibit 4.5 to Form 6-K filed on November 10, 2011.
16. Incorporated by reference to Exhibit 4.6 to Form 6-K filed on November 10, 2011.

17. Incorporated by reference to Exhibit 4.2 to Form 6-K filed on April 4, 2012.
18. Incorporated by reference to Exhibit 4.1 to Form 6-K filed on April 25, 2012.
19. Incorporated by reference to Exhibit 4.2 to Form 6-K filed on April 25, 2012.
20. Incorporated by reference to Exhibit 4.1 to Form 6-K filed on March 31, 2015.
21. Incorporated by reference to Exhibit 4.2 to Form 6-K filed on March 31, 2015.

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22. Incorporated by reference to Exhibit 4.2 to Form 6-K filed on July 25, 2016.
23. Incorporated by reference to Exhibit 4.1 to Form 6-K filed on July 21, 2016.
24. Incorporated by reference to Exhibit 4.2 to Form 6-K filed on July 21, 2016.
25. Incorporated by reference to Exhibit 4.1 to Form 6-K filed on July 28, 2016.
26. Incorporated by reference to Exhibit 4.2 to Form 6-K filed on July 28, 2016.
27. Incorporated by reference to Exhibit 4.3 to Form 6-K filed on July 28, 2016.
28. Incorporated by reference to Exhibit 4.4 to Form 6-K filed on July 28, 2016.
29. Incorporated by reference to Exhibit 4.5 to Form 6-K filed on July 28, 2016.
30. Incorporated by reference to Exhibit 4.6 to Form 6-K filed on July 28, 2016.
31. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed on March 14, 2018.
32. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed on March 14, 2018.
33. Incorporated by reference to Exhibit 4.4 to Current Report on Form 8-K filed on March 14, 2018.
34. Incorporated by reference to Exhibit 4.5 to Current Report on Form 8-K filed on March 14, 2018.
35. Incorporated by reference to Exhibit 4.6 to Current Report on Form 8-K filed on March 14, 2018.
36. Incorporated by reference to Exhibit 4.8 to Current Report on Form 8-K filed on March 14, 2018.
37. Incorporated by reference to Exhibit 2.1 to Form 6-K filed on May 9, 2012.
38. Incorporated by reference to Exhibit 2.27 to Form 20-F filed on February 9, 2015.
39. Incorporated by reference to Exhibit 99.1 to Form 6-K filed on November 18, 2015.
40. Incorporated by reference to Exhibit 99.2 to Form 6-K filed on November 18, 2015.
41. Incorporated by reference to Exhibit 2.1 to Form 6-K filed on May 11, 2017.
42. Incorporated by reference to Exhibit 10.6 to Annual Report on Form 10-K filed on February 12, 2018.
43. Incorporated by reference to Exhibit 10.7 to Annual Report on Form 10-K filed on February 12, 2018.
44. Incorporated by reference to Exhibit 10.8 to Annual Report on Form 10-K filed on February 12, 2018.
45. Incorporated by reference to Exhibit 99.1 to Form 6-K filed on September 19, 2017.
46. Incorporated by reference to Exhibit 99.2 to Form 6-K filed on September 19, 2017.
47. Incorporated by reference to Exhibit 99.3 to Form 6-K filed on September 19, 2017.
48. Incorporated by reference to Exhibit 99.4 to Form 6-K filed on September 19, 2017.
49. Incorporated by reference to Exhibit 99.5 to Form 6-K filed on September 19, 2017.
50. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on February 1, 2018.
51. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed on February 1, 2018.
52. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed on February 1, 2018.
53. Incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K filed on February 1, 2018.
54. Incorporated by reference to Exhibit 10.5 to Current Report on Form 8-K filed on February 1, 2018.
55. Incorporated by reference to Exhibit 10.20 to Annual Report on Form 10-K filed on February 12, 2018.
56. Incorporated by reference to Exhibit 10.27 to Annual Report on Form 10-K filed on February 12, 2018.
57. Incorporated by reference to Exhibit 10.28 to Annual Report on Form 10-K filed on February 12, 2018.
58. Incorporated by reference to Exhibit 10.29 to Annual Report on Form 10-K filed on February 12, 2018.
59. Incorporated by reference to Exhibit 10.30 to Annual Report on Form 10-K filed on February 12, 2018.
60. Incorporated by reference to Exhibit 10.31 to Annual Report on Form 10-K filed on February 12, 2018.
61. Incorporated by reference to Exhibit 10.32 to Annual Report on Form 10-K filed on February 12, 2018.
62. Incorporated by reference to Exhibit 10.33 to Annual Report on Form 10-K filed on February 12, 2018.
63. Incorporated by reference to Exhibit 10.34 to Annual Report on Form 10-K filed on February 12, 2018.
64. Incorporated by reference to Exhibit 10.35 to Annual Report on Form 10-K filed on February 12, 2018.
65. Incorporated by reference to Exhibit 10.36 to Annual Report on Form 10-K filed on February 12, 2018.
66. Incorporated by reference to Exhibit 10.37 to Annual Report on Form 10-K filed on February 12, 2018.
67. Incorporated by reference to Exhibit 10.38 to Annual Report on Form 10-K filed on February 12, 2018.
68. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed on November 1, 2018.
69. Incorporated by reference to Exhibit 10.46 to Annual Report on Form 10-K filed on February 12, 2018.

- 70. Incorporated by reference to Exhibit A to Proxy Statement filed on June 8, 2017.
- 71. Incorporated by reference to Exhibit B to Proxy Statement filed on June 8, 2017.
- 72. Incorporated by reference to Exhibit 10.49 to Annual Report on Form 10-K filed on February 12, 2018.
- 73. Incorporated by reference to Exhibit 10.50 to Annual Report on Form 10-K filed on February 12, 2018.

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- 74. Incorporated by reference to Exhibit 10.51 to Annual Report on Form 10-K filed on February 12, 2018.
- 75. Incorporated by reference to Exhibit 10.52 to Annual Report on Form 10-K filed on February 12, 2018.
- 76. Incorporated by reference to Exhibit 10.53 to Annual Report on Form 10-K filed on February 12, 2018.
- 77. Incorporated by reference to Exhibit 10.54 to Annual Report on Form 10-K filed on February 12, 2018.
- 78. Incorporated by reference to Exhibit 10.55 to Annual Report on Form 10-K filed on February 12, 2018.
- 79. Incorporated by reference to Exhibit 10.56 to Annual Report on Form 10-K filed on February 12, 2018.
- 80. Incorporated by reference to Exhibit 10.57 to Annual Report on Form 10-K filed on February 12, 2018.
- 81. Incorporated by reference to Exhibit 10.58 to Annual Report on Form 10-K filed on February 12, 2018.
- 82. Incorporated by reference to Exhibit 10.59 to Annual Report on Form 10-K filed on February 12, 2018.
- 83. Incorporated by reference to Exhibit 10.60 to Annual Report on Form 10-K filed on February 12, 2018.
- 84. Incorporated by reference to Exhibit 10.61 to Annual Report on Form 10-K filed on February 12, 2018.
- 85. Incorporated by reference to Exhibit 10.62 to Annual Report on Form 10-K filed on February 12, 2018.
- 86. Incorporated by reference to Exhibit 10.63 to Annual Report on Form 10-K filed on February 12, 2018.
- 87. Incorporated by reference to Exhibit 10.64 to Annual Report on Form 10-K filed on February 12, 2018.
- 88. Incorporated by reference to Exhibit 10.65 to Annual Report on Form 10-K filed on February 12, 2018.
- 89. Incorporated by reference to Exhibit 10.66 to Annual Report on Form 10-K filed on February 12, 2018.

**ITEM 16. FORM 10-K SUMMARY**

None.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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**

By: /s/ Kåre Schultz  
 Name: Kåre Schultz  
 Title: President and Chief Executive Officer  
 Dated: February 19, 2019

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENT, that each of the undersigned directors and/or officers of Teva Pharmaceutical Industries Limited, a corporation organized under the laws of Israel, hereby constitutes and appoints Kåre Schultz, Michael McClellan, David M. Stark and Deborah A. Griffin, and each of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign, execute and deliver with the U.S. Securities and Exchange Commission any and all amendments to this annual report on Form 10-K, with all exhibits thereto, and other documents in connection therewith, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this annual report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Name</b>	<b>Title</b>	<b>Date</b>
By: /s/ Dr. Sol J. Barer  Dr. Sol J. Barer	Chairman of the Board of Directors	February 19, 2019
By: /s/ Kåre Schultz  Kåre Schultz	President and Chief Executive Officer and Director	February 19, 2019
By: /s/ Michael McClellan  Michael McClellan	Executive Vice President, Chief Financial Officer (Principal Financial Officer)	February 19, 2019
By: /s/ Deborah A. Griffin	Senior Vice President, Chief Accounting Officer	February 19, 2019

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Deborah A. Griffin (Principal Accounting Officer)

By: /s/ Rosemary A. Crane Director February 19, 2019

Rosemary A. Crane

By: /s/ Amir Elstein Director February 19, 2019

Amir Elstein

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<b>Name</b>		<b>Title</b>	<b>Date</b>
By: /s/ Murray A. Goldberg	Director		February 19, 2019
Murray A. Goldberg			
By: /s/ Jean-Michel Halfon	Director		February 19, 2019
Jean-Michel Halfon			
By: /s/ Gerald M. Lieberman	Director		February 19, 2019
Gerald M. Lieberman			
By: /s/ Roberto A. Mignone	Director		February 19, 2019
Roberto A. Mignone			
By: /s/ Dr. Perry D. Nisen	Director		February 19, 2019
Dr. Perry D. Nisen			
By: /s/ Nechemia (Chemi) J. Peres	Director		February 19, 2019
Nechemia (Chemi) J. Peres			
By: /s/ Prof. Ronit Satchi-Fainaro	Director		February 19, 2019
Prof. Ronit Satchi-Fainaro			