TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 20-F
February 15, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of event requiring this shell company report:

Commission File number: 001-16174

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant s name into English)

ISRAEL

(Jurisdiction of incorporation or organization)

5 Basel Street

P.O. Box 3190

Petach Tikva 4951033, Israel

(Address of principal executive offices)

Eyal Desheh

Group Executive Vice President, Chief Financial Officer

Teva Pharmaceutical Industries Limited

5 Basel Street

P.O. Box 3190

Petach Tikva 4951033, Israel

Tel: 972-3-914-8171

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(Name, telephone, e-mail and/or facsimile number and address of Company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	**Name of each exchange on which registered**
American Depositary Shares, each representing one Ordinary Share	**New York Stock Exchange**

Securities registered or to be registered pursuant to Section 12(g) of the Act.

None

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report.

1,014,990,306 Ordinary Shares

829,521,850 American Depositary Shares

3,712,500 Mandatory Convertible Preferred Shares

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

Note Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

US GAAP

International Financial Reporting Standards as issued by the International Accounting Standards Board

Other

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

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If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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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, 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 IMS Health Inc., a provider of market research to the pharmaceutical industry (IMS), unless otherwise stated. References to ROW are to our Rest of the World markets. References to Actavis Generics are to the generic pharmaceuticals business we purchased from Allergan plc on August 2, 2016. References to P&G are to The Procter & Gamble Company and references to PGT are to PGT Healthcare, the joint venture we formed with P&G. References to R&D are to Research and Development. References to S&M are to Selling and Marketing. References to G&A are to General and Administrative.

FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements, which express management s current beliefs or expectations with regard to future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as anticipate, estimate, expect, project, intend, plan, believe and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. In particular, these statements relate to, among other things:

- our business strategy;
- our ability to integrate the acquisition of Actavis Generics and to realize the anticipated benefits of the acquisition;
- potential restrictions on our ability to engage in additional transactions or incur additional indebtedness as a result of the substantial amount of debt we incurred to finance the Actavis Generics acquisition;
- the development and launch of our products, including product approvals and results of clinical trials;
- projected markets and market size;
- anticipated results of litigation and regulatory proceedings;
- our projected revenues, market share, expenses, net income margins and capital expenditures; and
- our liquidity.

The forward-looking statements contained herein involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements.

You should understand that many important factors, in addition to those discussed or incorporated by reference in this report, could cause our results to differ materially from those expressed in the forward-looking statements. Potential factors that could affect our results include, in addition to others not described in this report, those described under Item 3- Key Information Risk Factors. These are factors that we think could cause our actual results to differ materially from expected results.

Forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update any forward-looking statements or other information contained in this report, whether as a result of new information, future events or otherwise. You are advised, however, to consult any additional disclosures we make in our reports on Form 6-K filed with the U.S. Securities and Exchange Commission (SEC). Please also see the cautionary discussion of risks and uncertainties under Item 3 Key Information Risk Factors starting on page 5 of this report. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

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PART I

ITEM 1: IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not Applicable.

ITEM 2: OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable.

ITEM 3: KEY INFORMATION

SELECTED FINANCIAL DATA

The Israeli Securities Law allows Israeli companies, such as Teva, whose securities are listed both on the Tel Aviv Stock Exchange and on certain stock exchanges in the U.S. (including the New York Stock Exchange), to report exclusively under the rules of the SEC and generally accepted accounting principles in the United States (U.S. GAAP). Except as otherwise indicated, all financial statements and other financial information included in this annual report are presented solely under U.S. GAAP.

The following selected operating data for each of the years in the three-year period ended December 31, 2016 and selected balance sheet data at December 31, 2016 and 2015 are derived from our audited consolidated financial statements set forth elsewhere in this report, which have been prepared in accordance with U.S. GAAP. The selected operating data for each of the years in the two-year period ended December 31, 2013 and selected balance sheet data at December 31, 2014, 2013 and 2012 are derived from our audited financial statements not appearing in this report, which have also been prepared in accordance with U.S. GAAP.

The selected financial data should be read in conjunction with our consolidated financial statements, related notes and other financial information included in this report.

The currency of the primary economic environment in which our operations in Israel and the United States are conducted is the U.S. dollar. The functional currency of some subsidiaries and associated companies is their local currency.

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Operating Data

	For the year ended December 31,				
	2016	2015	2014	2013	2012
	U.S. dollars in millions (except share and per share amounts)				
Net revenues	21,903	19,652	20,272	20,314	20,317
Cost of sales	10,044	8,296	9,216	9,607	9,665
Gross profit	11,859	11,356	11,056	10,707	10,652
Research and development expenses	2,111	1,525	1,488	1,427	1,356
Selling and marketing expenses	3,860	3,478	3,861	4,080	3,879
General and administrative expenses	1,236	1,239	1,217	1,239	1,238
Impairments, restructuring and others	699	1,131	650	788	1,259
Legal settlements and loss contingencies	899	631	(111)	1,524	715
Goodwill impairment charge	900				
Operating income	2,154	3,352	3,951	1,649	2,205
Financial expenses net	1,330	1,000	313	399	386
Income before income taxes	824	2,352	3,638	1,250	1,819
Income taxes	521	634	591	(43)	(137)
Share in (profits) losses of associated companies net	(8)	121	5	40	46
Net income	311	1,597	3,042	1,253	1,910
Net income (loss) attributable to non-controlling interests	(18)	9	(13)	(16)	(53)
Net income attributable to Teva	329	1,588	3,055	1,269	1,963
Accrued dividends on preferred shares	261	15			
Net income attributable to ordinary shareholders	68	1,573	3,055	1,269	1,963
Earnings per share attributable to ordinary shareholders:					
Basic ($)	0.07	1.84	3.58	1.49	2.25
Diluted ($)	0.07	1.82	3.56	1.49	2.25
Weighted average number of shares (in millions):					
Basic	955	855	853	849	872
Diluted	961	864	858	850	873

Balance Sheet Data

	As at December 31,				
	2016	2015	2014	2013	2012
	(U.S. dollars in millions)				
Financial assets (cash, cash equivalents and investment in securities)	1,949	8,404	2,601	1,245	3,089
Identifiable intangible assets, net	21,487	7,675	5,512	6,476	7,745
Goodwill	44,409	19,025	18,408	18,981	18,856

Working capital (operating assets minus liabilities)	5	32	1,642	2,493	3,589
Total assets	92,890	54,258	46,420	47,508	50,609
Short-term debt, including current maturities	3,276	1,585	1,761	1,804	3,006
Long-term debt, net of current maturities	32,524	8,358	8,566	10,387	11,712
Total debt	35,800	9,943	10,327	12,191	14,718
Total equity	34,993	29,927	23,355	22,636	22,867

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Dividends

We have paid dividends on a regular quarterly basis since 1986. 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 may be restricted by instruments governing our debt obligations. Dividends are declared in U.S. dollars and are paid by the depositary of our American Depositary Shares (ADSs) for the benefit of owners of ADSs.

Dividends on our mandatory convertible preferred shares are payable on a cumulative basis when, as and if declared by our board of directors at an annual rate of 7% on the liquidation preference of $1,000 per mandatory convertible preferred share. Declared dividends are paid in cash on March 15, June 15, September 15 and December 15 of each year to and including December 15, 2018. So long as any mandatory convertible preferred shares remain outstanding, no dividends may be declared or paid on our ordinary shares or ADSs, unless all accumulated and unpaid dividends for all preceding dividend periods have been declared and paid, or a sufficient sum of cash has been set apart for the payment of such dividends, for all outstanding mandatory convertible preferred shares.

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 15% tax will be withheld on the dividend declared and distributed for the fourth quarter of 2016.

The following table sets forth the amounts of the dividends declared on our ordinary shares/ADSs in respect of each period indicated prior to deduction for applicable Israeli withholding taxes (in cents per share):

	2016	2015	2014	2013	2012
	In cents per share				
1st interim	34.0	34.0	34.7	32.0	26.3
2nd interim	34.0	34.0	35.3	32.2	25.0
3rd interim	34.0	34.0	32.1	32.6	25.7
4th interim	34.0	34.0	33.8	34.3	31.1

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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 generics medicines business

As a result of the acquisition of Allergan plc s worldwide generic pharmaceuticals business (Actavis Generics), we are dependent to a much larger extent than previously on our generic pharmaceutical business, and therefore are increasingly subject to the significant risks associated with that business.

In 2016, revenues from our generic medicines segment were approximately $12.0 billion, or 55% of our total revenues. Gross profit from our generic medicines segment was approximately $5.7 billion, or 48% of our total gross profit. These figures reflect less than five months contribution from the Actavis Generics business, and as a result the relative importance of our generics business for the full year 2017 and beyond is expected to be substantially greater. We expect that the proportion of our revenues attributable to generic pharmaceuticals will approach two-thirds in 2017 and that such proportion is unlikely to be significantly lower over the next few years, and may even increase. Generic pharmaceuticals are, as a general matter, less profitable than specialty pharmaceuticals, and face regular and increasing price erosion each year, placing even greater importance on our ability to continually introduce new products. Accordingly, we expect to be more dependent on our generics business and increasingly subject to market and regulatory factors and other risks affecting generic pharmaceuticals worldwide.

We may fail to realize the anticipated benefits of the Actavis Generics acquisition, or those benefits may take longer to realize than expected. We may also encounter significant difficulties in integrating Actavis Generics.

Our ability to realize the anticipated benefits of the Actavis Generics acquisition depends, to a large extent, on our ability to integrate the Actavis Generics business. The combination of two formerly independent, competitive businesses is a complex, costly and time-consuming process. We are devoting significant management attention and resources to the integration of our combined business practices and operations. The integration process may disrupt the businesses and, if implemented ineffectively, would impede the realization of the full expected benefits. The failure to meet the challenges involved in integrating the two businesses and to realize the anticipated benefits of the transaction could cause an interruption of, or a loss of momentum in, the activities of the combined businesses and could adversely affect our results of operations.

In addition, the integration of the businesses may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customers and other business relationships, and diversion of management s attention. The difficulties of combining the Teva and Actavis Generics operations include, among others:

- the diversion of management s attention to integration matters;
- difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects from the combination;
- difficulties in the integration of operations and systems;
- conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the two companies;

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challenges in retaining key Actavis Generics personnel and recruiting additional personnel as needed;

difficulties in the assimilation of employees;

difficulties in managing the expanded operations of a significantly larger and more complex company;

challenges in keeping existing customers and obtaining new customers; and

coordinating a geographically dispersed organization.

The recent departure of Sigurdur Olafsson, then the head of our global generics business, who had previously run the Actavis Generics business, may exacerbate the challenges we face in integrating Actavis Generics and retaining key Actavis Generics employees.

Many of these factors are outside of our control, and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management s time and energy, which could materially impact our business, financial condition and results of operations. As a result, it cannot be assured that we will realize the full benefits anticipated from the Actavis Generics acquisition.

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 Hatch-Waxman exclusivity, 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 failure to maintain our industry-leading performance in the U.S. 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 or, in certain cases, can be triggered by a final court decision that is no longer subject to appeal holding the applicable patents to be invalid, unenforceable or not infringed. However, the exclusivity period can be forfeited by our failure to obtain tentative approval of our product within a specified statutory period or to launch a product following such a court decision. 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 triggered or forfeited before we are able to commercialize a product and therefore may not be able to exploit a given exclusivity period for specific products.

Our revenues and profits from generic pharmaceutical products typically decline as a result of competition, both from other pharmaceutical companies and as a result of increased governmental pricing pressure.

Our generic drugs face intense competition. Prices of generic drugs typically decline, often dramatically, especially as additional generic pharmaceutical companies (including low-cost generic producers based in China

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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 last fall under the Generic Drug User Fee Act, and increased funding of the FDA s Office of Generic Drugs, may lead to more and faster generic approvals, and consequently increased competition on some products. 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.

In addition, intense pressure from government healthcare authorities, particularly in highly regulated European markets, to reduce their expenditures on prescription drugs has resulted in lower pharmaceutical pricing, causing decreases in revenues and profits.

Furthermore, brand pharmaceutical companies continue to defend their products vigorously. 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.

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

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. For example, we have started design activities for a new biologics manufacturing facility, and in October 2016, we entered into an exclusive partnership with Celltrion, Inc. to commercialize two of its biosimilar products in development for the U.S. and Canadian markets. We cannot assure you that our current and future investments and collaborations regarding biosimilar products will be successful.

Risks related to our specialty medicines business

Our leading specialty medicine, Copaxone®, faces increasing competition, including from a generic version of our 20 mg/mL product and potential generic competitors to our 40 mg/mL version, as well as from orally-administered therapies.

We rely heavily on the continued absence of a generic version of our 40 mg/mL, three-times-a-week version of Copaxone®. Over 84% of total U.S. Copaxone® prescriptions are now filled with the 40 mg/mL version. Our ability to rely on patent protection for this 40 mg/mL version as a barrier to entry for potential generic versions currently faces significant uncertainty in light of decisions in August and September 2016 by the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office that all claims in three of the five U.S. Orange Book patents are unpatentable and a court ruling in January 2017 invalidating all asserted claims of four of our patents on the 40 mg/mL version. A fourth patent is also subject to an inter partes review proceeding. We already face generic competition on the 20 mg/mL version of Copaxone®, following the expiration in 2014 and 2015 of the patents relating to this product.

In addition, Copaxone® faces significant and increasing competition as a result of new and emerging therapies, particularly oral treatments, such as Tecfidera® by Biogen, Gilenya® by Novartis, and Aubagio® by Genzyme, which provide especially intense competition in light of their substantial convenience in comparison to

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injectables such as Copaxone®. Copaxone® also continues to face competition from existing injectable products, such as beta-interferons Avonex®, Betaseron®, Extavia®, Plegridy® and Rebif®, as well as from monoclonal antibodies Tysabri®, Lemtrada® and Zinbryta®.

Our multiple sclerosis franchise reflects Copaxone® revenues less cost of goods sold and S&M and R&D expenses related to our MS franchise. (It does not include G&A expenses, amortization, research and development in process, inventory step up and certain other items.) Our MS franchise profitability was $3.4 billion, $3.1 billion, and $3.2 billion in 2016, 2015 and 2014, respectively. Profitability of our multiple sclerosis franchise as a percentage of Copaxone® revenues was 81%, 77% and 75% in 2016, 2015 and 2014, respectively. Accordingly, the failure to achieve and maintain our objectives for Copaxone® 40 mg/mL would have a material adverse effect on our financial results and cash flow.

Certain of our other leading specialty medicines also face patent challenges and impending patent expirations. For example, a generic version of Azilect® was launched in January 2017, our ProAir® HFA product is expected to face generic competition in the third quarter of 2017, and Treanda® is expected to face generic competition prior to patent expiration beginning in 2019.

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

We must invest significant resources to develop specialty medicines (including innovations utilizing existing molecules, as well as the development of complex generics), 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 expiration of our patents covering the 20 mg/mL version of our leading specialty medicine, Copaxone®, the patent challenges facing the 40 mg/mL version 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 recent acquisitions of Auspex Pharmaceuticals, Inc. and Labrys Biologics, Inc. and an in-licensing transaction with Eagle Pharmaceuticals, Inc.

The development of specialty medicines involves processes and expertise different from those used in the development of generic medicines, which increases the risks of failure that we face. For example, the time from discovery to commercial launch of a specialty medicine can be 15 years or even longer, and involves multiple stages: not only intensive preclinical and clinical testing, but also highly complex, lengthy and expensive approval processes which can vary from country to country. The longer it takes to develop a product, the less time there will be for us to recover our development costs and generate profits.

During each stage, we may encounter obstacles that delay the development process and increase expenses, leading to significant risks that we will not achieve our goals and may be forced to abandon a potential product in which we 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 failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured. For example, in 2016, we experienced a delay in the regulatory review of SD-809 for the treatment of chorea associated with Huntington disease and a delay in the clinical trial for fasinumab, which we are developing in partnership with Regeneron, and suspended the marketing of Zecuity® in the United States following reports of adverse site reactions.

Because of the amounts required to be invested in augmenting our pipeline of specialty and other products, we are also increasingly reliant on partnerships and joint ventures with third parties, such as our collaborations with Celltrion, Regeneron and Eagle, 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

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profit goals. 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 for such acquisition targets.

Our specialty pharmaceuticals business faces intense competition from companies that have greater resources and capabilities.

We face intense competition in our specialty pharmaceutical business. 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, for these product categories we must demonstrate to physicians, patients and third-party payors the benefits of our products relative to competing products that are often more familiar or otherwise better established. 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.

In addition, our specialty pharmaceuticals business requires much greater use of a direct sales force than does our core generic 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 penetration in the market. 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 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.

As discussed above, we have recently 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. While we intend to defend the validity of these patents vigorously, and will seek to prevent their infringement, such efforts are expensive and time-consuming. Due to the nature of litigation, 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 these or other specialty medicines could materially impact our business, results of operations, financial conditions or 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. 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

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known or be independently developed by our competitors or we may not be able to maintain the confidentiality of information relating to such products.

Risks related to our substantially increased indebtedness

We incurred approximately $27 billion in debt to finance the Actavis Generics acquisition, which has increased our expenses and restricts our ability to incur additional indebtedness or engage in other transactions and may result in a downgrade of our credit ratings.

Following the completion of the Actavis Generics acquisition our consolidated debt was approximately $35.8 billion at December 31, 2016, compared to approximately $10 billion at December 31, 2015. As a result, our borrowing costs have increased significantly. In addition, we have approximately $3.7 billion aggregate liquidation preference of our mandatory convertible preferred stock outstanding as well.

In addition, we have, and expect to have for the foreseeable future, significantly less cash and cash equivalents on hand than the approximately $6.9 billion of cash and cash equivalents we had at December 31, 2015. For example, at December 31, 2016, we had approximately $1 billion of cash and cash equivalents. We may also have lower-than-anticipated cash flow (whether due to adverse internal or external factors), which would further reduce our available cash. Although we believe that we will have access to cash sufficient to meet our business objectives and capital needs, this reduced availability of cash could constrain our ability to grow our business.

This substantial level of debt and lower levels of cash could have important consequences to our business, including, but not limited to:

- reducing the benefits we expect to receive from the Actavis Generics acquisition;
- 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;
- restricting us from pursuing certain business opportunities; and
- requiring us to sell assets and/or reduce our dividends.

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 and Moody s Investor Service, Inc. 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. Such reductions in our credit ratings limit our ability to borrow at interest rates consistent with the interest rates that were available to us prior to the acquisition. If our credit ratings are further downgraded or put on watch for a potential downgrade, we may not be able to sell additional debt securities or borrow money in the amounts, at the times or interest rates or upon the more favorable terms and conditions that might be available if our current credit ratings are maintained.

In addition, in light of the amount of unhedged floating-rate debt we currently have outstanding (approximately $7.7 billion at December 31, 2016), we have substantial exposure to increases in interest rates, which are becoming more likely.

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Additional risks related to our business and operations

Uncertainties related to our recent management changes may adversely affect our business, strategy and financial results.

On February 6, 2017, we announced the appointment of Dr. Yitzhak Peterburg, formerly Chairman of our Board of Directors, as Interim President and Chief Executive Officer, effective immediately, replacing Erez Vigodman. Dr. Peterburg is our sixth CEO since 2007 and fifth since 2012, and Mr. Vigodman is the second consecutive CEO to leave prior to the expiration of his term. Dr. Sol Barer, a current director, succeeded Dr. Peterburg as Chairman of the Board. In connection with his appointment, Dr. Peterburg announced that he will review the Company s business and operations, including its current global manufacturing footprint, key therapeutic areas, pipeline assets in both speciality and generics and existing business lines and markets.

As a result of these frequent management transitions, combined with the current challenges facing our businesses, we are subject to significant uncertainties regarding our future business strategy and direction. These uncertainties may cause or result in disruptions to our business and distractions to our employees and management; difficulty in recruiting, hiring, motivating, and retaining talented and skilled personnel, including current members of management; and difficulty in negotiating, maintaining, or consummating business or strategic relationships or transactions.

Furthermore, the search for a permanent CEO may be prolonged, and in light of past experience, we cannot assure you that the selected person will effectively transition into the role or ultimately be successful. During this search and transition period, there may continue to be uncertainties and concerns for employees and management, as well as for current and potential customers, other business partners and shareholders. Any of these factors could have a material adverse effect on our business, financial condition, cash flows and results of operations or reputation, and could cause the market value of our shares and/or debt securities to decline.

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 pharmaceutical products, both specialty and generic, particularly in light of the patent challenges facing the 40 mg/mL version of our leading specialty medicine, Copaxone®, the expiration of our patents covering the 20 mg/mL version of Copaxone® and the emergence of generic competition thereto, and patent challenges and impending patent expirations facing certain of our other specialty medicines. Commercialization requires that we successfully develop, test and manufacture both generic and specialty 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.

The development and commercialization process, particularly with respect to specialty 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 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 recent 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 U.S. 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 and our business, financial condition or results of operations.

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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 includes 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. We are awaiting the scheduling of a plea and sentencing hearing for the guilty plea agreement by our Russian subsidiary.

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 have been informed by Israeli authorities that they have initiated 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. 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 and our business, financial condition or 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 U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and other healthcare regulators with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply strictly 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 current good manufacturing practices (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.

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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 facilities 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 discontinued manufacturing activities at our facility in Godollo, Hungary following an FDA inspection earlier this year, halted operations at our facility in Guadalajara, Mexico (acquired as part of the Rimsa acquisition) due to compliance issues that existed prior to the acquisition, and are in the process of addressing quality issues raised in connection with an FDA audit of our active ingredient production facility in China. 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 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 also could have a material adverse effect on our business, financial position and results of operations.

As a result of the Actavis Generics acquisition, our manufacturing network has increased substantially. If we determine that any of the new facilities have quality or environmental issues, we could experience production or supply disruptions or be required to expend unanticipated costs on remediation and repairs. In addition, any delays in product transfers between our existing facilities and the newly-acquired sites may result in such disruptions.

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. 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 example, we purchase raw materials for most of our oral contraceptive products, which make up a substantial portion of our women s health business, exclusively or primarily from the same external source. If our supply of certain raw materials or finished products is interrupted from time to time, or proves insufficient to meet demand, our results of operations could be adversely impacted. Moreover, as we streamline our production capacity, particularly following the Actavis Generics acquisition, we may become more dependent on certain plants and operations for our supply.

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.

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 adversely affect our business.

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, including intellectual property, proprietary business information (both ours and that of our customers, suppliers and business partners,

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and personally identifiable information of our employees, in our data centers and on our networks. 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 assure you 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, including those who joined Teva as part of the Actavis Generics acquisition, or to attract additional executive and managerial talent, could adversely affect our business.

Given the increasing size, complexity and global reach of our business and our multiple areas of focus, each of which would be a significant stand-alone company, we are especially reliant upon our ability to recruit and retain highly qualified management and other employees. Our ability to retain key Actavis Generics employees may be diminished by the recent departure of Sigurdur Olafsson, then the head of our global generics business, who had previously run the Actavis Generics business. In addition, the success of our research and development activities depends on our ability to attract and retain sufficient numbers of skilled scientific personnel. 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.

The restructuring and streamlining of our manufacturing network, and resulting announcements of sales or closures of manufacturing sites, could trigger labor unrest, which could result in product supply disruptions.

Following the Actavis Generics acquisition, we are in the process of assessing our overall manufacturing network. At the conclusion of this assessment, we may decide to sell or close various manufacturing sites. The announcement of such plans could trigger labor unrest or strikes, which could result in product supply disruptions of unpredictable duration, with potentially material negative effects on our financial results.

Sales of our products may be adversely affected by the continuing consolidation of our customer base.

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 are continuing to undergo significant consolidation. Net sales to one such customer in 2016 accounted for 19% of our total consolidated sales. Such consolidation has provided and may continue to provide them with additional purchasing leverage, and consequently may increase the pricing pressures that we face. Additionally, the emergence of large buying groups representing independent retail pharmacies, and the prevalence and influence of managed care organizations and similar institutions, enable those groups to extract price discounts on our products.

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

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

We are subject to patent legislation in all countries where we have manufacturing facilities. Modifications of such legislation or court decisions regarding such legislation may adversely affect us and may impact our ability

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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 (with potentially serious timing delays) or otherwise adversely affect our ability to export certain products from such countries.

We have significant operations in countries that may be adversely affected by political or economic instability, major hostilities or acts of terrorism.

We are a global pharmaceutical company with worldwide operations. Although nearly 80% of our sales are in the United States and Europe, we expect to derive an increasing portion of our sales and future growth from other regions, such as Latin America, Central and Eastern Europe and Asia, which may be more susceptible to political and economic instability. Our operations in Venezuela are increasingly challenging due to instability there. 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 in particular, the new administration s opposition to free trade agreements was a significant issue in the recent election, and the possibility of significant reforms in the U.S. tax code, including the possible implementation of a border adjustment tax or other restrictions on trade could interfere with international trade in pharmaceuticals. As a company that manufactures most of its products outside the U.S., such a tax or other restriction, if enacted, may have a material adverse effect on our revenues, results of operations, and financial condition.

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.

Our executive offices and a substantial percentage of our manufacturing capabilities are located in Israel. Our Israeli operations are dependent upon materials imported from outside Israel. We also export significant amounts of products from 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 curtailed, including as a result of acts of terrorism in the United States or elsewhere.

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 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 additional 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.

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We may fail to integrate acquisitions successfully in accordance with our business strategy or achieve expected synergies and other results.

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, as occurred in the Rimsa transaction.

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 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 2016 we experienced delays in obtaining approvals for various generic and specialty products as anticipated, 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.

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 payors 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, particularly as public resources have been stretched by financial and economic crises in the United States, Western Europe and elsewhere. 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. 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. These changes frequently adversely affect pricing and profitability and may cause delays in market entry. Public scrutiny has increased political and

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other pressures on pharmaceutical pricing, further inhibiting the raising of prices, which, in many cases, had become routine. 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.

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 Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act), 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 payors. 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 administration, which had promised to repeal and replace the Affordable Care Act, took office in the United States. We cannot predict the form any such replacement of the Affordable Care Act may take, although it may have the impact of reducing the number of insureds 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.

Governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products, 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 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 s attention. Such proceedings are unpredictable and may develop over lengthy periods of time. Future settlements may involve large cash 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.

We have sold and may in the future elect to sell generic 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

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commercial factors, we may elect to sell a generic 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 more 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.

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 is likely to 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. The FTC has publicly stated that, in its view, some of the brand-generic settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies, including us, that have entered into such agreements. 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, or others, such as customers, may commence an action against us alleging violations of the antitrust laws. Such settlement agreements may further expose us to claims by purchasers of the products for unlawfully inhibiting competition. We are currently defendants in private antitrust actions involving numerous settlement agreements.

Similarly, the European Commission (EU Commission) has placed our European operations, as well as those of several brand and generic companies, under intense scrutiny in connection with its inquiry into possible anticompetitive conditions in the European pharmaceutical sector. The EU Commission has initiated proceedings

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against us in connection with one settlement agreement, and is investigating another agreement. Although we have argued that those agreements did not restrict competition, the EU Commission may rule against us, possibly imposing fines. It is also possible that the EU Commission would open investigations relating to subsequent agreements we have entered into. More generally, there is a risk that the increased scrutiny of the European pharmaceutical sector may lead to changes in the regulation of our business that would 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 attorneys general 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, 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.

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. In the normal course of our business, we are 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 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 2016, approximately 44% of our 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 (including Venezuela), 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 2016 (excluding Venezuela) in comparison with 2015 decreased revenues by $174 million and decreased operating income by $81 million. In addition, the Venezuelan bolivar exchange rates that we used and inflation-driven price increases in Venezuela increased revenues by $526 million and increased operating income by $23 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.

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For example, our net monetary balance sheet items in Venezuela, which suffers from hyperinflation, totaled negative $2 million at December 31, 2016. We impaired our monetary balance sheet items in Venezuela in March 2016, incurring financial expenses of $246 million, and further devalued our assets there in December 2016, incurring an additional charge of $500 million. As a result, if there is a further devaluation of the Venezuelan currency or if our use of our current blended DIPRO/DICOM rate in our financial statements can no longer be supported, we would incur an additional impairment charge and our financial results, including our operating results and cash flow, would be adversely affected. See Operating and Financial Review and Prospects Impact of Currency Fluctuations on Results of Operations.

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 2016 we recorded sales and expenses in various other currencies. Approximately 53% of our operating costs in 2016 were in non-USD currencies (18% in euro and 9% in NIS).

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.

The large amount of long lived assets recorded on our balance sheet has significantly increased and may continue to lead to significant impairment charges 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-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 more than doubled in the past five years to $74 billion mainly as a result of our acquisitions, including an increase of $42 billion in 2016 alone due to the consummation of the Actavis Generics, Rimsa and Anda acquisitions. For example, in 2016 we recorded impairment charges on long-lived assets of $1.6 billion, of which $0.9 billion related to the Rimsa acquisition. We may incur additional significant charges in 2017 related to the Actavis Generics acquisition or other transactions. Due to the nature of our recently acquired assets, we expect to record impairments of in-process R&D regularly in future years. Changes in market conditions or other changes in the future outlook of value may lead to further impairment charges in the future. In addition, we may from time to time sell assets that we determine are not critical to our strategy or execution. Future events or decisions may lead to asset impairments and/or related charges. 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 charges 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.

For example, in 2013, we paid the Israeli tax authorities approximately $790 million in additional income taxes, applying the provisions of Amendment 69 to the Israeli Law for the Encouragement of Capital

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Investments, 1959 to certain previously tax-exempt profits, as well as to settle tax assessments for the years 2005 to 2007. 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.

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 (such was the case when certain Israeli tax benefits were discontinued in 2014);
- we may be unable to meet the requirements for continuing to qualify for some programs;
- these programs and tax benefits may be unavailable at their current levels;
- 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.

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ITEM 4: INFORMATION ON THE COMPANY

Introduction

We are a global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic medicines and a focused portfolio of specialty medicines. We operate worldwide, with a significant presence in the United States, Europe and many other markets around the world. Our key strengths include our world-leading generics expertise and portfolio, focused specialty portfolio, robust R&D capabilities, global infrastructure and scale and dedicated leadership and employees.

We believe we are strategically positioned to benefit from market, economic and regulatory trends in global healthcare. These trends include aging populations, the increasing prevalence of chronic diseases, economic pressure on governments and private payors to provide affordable healthcare solutions, legislative and regulatory reforms, scientific and technological advances, increased patient awareness and involvement, the impact of the digital revolution on consumer healthcare, increased spending on pharmaceuticals in emerging markets and the growing importance of over-the-counter (OTC) medicines.

We operate our business in two segments:

- **Generic medicines**, which includes chemical and therapeutic equivalents of originator medicines in a variety of dosage forms, such as tablets, capsules, injectables, inhalants, liquids, ointments and creams. We are the leading generic drug company in the United States and Europe, and we have a significant presence in certain ROW markets. This segment includes our OTC business, conducted primarily through PGT, our consumer healthcare joint venture with P&G, as well as our world-leading active pharmaceutical ingredient (API) manufacturing business.

- **Specialty medicines**, which includes our core therapeutic areas of central nervous system (CNS) medicines such as Copaxone® and Azilect® and respiratory medicines such as ProAir® and QVAR®. Our specialty medicines segment also includes products in other therapeutic areas, such as Bendeka®/ Treanda® in oncology and ParaGard® in women s health.

In addition to these two segments, we have other activities, primarily sales of third-party products for which we act as distributor in the United States, Israel and Hungary.

In 2016, 55% of our revenues were generated from our generic medicines segment and 40% of our revenues were generated from specialty medicines segment.

In 2016, we generated 38% of our generic revenues in the United States, 30% in Europe and 32% in our ROW markets.

For a breakdown of our revenues and profitability by segment and by geography, see Item 5 Operating and Financial Review and Prospects Results of Operations.

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 executive offices are located at 5 Basel Street, P.O. Box 3190, Petach Tikva 4951033, Israel, and our telephone number is +972-3-926-7267. Our website is www.tevapharm.com.

Strategy

Our strategy aims to capitalize on our strengths including the largest generic medicines business in the world, a focused specialty medicines business, a global OTC business, our robust R&D and API capabilities and

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global infrastructure and scale to better address patient needs. Fundamental to our strategy are our efforts to enhance our financial profile with diversified revenue sources and profit streams, backed by strong product development engines in both generics and specialty.

Underlying our strategy is our focus on cash generation and debt repayment. As we execute our disciplined strategy, we seek to continue generating significant cash flow, which we plan to use to pay down debt and maintain our current credit ratings.

The key elements of our strategy are:

Driving continuous growth and improving profitability in our generics business. We are the leading generics company worldwide, delivering high quality generic medicines at competitive prices. Our strong legacy generics business, combined with the Actavis Generics business, has a world-leading product portfolio, comprehensive R&D capabilities, a robust product pipeline and an efficient global operational network. Our generics business includes:

- a wide-reaching commercial presence, as the market leader in the United States and a top-three leadership position in over 40 other countries;
- a global portfolio of more than 1,800 molecules, treating millions of patients every day around the world; and
- a world-leading generic pipeline that includes, as of December 31, 2016, 330 product applications awaiting FDA approval in the U.S., including 71 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. Nearly 70% of pending applications include a paragraph IV patent challenge, and we believe we are first to file with respect to 95 of these products, or 119 products including final approvals where launch is pending a settlement agreement or court decision. During 2016, we received 1,655 generic approvals in Europe, including two EMA approvals valid in 30 EU member states, and approximately 2,435 marketing authorization applications pending approval in 37 European countries, including one application pending with the EMA for four strengths in 30 countries. Our global pipeline of generic products positions us for an increasing number of first-to-file opportunities and other key generic launches, as well as further expanding our product portfolio.

This world-leading product pipeline, which includes a large number of smaller opportunities, will lessen our dependence on any single product and be critical to our growth while improving profitability in the face of the continuing price erosion expected in the generics market.

Achieving synergies from the Actavis Generics acquisition and driving efficiency and effectiveness throughout our organization. We seek to manage our business to extract the greatest benefit from synergies from the Actavis Generics acquisition. At the same time, we are expanding our cost reduction activities to continue improving the profitability of our business.

Delivering on the promise of our specialty pipeline. We seek leadership positions in our core therapeutic areas of CNS (including multiple sclerosis (MS), neurodegenerative diseases, movement disorders, pain care and migraine) and respiratory (including asthma and chronic obstructive pulmonary disease (COPD)). We have taken significant steps to leverage the existing platforms in our core therapeutic areas to develop promising pipeline assets, addressing illnesses such as MS, Huntington disease, chronic pain, migraine and severe respiratory conditions.

Maintaining Copaxone® and other key specialty products. We enhanced our MS franchise through the introduction of our three-times-a-week Copaxone® 40 mg/mL product in the United States in 2014 and in additional countries since 2015. We also enhanced our oncology portfolio with the launch of Bendeka® in January 2016, which extended our bendamustine franchise. We will continue to support

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Copaxone® and our other key products by vigorously defending our intellectual property and through patient support programs and product enhancements.

Actavis Generics and Anda Acquisitions

In August 2016, we completed our acquisition of Allergan plc s worldwide generic pharmaceuticals business (Actavis Generics). At closing, we paid Allergan consideration of approximately $33.4 billion in cash and approximately 100.3 million Teva shares. The acquisition significantly expanded our generics product portfolio and pipeline, R&D capabilities and global operational network.

In October 2016, we completed the acquisition of Anda Inc., the fourth largest distributor of generic pharmaceuticals in the United States, from Allergan plc, for $500 million in cash.

As part of the Actavis Generics acquisition, we divested certain products in the U.S. and Europe, to meet antitrust regulatory requirements. In January 2017, we completed the divestiture of certain assets and operations of Actavis Generics in the U.K. and Ireland for GBP 603 million, as required by our undertaking to the European Commission in connection with the Actavis Generics acquisition.

Other Recent Transactions

Attenukine™ out-license: In December 2016, we entered into a license agreement for research, development, manufacture and commercializing of Attenukine™ with a subsidiary of Takeda, for a $30 million upfront payment to us, with additional milestone payments of up to $280 million and royalties.

Ninlaro® out-license: In November 2016, we entered into an agreement to sell our royalties and other rights in Ninlaro® (ixazomib) to a subsidiary of Takeda, for a $150 million upfront payment to us, with additional consideration of up to $150 million dependent on future sales. We were 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.

Celltrion partnership: In October 2016, we entered into a collaborative agreement with Celltrion, Inc. 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.

Regeneron partnership: In September 2016, we entered into a collaborative agreement with Regeneron Pharmaceuticals, Inc. to develop and commercialize Regeneron s pain medication product, fasinumab. We paid Regeneron $250 million upfront and will share the global commercial benefits of this product, as well as ongoing associated research and development costs of approximately $1 billion, equally with Regeneron. Following the termination of the phase 2 clinical study for chronic low back pain in October 2016, we and Regeneron plan to design a phase 3 study in chronic low back pain that excludes patients with advanced osteoarthritis. See Specialty Medicines Central Nervous System Pipeline below.

Japanese business venture: In April 2016, we established a business venture with Takeda in Japan in which we own a 51% stake and Takeda owns the remaining 49%. The business venture combined our Japanese generics business with Takeda s portfolio of off-patent products, leveraging Takeda s leading brand reputation and strong distribution presence in Japan with our expertise in supply chain, operational network, infrastructure and R&D, to meet the wide-ranging needs of patients and growing importance of generic medicines in Japan through the provision of off-patent medicines.

Rimsa acquisition: In March 2016, we completed the acquisition of Representaciones e Investigaciones Médicas, S.A. de C.V. (Rimsa), a pharmaceutical manufacturing and distribution

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company in Mexico, for $2.3 billion. Following the closing, we identified issues concerning Rimsa s pre-acquisition quality, manufacturing and other practices. In September 2016, two lawsuits were filed: a pre-emptive suit by the Rimsa sellers against Teva, and our 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. We have conducted an assessment and recognized an impairment of $900 million and are currently executing a remediation plan in order to resume operations at the Rimsa facility. See note 2 to our consolidated financial statements.

Our Segments

Generic Medicines

Overview

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 regulations as their brand-name equivalents offered or sold by the originator, 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.

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, narcotics, high-potency drugs and cytotoxic substances, in both parenteral and solid dosage forms.

In August 2016, we completed the Actavis Generics acquisition. Our strong legacy generics business, combined with the Actavis Generics business, has a world-leading product portfolio, comprehensive R&D capabilities, robust product pipeline and an efficient global operational network. The combined generic business has a wide-reaching commercial presence, as the market leader in the United States and a top three leadership position in over 40 countries, including some of our key European markets. The combined business benefits from a leading and diverse pipeline of products, which will help us continue executing key generic launches and further expand our product pipeline, focusing on both large and small opportunities. We expect that a larger number of smaller but more durable launches will help offset expected price erosion while diversifying our revenue stream.

Through coordination between our global portfolio, business development and global R&D teams, we seek to achieve and maintain market leadership in all markets where we strategically choose to operate. In particular, we seek to establish a leadership position in high-barrier, complex products, while continuing to pursue patent challenge opportunities and early launches globally.

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 recommendations, manufacturing capabilities, regulatory considerations, commercial factors and the intellectual property landscape. We will challenge patents if we believe they are either invalid or would not be infringed by a generic version. We may seek alliances to acquire rights to products we do not have in our portfolio or to otherwise share development costs or litigation risks, or to resolve patent and regulatory barriers to entry.

One of our top priorities is to increase the profitability of our generics business, by placing a strong emphasis on the cost of goods sold, product mix and overall cost structure. We have also prioritized the most important markets for us to do business. We expect these efforts to continue and improve as we integrate the Actavis Generics business.

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Sales of generic medicines have benefitted from increasing awareness and acceptance on the part of healthcare insurers and institutions, consumers, physicians and pharmacists globally. 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. Further, in countries as diverse as France and Japan, governments have issued regulations designed to increase generic penetration. These conditions also result in intense competition in the generic market, with generic companies competing for advantage based on pricing, time to market, reputation, customer service and breadth of product line. We believe that these factors, together with an aging population, an increase in global spending on healthcare, economic pressure on governments to provide less expensive healthcare solutions, legislative and regulatory reforms and a shift of decision-making power to payors, will lead to our continued expansion in the global generic market, as well as increased competition. We believe that our robust product pipeline, which has been enhanced with the Actavis Generics business, and ability to continuously launch new products are critical to our growth in the face of continuing price erosion expected in the generics market.

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 or patients have little control over the choice of generic manufacturer, and consequently generic medicines are not actively marketed or promoted to physicians. 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 contrast, in Russia, Ukraine, Kazakhstan, some Asian and Latin American countries as well as certain European markets, generic medicines are generally sold under brand names alongside the originator brand. In many of these branded generic markets, pharmacists dispense the specific medicine prescribed by the physician, and substitution between originator brand, branded generic and/or generic manufacturers is often limited without the physician s consent. In some of these markets, branded generic products are actively promoted and a sales force is necessary. 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 own products.

In most markets in which we operate, we use an integrated and comprehensive marketing model, offering a portfolio of generic, specialty and OTC products.

OTC

We have a global OTC business, primarily through PGT, our consumer healthcare joint venture with P&G, formed in 2011. PGT manufactures and markets more than 200 consumer healthcare brands, including OTC medicines and vitamins, minerals and food supplements, in more than 70 countries around the world. Its portfolio includes the leading cough and cold brand Vicks®, Germany s leading OTC brand, ratiopharm, and other leading brands.

We own 49% and P&G owns 51% of the joint venture, which incorporates the two companies OTC businesses outside of North America and benefits from both companies core strengths and capabilities. The joint venture combines the consumer brand-building capabilities of P&G with Teva s pharmaceutical supply, regulatory and development capabilities. The two companies combined efforts through PGT facilitate expansion into new countries and categories, enabling PGT to quickly reach a significant number of consumers.

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PGT s growth strategy includes the following:

- Building on the Vicks® franchise and other leading multi-country respiratory brands where it has a strong presence, to increase its presence in the areas of cough, cold and nasal decongestion;
- Leveraging our generic capabilities under brands like ratiopharm, which offers quality, affordable OTC healthcare in Germany, to broaden its portfolio and expand to new markets;
- Expanding its vitamin, mineral and supplement product portfolio globally, in collaboration with Swisse Wellness, Australia s market-leading wellness brand; and
- Developing existing local brands that have market leading potential in individual or groups of countries.

APIs

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 peptides 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.

Below is a description of our generic medicines business by the main geographic areas in which we operate:

United States

We are the leading generic drug company in the United States. We market over 500 generic products in more than 2,000 dosage strengths and packaging sizes, including oral, injectable and inhaled products. We believe that the breadth of our product portfolio provides us with a strategic advantage, particularly as the market is impacted by consolidation that continues among purchasers, including large drugstore chains, wholesaling organizations and buying groups. Our growth strategy focuses on a broad portfolio of products and a large and diverse pipeline that will provide added value to our patients, payors and customers, utilizing new and advanced technologies.

We seek to continue our U.S. market leadership based on our ability to introduce new generic equivalents for brand-name products on a timely basis, with a focus on complex generics and other high-barrier products that we believe will create more value for patients and customers, our strong emphasis on customer service, the breadth of our product line, our commitment to quality and regulatory compliance and our cost-effective production, including through our recent acquisition of Actavis Generics, which has substantially expanded our generics operations and pipeline.

In the United States, we are subject to intense competition in the generic drug market from domestic and international generic drug manufacturers, brand-name pharmaceutical companies through lifecycle management initiatives, authorized generics, existing brand equivalents and manufacturers of therapeutically similar drugs. Price competition from additional generic versions of the same product typically results in margin pressures. We believe that our primary competitive advantages are our ability to continually introduce new and complex generic equivalents for brand-name drug products on a timely basis, our quality, our customer service and the breadth of our product portfolio.

Almost all of our U.S. generic sales are made to retail drug chains and wholesalers, which continue to undergo significant consolidation and globalization. Our portfolio selection, breadth of product offerings and our global network capabilities have provided mutually beneficial strategic advantages to both our customers and us. We believe that, with our global landscape and presence, we are best suited to match our customers needs for scale. We are committed to the success of our customers and work closely with them as important business partners.

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In the United States, our wholesale and retail selling efforts are supported by participating in key medical and 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 generics through partnerships and digital marketing programs.

For information about our pipeline of generic medicines in the United States, see Item 5 Operating and Financial Review and Prospects Segment Information Generic Medicines Segment.

Europe

We define our European region as 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 25 markets across Europe. No single market in Europe represents more than 25% of our total European generic revenues, and as a result 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.

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 it is in the U.S. market. We are one of a few companies with a pan-European footprint. Most competitors focus on a select few markets or business lines.

Our strategy for generic medicines in Europe is to seek sustainable and profitable growth by differentiated investment levels in different countries. While building on our global knowledge and resources and strong market position, we are able to understand and adapt to the local needs of our patients, payors and customers. In parallel, we seek to enhance the efficiency of our operations by selectively investing in markets, optimizing our existing portfolio and pricing, and rigorously controlling cost. We closely monitor the disciplined execution of our strategy to further increase the value realized by our European generic business while maintaining our market leadership position in key countries.

The European market continues to be ever more competitive, especially in terms of pricing, higher quality standards, customer service and portfolio relevance. Our leadership position provides us a solid base to be reliable partners to fulfill the needs of patients, physicians, pharmacies, customers and payors.

For information about our pipeline of generic medicines in the Europe, see Item 5 Operating and Financial Review and Prospects Segment Information Generic Medicines Segment.

Key market highlights

Germany is the largest European pharmaceutical market. We are the second largest provider in the overall generics market, and our ratiopharm brand continues to be a leader in the retail generics segment. Germany has a hybrid market, partially driven by prescriptions of physicians and partially by tenders with increasing price pressure. We participate in both segments; however, we compete on tenders only if they can generate sustainable value to the business.

We believe that our balanced presence and strong track record with new launches are competitive advantages for us over most companies in Germany.

In the **United Kingdom**, we are one of the largest suppliers by volume to the National Health Service, supplying one in every five generic prescriptions dispensed, focusing on major retail chains as well as independent pharmacies.

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The United Kingdom is a pure generic market with low barriers to entry and very high generic penetration. In general, retail pricing of generics to pharmacies is unregulated (thus prices can increase or decrease), leading to very strong price competition. Pricing is heavily influenced by government regulations, such as Scheme M that limits pharmacies reimbursement profit.

Customers and wholesalers are highly vertically integrated, which further drives competition in terms of pricing. Pharmaceutical companies seek differentiation strategies to maximize value in a market where prices are already among the lowest in Europe, while quality and reliability of medicine has become the driver of competitive advantage.

In January 2017, we completed the divestiture of certain assets and operations of Actavis Generics in the U.K. and Ireland, as part of our undertaking to the European Commission in connection with the Actavis Generics acquisition.

In **Italy**, we continue to be a generic market leader, supplying about 20% of the country s generic medicines. The market is concentrated, with the top five players holding approximately 86% of market share. Generic penetration is low compared to most other European countries and is currently growing at a slow pace, although pharmacists have increasing influence to substitute with generics.

We aim to benefit from any increases in the total value of the generic market in Italy as we seek to further strengthen our leadership position and our presence in pharmacies. The Teva brand is increasingly recognized among patients, pharmacists and physicians alike.

In **Switzerland** we are the largest supplier in the generics market. We offer a comprehensive portfolio and own the leading brand in the generic retail segment. Generic penetration is relatively low in Switzerland, and the generic market is concentrated with the top two suppliers holding about 70% of the market share. Pricing measures of the government for originator products are increasing the pressure on prices also for generic pharmaceuticals. We aim to further strengthen our leadership in the generic market as well as to maintain our position as the second largest supplier in the overall retail pharmaceutical market, by leveraging our brand power, using quality and service as competitive advantages, being the preferred partner in the generic market and promoting generic substitution in pharmacies.

In **Poland** we are the second largest supplier in the generics market. Our portfolio covers both branded generic products as well as OTC products. While generic penetration in Poland is high, the rate of untreated population remains higher than average compared to other Western European markets.

In **France**, we continue to see strong pricing pressures and increased generic penetration due to government measures. We are focused on a selective approach to generate sustainable and profitable business that is customer centered.

The market in **Spain** was characterized in 2016 by further government pricing and reimbursement reforms which increased generic penetration. Our strategy in Spain is to compete for sustainable and profitable business in this market.

Rest of the World Markets

Our ROW markets include all countries other than the United States and those included under Europe. Our key ROW markets are Venezuela, Japan, Canada and Russia. The countries in this category range from highly regulated, pure generic markets such as Canada and Israel, to hybrid markets such as Japan and Brazil, to branded generics oriented markets such as Russia and certain Commonwealth of Independent States (CIS), Latin American markets and Asia Pacific markets.

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Our ROW strategy is to be selective as to where we do business, focusing on the countries and segments where we can achieve a significant position. Over time and with the right opportunities, we intend to expand our presence in markets such as China and Brazil and enhance our existing presence in other high growth markets such as Russia, Mexico, South Korea, Australia and Turkey. In other markets, we will optimize our existing assets and may minimize or divest our operations.

As part of this strategy, we acquired Rimsa, a pharmaceutical manufacturing and distribution company in Mexico, in March 2016. Following the closing, we identified issues concerning Rimsa s pre-acquisition quality, manufacturing and other practices. We have conducted an assessment and recognized an impairment of $900 million, and are currently executing a remediation plan in order to resume operations at the Rimsa facility.

Key market highlights

We operate in **Venezuela** with a product portfolio consisting mainly of branded generic medicines and OTC products. Venezuela is a hyperinflationary economy, and the financial outlook there remains challenging and uncertain. In November 2016, the unofficial exchange rate increased at an accelerated rate, indicating further economic distress. This development, together with a decrease in scope of transactions involving the importation, manufacture and distribution of pharmaceutical products that were settled using the DIPRO rate of 10 bolivars per dollar, led us to replace the official DIPRO rate we had used to report our Venezuelan financial position, results of operations and cash flows with a blended exchange rate of 273 bolivar per dollar. See Item 5 Operating and Financial Review and Prospects.

In April 2016, we established a business venture with Takeda in **Japan**. We own a 51% stake and Takeda owns 49% in the business venture. The business venture combined our Japanese generics business with Takeda s portfolio of off-patent products, leveraging Takeda s leading brand reputation and strong distribution presence in Japan with our expertise in supply chain, operational network, infrastructure and R&D. This business venture meets the wide-ranging needs of patients and growing importance of generics in Japan through the provision of off-patent medicines. We are one of the top three generics companies in Japan.

Japan is one of the largest and fastest growing generic pharmaceutical markets in the world. The generics market is expected to continue growing over the next several years due to government incentive programs targeted at both physicians and dispensing channels and due to patent expirations of major drugs.

Following the Actavis Generics acquisition, we are the leading generic pharmaceutical company in **Canada** in terms of prescriptions and sales, offering a broad portfolio of medicines. We aim to maintain our leading market position, grow our portfolio strategically and continue to drive first-to-market opportunities.

We market generic products to retail chains, retail buying groups and independent pharmacies, reaching approximately 8,800 outlets. We also market solid dose and injectable medications to hospitals and hospital buying groups across the country. We continue to see consolidation of independent retail pharmacies and increased expansion of retail chains and buying groups, with the top four retail chains in Canada now representing approximately 65% of the market (in terms of value). These larger corporate retailers work closely with selected suppliers, listing products as part of a chain-wide formulary. We continue to experience increased government pressure on pricing. Customers look to generic suppliers to timely launch cost effective generic products, maintain high levels of product availability and provide increased levels of overall customer value and service.

In Canada, the competitive landscape continues to intensify with the increasing presence of multinational companies. The top five manufacturers satisfy over 80% of the Canadian demand for generic pharmaceuticals. In addition, the major branded pharmaceutical companies have intensified their efforts to compete with the generic players, and are now offering incentives to patients and customers to offset generic cost savings.

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In **Russia**, which is primarily a branded generic market, we market a diverse portfolio of products. We are currently one of the top five pharmaceutical companies and the largest generics company in Russia, operating in the commercial retail (branded generics and OTC), hospital and state funded segments.

The Russian government seeks to increase the share of domestically produced pharmaceutical products by implementing a policy to encourage local production to meet state and local needs. In order to take advantage of this policy, we established a manufacturing facility in Yaroslavl, Russia, which became operational in 2016.

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 pain care including migraine) and respiratory medicines (with a focus on asthma and chronic obstructive pulmonary disease). We also have specialty products in oncology, women s health and selected other areas.

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 U.S. 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 and to our market and stakeholders needs.

Our specialty medicines organization focuses on our key therapeutic areas and selected local opportunities, with medical and sales and marketing professionals within each area who seek to address the needs of patients and healthcare professionals. We tailor our patient support, payor relations and medical affairs activities to the distinct characteristics of each therapeutic area and medicine.

Our U.S. specialty medicines revenues were $6.7 billion in 2016, comprising the most significant part of our specialty business. In 2016, our European specialty medicines revenues were $1.6 billion and our ROW specialty medicines revenues were $352 million. In Europe and our ROW markets, we leverage existing synergies with our generics and OTC businesses through integrated in-market structures. Our specialty presence in ROW 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 a specialized capability 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, known as Patient Support Programs, reflect the importance we place on supporting patients and are a critical part of our success. While originally focused on supporting MS patients in the United States, we have expanded this capability to other regions and therapeutic areas. We currently operate Patient Support Programs in 35 countries around the world in multiple therapeutic areas. We believe that we can provide a range of services and solutions appropriately tailored to meet the needs of patients according to their specific condition and local market requirements. We believe this capability provides us with an important competitive advantage in the specialty medicines market.

Below is a description of our key therapeutic areas, products and pipeline:

Central Nervous System Medicines

Our CNS portfolio, one of our two core therapeutic areas, includes Copaxone® for the treatment of relapsing forms of multiple sclerosis and Azilect® for the treatment of the symptoms of Parkinson s disease, as well as several other medicines.

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Copaxone® (glatiramer acetate injection) is the leading multiple sclerosis therapy in the United States and worldwide. Copaxone® is indicated for the treatment of patients with relapsing forms of multiple sclerosis (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 multiple sclerosis.

Multiple sclerosis is the most common cause of neurological disability in young adults and affects more than 2.5 million people worldwide. In the majority of patients, the disease is of the relapsing-remitting form, which is manifested by relapses and slow progression of the disease that can affect the functioning of multiple systems. Our MS portfolio consists of Copaxone® as well as laquinimod, a phase 3 investigational compound currently under development.

Copaxone®, the first non-interferon immunomodulator approved for the treatment of RRMS, 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.

Our U.S. Orange Book patents covering Copaxone® 20 mg/mL expired in May 2014. Our patents on Copaxone® 20 mg/mL expired in May 2015 in most of the rest of the world.

Accordingly, a key part of our strategy has been the introduction of Copaxone® 40 mg/mL, a higher dose of Copaxone® with a three times a week dosing regimen for patients with RRMS, which was launched in the United States in January 2014. This formulation allows for a less-frequent dosing regimen administered subcutaneously for patients with relapsing forms of MS. In December 2014, we received European Medicines Agency (EMA) approval in a decentralized procedure for Copaxone® 40 mg/mL in Europe. In December 2016, we received approval to remove the pregnancy contraindication from the European label for Copaxone®. To date, we have launched Copaxone® 40mg/mL in most of our European markets. Copaxone® 40 mg/mL has also launched in Australia, Argentina, Canada, Chile, Colombia, Hong Kong, Israel, Russia, South Korea and Ukraine. We expect to receive marketing approvals in other ROW markets during 2017.

Copaxone® 40 mg/mL was protected by five U.S. Orange Book patents that expire in 2030. All of the claims of three of those patents were declared to be unpatentable by the U.S. Patent Office in inter parties review (IPR) proceedings, and we have appealed those decisions. In addition, a petition for an IPR has been filed against a fourth Orange Book patent; a decision on whether the Patent Office will move forward with this proceeding is expected by May 2017. These four patents have also been challenged in paragraph IV litigation in the United States. A trial was held in the United States District Court for the District of Delaware, and in January 2017 the court held that the asserted claims of these four patents were invalid. We have appealed this decision; however, it is possible that certain competitors may receive FDA approval and launch before either appeal is decided. The fifth Orange Book patent, which was issued in August 2016, is being challenged in a separate paragraph IV litigation in the United States. We have also filed suit against multiple ANDA filers to assert a non-Orange Book process patent in various jurisdictions. Copaxone® 40 mg/mL is also protected by one European patent expiring in 2030.

As of December 31, 2016, over 84% of the total U.S. Copaxone® prescriptions and over 67% of the total European Copaxone® prescriptions were filled with the 40 mg/mL version, driven by patient and physician choice of the 40 mg/mL version supported by payor access and patient support activities.

Copaxone® accounted for $4.2 billion (including $3.5 billion in the U.S.), or 19% of our revenues in 2016, and contributed a significantly higher percentage to our profits and cash flow from operations during such period.

The market for MS treatments continues to change as a result of new and emerging therapies as well as a generic version of Copaxone® 20 mg/mL in the U.S. and follow-on products in some European countries and

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potential competing purported generic versions of Copaxone® 40 mg/mL following the court ruling invalidating four Copaxone® 40 mg/mL patents in January 2017. In particular, the increasing number of oral treatments, such as Tecfidera® by Biogen, Gilenya® by Novartis, and Aubagio® by Genzyme, continue to present significant and increasing competition. Copaxone® also continues to face competition from existing injectable products, such as five beta-interferons Avonex®, Plegridy®, Betaseron®, Extavia® and Rebif®, as well as from monoclonal antibodies such as Tysabri®, Lemtrada® and Zinbryta®.

Azilect® (rasagiline tablets) is indicated as initial monotherapy and as an adjunct to levodopa for the treatment of the signs and symptoms of Parkinson s disease, the second most common neurodegenerative disorder.

Azilect® is a second-generation, irreversible monoamine oxidase type B (MAO-B) inhibitor. Although other symptom-reducing therapies are available, many of them have efficacy, safety and tolerability concerns.

We exclusively market Azilect® in the United States, but generic competition commenced in January 2017. In Europe, we shared marketing rights with Lundbeck until the end of 2015, when the initial period of our agreement with Lundbeck ended and all marketing rights reverted to us. We continue to share marketing rights with Lundbeck in certain of our ROW markets. Data exclusivity protection for Azilect® in the EU expired in 2015.

Azilect® s competitors include both specialty and generic versions of the newer non-ergot dopamine agonists class, including Mirapex®/Sifrol® (pramipexole), Requip® (ropinirole) and Neupro® (rotigotine), which are indicated for all stages of Parkinson s disease, as well as Comtan®, a COMT inhibitor, indicated only for adjunct therapy in moderate to advanced stages of the disease.

Nuvigil® (armodafinil), the R-isomer of modafinil, is indicated for the treatment of excessive sleepiness associated with narcolepsy and certain other disorders. Generic competition from several manufacturers began in mid-2016.

Our CNS portfolio also includes: Actiq® (fentanyl oral transmucosal lozenge) for the treatment of breakthrough pain in opioid-tolerant adult patients with cancer; and Amrix® (cyclobenzaprine hydrochloride extended-release capsules) in the United States, for relief of muscle spasm in acute, painful, musculoskeletal conditions.

Central Nervous System Pipeline

Our clinical pipeline of ***neurology*** and ***neuropsychiatry*** products includes:

Products	Potential Indication(s)	Route of Administration	Development Phase (date entered phase 3)
SD-809 (deutetrabenazine)	Chorea associated with Huntington disease	Oral	NDA re-submitted in U.S. (October 2016)
	Tardive dyskinesia		3 (October 2014)
	Tourette syndrome		1
Laquinimod	Relapsing remitting multiple sclerosis	Oral	3 (February 2013)
	Progressive forms of multiple sclerosis		2
	Huntington disease		2
Pridopidine	Huntington disease	Oral	2

SD-809 (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. SD-809 was granted Orphan Drug Designation by the FDA for the treatment of chorea associated with

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Huntington disease in November 2014 and we expect to be granted seven years of orphan drug exclusivity. The SD-809 NDA submission for the treatment of chorea associated with Huntington disease was accepted for filing by the FDA in August 2015 based on positive results from two phase 3 studies (FIRST-HD and ARC-HD). We re-submitted the NDA in October 2016 following the receipt of a complete response letter from the FDA in May 2016.

SD-809 is also currently in clinical development for the treatment of tardive dyskinesia. Results from the pivotal phase 3 clinical study AIM-TD (Addressing Involuntary Movements in Tardive Dyskinesia) demonstrated all doses improved AIMS scores compared to placebo.

A phase 3 clinical study of SD-809 for the treatment of Tourette syndrome is planned to commence in 2017.

SD-809 is protected by patents expiring in 2029 in Europe and in 2031 in the United States.

Laquinimod is a once-daily, orally administered immunomodulatory compound being developed for treatment of relapsing-remitting and progressive forms of multiple sclerosis. We have the exclusive rights to develop, register, manufacture and commercialize laquinimod worldwide, in return for an upfront payment and possible future milestone payments and royalties.

In 2012, we submitted a Marketing Authorization Application to the EMA and a New Drug Submission to Health Canada following completion of two phase 3 studies in 2011. In 2014, the EMA confirmed that the risk-benefit profile of laquinimod is not favorable. The ongoing phase 3 CONCERTO trial (laquinimod versus placebo using confirmed disability progression as the primary endpoint) is intended to further address the risk-benefit profile of laquinimod. In addition, we are conducting studies to address nonclinical findings noted by the Committee for Medicinal Products for Human Use (CHMP) and clarify the molecular mechanism of action.

In January 2016, we discontinued the highest dose of laquinimod in all studies after the occurrence of cardiovascular events (none of which were fatal) in eight patients receiving the highest doses in the CONCERTO trial and in the other ongoing study for progressive forms of multiple sclerosis. The studies are continuing with the lower- and mid-dosages. On January 31, 2017, laquinimod was granted orphan-drug designation for the treatment of Huntington Disease by the FDA s Office of Orphan Products Development.

Laquinimod is protected by patents expiring in 2019 worldwide, with potential for extensions in various markets.

Pridopidine is an oral small molecule dopamine stabilizer being developed for the symptomatic treatment of motor disorders (including Huntington disease). Results from the phase 2 Pride-HD clinical study demonstrated an unusually high placebo effect, which limited the ability to determine the effect of treatment on Huntington disease motor scores. However, evidence of symptomatic impact was seen in the early stage Huntington patient sub-population, with improvement in total motor score and dystonia observed at 26 and 52 weeks in this patient sub-set (stage 1 Huntington disease) at specific doses. A phase 3 clinical study of pridopidine is planned to commence in 2017. We expect to be granted seven years of orphan drug exclusivity in the U.S. for this product.

Pridopidine is protected by patents worldwide that expire in 2020, with potential for extension in various markets.

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Our clinical pipeline of ***migraine*** and ***other pain products*** includes:

Migraine and Pain Products	Potential Indication(s)	Route of Administration	Development Phase (date entered phase 3)
Vantrela ER	Pain	Oral	Approved in U.S. (January 2017)
TEV-48125 (anti CGRP) (fremanezumab)			
	Chronic and episodic migraine		3 (February 2016)
		Subcutaneous	
	Cluster headache		3 (November 2016)
TV-46763 (abuse deterrent)	Pain	Oral	3 (July 2015)
TV-46139 (abuse deterrent)	Pain	Oral	1
Fasinumab	Osteoarthritis pain		3 (March 2016)
	Chronic lower back pain		2
TV-45070 Topical	Neuropathic pain	Topical	2

Vantrela ER is our formulation of hydrocodone, an opioid analgesic, utilizing OraGuard®, our proprietary abuse deterrence technology platform that has been evaluated for resistance to physical manipulations, chemical extractions and multi-step chemical extraction methods.

Vantrela ER was approved by the FDA in January 2017 with abuse-deterrent properties that are expected to reduce, but not totally prevent, oral, intranasal and intravenous abuse of the drug when the tablets are manipulated.

Vantrela ER is protected by patents in Europe that expire in 2027 and in the United States that expire in 2029.

TEV-48125 (anti CGRP) (fremanezumab) is a fully humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP). Fremanezumab is being developed for the prevention of chronic and high frequency episodic migraine. In the phase 2b trial, Fremanezumab met both primary and secondary endpoints in episodic migraine, achieving highly significant reductions in mean monthly migraine days and monthly headache days relative to baseline. Phase 3 clinical development for chronic and episodic migraine was initiated in February 2016.

Fremanezumab is also in phase 3 clinical development to evaluate its safety and efficacy in the treatment of chronic and episodic cluster headache. The clinical study was initiated in February 2016.

Fremanezumab is protected by patents expiring in 2026 in Europe and in 2027 in the United States.

TV-46763 and ***TV-46139*** are two pain products with potential abuse-deterrent properties, developed using our OraGuard® technology platform. Phase 3 clinical development is in progress for TV-46763 while TV-46139 remains in early clinical development.

Fasinumab is 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. In September 2016, we entered into collaboration with Regeneron to develop and commercialize fasinumab. Fasinumab is currently in phase 3 clinical development for osteoarthritis pain.

The phase 2 clinical study for chronic low back pain was discontinued in October 2016 after observing a case of adjudicated arthropathy in a patient receiving high dose fasinumab who had advanced osteoarthritis at study entry. Regeneron completed an unplanned interim review of results, which demonstrated efficacy with improvement in pain scores in all fasinumab groups compared to placebo at the 8- and 12-week time points. Regeneron and Teva plan to design a pivotal phase 3 study in chronic low back pain that excludes patients with advanced osteoarthritis.

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Fasinumab is protected by patents expiring in 2028, and will also be protected by regulatory exclusivity of 12 years from marketing approval in the U.S. and 10 years from marketing approval in Europe.

TV-45070 Topical is a small molecule intended to treat pain locally at its source through blocking of Nav1.7 and Nav1.8 sodium channels, which are found in sensory nerve endings that can increase in chronic painful conditions. TV-45070 was licensed from Xenon Pharmaceuticals Inc. in December 2012. TV-45070 has been studied in human subjects in both oral and topical forms in neuropathic and inflammatory diseases. In an early study, oral TV-45070 was shown to be effective at relieving the pain associated with the rare neuropathic pain condition, erythromelalgia. In a phase 2 trial to evaluate effectiveness in alleviating the pain of post-herpetic neuralgia, topical TV-45070 led to significantly more meaningful reductions in pain as compared to placebo. TV-45070 is currently in phase 2 clinical development for neuropathic pain.

TV-45070 is protected by patents in Europe that expire in 2026 and in the United States that expire in 2028.

Respiratory Medicines

Our respiratory portfolio, one of our two core therapeutic areas, includes ProAir®, QVAR®, DuoResp Spiromax®, Qnasl®, Braltus® and Cinqair®/Cinqaero®.

We are committed to maintaining a leading presence in the respiratory market, our second core therapeutic area, by delivering a range of medicines for the treatment of asthma and chronic obstructive pulmonary disease (COPD). Our portfolio is centered on optimizing respiratory treatment for patients and healthcare providers through the development of novel 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, including a novel product for add-on maintenance treatment of patients with severe asthma. 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. Our proprietary inhalation technology tidal inhaler allows a person suffering from asthma or COPD to inhale their medication by breathing normally into the tidal inhaler device. We are developing a range of inhaled medicines for use in the tidal inhaler. See Respiratory Pipeline for more information on our tidal inhaler.

Below is a description of our main respiratory medicines:

ProAir® includes ProAir® hydrofluoroalkane (HFA) and ProAir® RespiClick®, both sold only in the United States.

ProAir® (albuterol sulfate) HFA 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. In March 2012, the FDA approved the addition of a dose counter, an innovation designed to help patients, as well as their caregivers, keep track of the number of doses remaining in the inhaler. The efficacy and safety profile of albuterol, which is used by millions of patients every day around the world, is well established, while HFA is an environmentally friendly propellant. ProAir® HFA is the leading quick relief inhaler in the United States. It is protected by various patents expiring between 2017 and 2028. In June 2014, we settled a patent challenge to ProAir® HFA with Perrigo Pharmaceuticals permitting Perrigo to launch its generic product in limited quantities once it receives FDA approval and without quantity limitations after June 2018.

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.

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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-activated, multi-dose, dry powder, short-acting beta-agonist inhaler available in the U.S. ProAir® Respiclick® is protected by various U.S. Orange Book patents expiring between 2017 and 2031.

Three major brands compete with ProAir® HFA and ProAir® Respiclick® in the United States in the short-acting beta agonist market: Ventolin® HFA (albuterol) by GlaxoSmithKline, Proventil® HFA (albuterol) by Merck and Xopenex® HFA (levalbuterol) by Sunovion.

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 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 U.S. We market QVAR®, which is manufactured by 3M, in the United States and in major European markets. QVAR® is protected by various U.S. Orange Book patents in the United States expiring between 2017 and 2031.

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

The actuator with dose counter used in connection with ProAir® HFA and QVAR® is protected by patents and applications expiring between December 2017 and May 2031.

DuoResp Spiromax® (budesonide/formoterol) is a combination of an inhaled corticosteroid and a long acting beta-agonist bronchodilator, and was approved for treatment of adults with asthma and COPD in Europe by the EMA in a centralized procedure. DuoResp Spiromax® is protected in Europe by patents expiring between 2017 and 2031. First launched in the EU in June 2014, DuoResp Spiromax® has been successfully introduced in 18 European markets.

The main competitors for DuoResp Spiromax® are Symbicort® Turbuhaler® (budesonide/formoterol) by AstraZeneca, Seretide® (fluticasone propionate/salmeterol) by GlaxoSmithKline and Foster® (beclomathasone/formoterol) by Chiesi.

Our respiratory portfolio also includes **Qnasl®** Nasal Aerosol (beclomethasone dipropionate HFA in a nasal actuator), for the treatment of seasonal and year-round nasal allergy symptoms in the United States.

In August 2016, we launched **Braltus®** (tiotropium bromide), a long-acting muscarinic antagonist, indicated for adult patients with COPD, delivered via the Zonda® inhaler.

Aerivio Spiromax® (fluticasone/salmeterol 500/50) was developed pursuant to EU guidance to achieve the same clinical outcomes as Seretide® Accuhaler®. Bioequivalence was demonstrated for the high strength product, which was approved in Europe in August 2016 and launched in January 2017.

Aerivio Spiromax® is protected by patents and applications expiring between June 2021 and October 2034.

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 for add-on maintenance treatment of patients with severe eosinophilic asthma aged 18 years and older. This biologic treatment became commercially available to patients

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in the U.S. in April 2016, began launching in individual European countries in November 2016 and is expected to launch in Canada in 2017. Additional regulatory filings have been submitted in other global markets.

Cinqair® is protected by patents in the United States that expire in 2017. We have requested extension of one of the patents until 2021. Cinqair® has biological exclusivity in the United States until 2028. We also expect the product to be entitled to 10 years regulatory exclusivity in Europe beginning on the date of approval. A subcutaneous version is in development (see below).

One major brand competes with Cinqair®/Cinqaero® in the United States, Europe and Canada in the IL-5 market: Nucala® (mepolizumab) by GlaxoSmithKline.

Respiratory Pipeline

The key areas of focus for respiratory R&D include development of differentiated respiratory therapies for patients using novel delivery systems and an emerging portfolio of biologic therapies.

Our novel delivery systems include:

- An advanced breath-actuated inhaler (BAI);
- Spiromax® (EU) or RespiClick® (US), a novel inhalation-driven multi-dose powder inhaler (MDPI); and
- Tidal inhaler, a unique nebulization device currently being evaluated for use in early stage development programs.

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.

Our devices and delivery systems are protected by the following patents and applications:

- The BAI device is protected by applications and patents expiring between June 2021 and July 2031.
- The Spiromax® (EU) or RespiClick® (US) device is protected by patents and applications expiring between June 2021 and October 2034.
- The tidal inhaler device is protected by patents and applications expiring between February 2025 and April 2036.

Our clinical pipeline of respiratory projects includes:

Respiratory Products	Potential Indication(s)	Route of Administration	Development Phase (date entered phase 3)
Cinqair®/Cinqaero® (reslizumab)	Severe asthma with eosinophilia	Subcutaneous	3 (August 2015)
QVAR® BAI US	Asthma, COPD	Oral inhalation	Submitted (October 2016)
ArmonairTM RespiClick® (Fluticasone Propionate MDPI US)	Asthma	Oral inhalation	Approved in U.S. for adults (January 2017)

AirduoTM RespiClick® (Fluticasone Salmeterol MDPI US)	Asthma	Oral inhalation	Approved in U.S. for adults (January 2017)
TV-44664 (Fluticasone Salmeterol DPI)	Asthma, COPD	Oral inhalation	1

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Cinqair®/ Cinqaero® (reslizumab) injection, is a humanized interleukin 5 antagonist monoclonal antibody for add-on maintenance treatment of adult patients with severe asthma and with an eosinophilic phenotype.

The phase 3 clinical program for the subcutaneous reslizumab product was initiated in August 2015 and is ongoing.

QVAR® BAI US (beclomethasone) is an oral aerosol corticosteroid in development for the treatment of asthma for ages four years and older. The BAI device is the next generation of our QVAR® product. It contains the same small particle aerosol formulation as the existing QVAR® in a breath-actuated device. The phase 3 clinical program was initiated in December 2013 and completed in mid-2016. The product was submitted to the FDA in October 2016.

The QVAR® BAI US product is protected by device patents and applications expiring between June 2021 and June 2030. The actuator with dose counter is protected by patents and applications expiring between December 2017 and July 2030.

Armonair™ RespiClick® (Fluticasone Propionate MDPI US) is a new formulation of long acting inhaled corticosteroid (ICS) using our multi-dose powder inhaler device, with an enhanced lung delivery designed to allow lower doses to achieve the same clinical outcomes as Flovent® Diskus.

Airduo™ RespiClick® (Fluticasone Salmeterol MDPI US) is a new formulation of ICS/LABA using our multi dose powder inhaler device, designed to achieve comparable efficacy to Advair® Diskus at lower doses.

Phase 3 clinical trial results for Fluticasone Salmeterol MDPI US received in November 2015 demonstrated clinically relevant and greater benefit at all doses compared to placebo and versus respective monotherapy (fluticasone propionate) in the improvement of lung function.

Both Armonair™ RespiClick® and Airduo™ RespiClick® were approved by the FDA in January 2017 and are protected by the device patents and applications noted above.

TV-44664 (Fluticasone Salmeterol DPI) is a long acting beta2-agonist and an inhaled corticosteroid combined for the treatment of asthma in patients 4 years of age and older. The TV-44664 phase 1 pivotal clinical study to demonstrate therapeutic equivalency to Advair® was initiated in November 2016.

Oncology

Our oncology portfolio includes Treanda®/ Bendeka® Granix® and Trisenox® in the United States and Lonquex®, Tevagrastim®/Ratiograstim® and Trisenox® outside the United States.

Treanda® / Bendeka® (bendamustine hydrochloride injection) are approved in the United States for the treatment of patients with chronic lymphocytic leukemia and patients with indolent B-cell non-Hodgkin s lymphoma 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 to complement our Treanda® franchise. Bendeka® is now the most-used bendamustine product on the U.S. market. The lyophilized formulation of Treanda® continues to be available, but its use has substantially declined in favor of Bendeka®.

Bendeka® s competitors 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 also newer targeted oral therapies, ibrutinib and idelilisib.

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We have U.S. Orange Book patents for Treanda® expiring between 2026 and 2031. To date, one company has filed a 505(b)(2) NDA for a liquid version of bendamustine, and 19 others have filed ANDAs for a generic version of the lyophilized form of Treanda®. All of these filings included patent challenges, which we are contesting. Trial against five of the 19 ANDA filers began in December 2015. In June 2016, the court issued a decision affirming the validity of certain claims of the patents. We have reached final settlements with 17 of the 19 ANDA filers, which provide for launch of generics prior to patent expiration.

Filgrastim (branded as **Tevagrastim®** (in the EU) and **Granix®** (in the U.S.)) and **Lonquex®** (lipegfilgrastim) are Granulocyte Colony Stimulating Factor (G-CSF) medicines that stimulate the production of white blood cells and are primarily used to reduce the risk of infections in oncology patients receiving chemotherapy.

Tevagrastim® (short-acting G-CSF) was the first biosimilar G-CSF to be approved by the EU in September 2008. Based on clinical trials, Tevagrastim® has been approved in the EU for multiple indications and is available in most European countries. Tevagrastim® is also marketed as Ratiograstim® and Biograstim® in the EU.

Granix® (short-acting G-CSF) was the first new G-CSF to be approved in the United States in more than ten years and was approved via a Biologics License Application by the FDA in 2012 and launched in November 2013. Granix® is not considered a biosimilar in the United States. The product is also approved and available in Japan and certain other markets. In December 2014, the FDA also approved Granix® injection for self-administration by patients and caregivers.

Lonquex® (long-acting G-CSF) is a G-CSF with the active ingredient lipegfilgrastim, a glycoPEGylated (PEG; polyethylene glycol) filgrastim molecule. This is the first long-acting G-CSF to be approved in Europe in more than ten years and offers a new alternative in G-CSF therapy. Lonquex® was launched in November 2013 in Germany and has since been launched in 22 additional European countries. Lonquex® is protected by patents expiring in 2024 in Europe, with extension to 2028 in several countries.

Competitors to Teva s filgrastim include short acting G-CSF products such as Neupogen® and Zarxio®, which was launched in September 2015 in the United States, and in Europe, also Zarxio/Zarzio® and Nivestim®. Several additional competing short-acting G-CSF biosimilars are expected to launch in 2017 in the United States, and the first long-acting G-CSF biosimilars are also expected to begin launching in the United States and Europe in 2017.

Oncology Pipeline

Our clinical pipeline of oncology products includes ***CT-P10 (biosimilar to Rituxan ® US) and CT-P6 (biosimilar to Herceptin® US)***. In October 2016, we entered into an exclusive biosimilar partnership with Celltrion, to commercialize two proposed monoclonal antibodies (mAb) in the U.S. and Canada. CT-P10 is a biosimilar to Rituxan® (rituximab) and CT-P6 is a biosimilar to Herceptin® (trastuzumab). Pivotal phase 3 clinical development is currently in progress for both products.

Women s Health

Our women s health portfolio includes ParaGard® and Plan B One-Step® OTC/Rx (levonorgestrel), along with other products that are marketed in various countries.

ParaGard® (intrauterine copper contraceptive) is a non-hormonal intrauterine contraceptive marketed in the United States. ParaGard® provides women with a highly effective, long-term, reversible, non-hormonal contraceptive option. It is the only intrauterine contraceptive approved for up to ten years of continuous use and is more than 99% effective at preventing pregnancy. ParaGard® faces competition from oral contraceptives, as well as intrauterine devices like Mirena®, Kyleena and Skyla® by Bayer, Liletta® by Allergan and patches and vaginal hormonal contraceptive rings like NuvaRing® by Merck.

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Plan B One-Step® OTC (levonorgestrel) is an emergency oral contraceptive which consists of a single tablet dose of levonorgestrel for emergency contraception. Plan B One-Step® is intended to prevent pregnancy when taken within 72 hours after unprotected intercourse or contraceptive failure. Plan B One-Step® has several generic competitors. However, in June 2013, it became the first FDA-approved emergency contraceptive to be available without age or point of sales restrictions. We are the only company that has conducted actual use and label comprehension studies required by the FDA, demonstrating that adolescents can understand how to use Plan B One-Step® just as well as adults.

Changes to Other Pipeline Projects During 2016

During 2016, development of the following pipeline projects was either discontinued or transferred:

Fluticasone Salmeterol (MDI) EU Development discontinued.

SD-560 Development discontinued.

TV-44649 (Budesonide Formoterol HFA MDI) Product development activities transferred to generic R&D.

CEP-41750 (Mesenchymal Precursor Cell, Revascor®) Rights for both cardiovascular products returned by Teva to Mesoblast in June 2016.

TEV-90110, TEV-90111, TEV-90112 and TEV-90113 Development discontinued.

Other Activities

We have other sources of revenues, primarily sales of third-party products for which we act as distributor, mostly in the United States, as well as in Israel and Hungary, sales of medical devices, contract manufacturing services related to products divested in connection with the Actavis Generics acquisition and other miscellaneous items. Our other activities are not included in our generics and specialty segments described above.

In the United States, we distribute generic, specialty and OTC pharmaceutical products from more than 300 third party manufacturers, as well as our own products, to independent retail pharmacies, pharmacy retail chains, hospitals and physician offices, through our recently acquired Anda business. Anda s strategic focus is primarily as a supplier that augments a customer s primary wholesale supplier, which means that we can experience high volatility in demand for these distribution services, depending on the performance of the primary suppliers. Anda is able to compete in the secondary distribution market by maintaining high inventory levels for a broad offering of products, next day delivery throughout the United States, competitive pricing and high-level customer service.

Research and Development

Our research and development activities span the breadth of our business, including generic medicines (finished goods and API), specialty pharmaceuticals, innovation of existing molecules (new therapeutic entities, or NTEs) and OTC medicines.

Generics

A major area of focus is the development of new generic medicines. We develop generic products in all therapeutic areas. Our emphasis is on developing high-value products, such as those with complex technologies and formulations which thus 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 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 1,500 generic products in our global pipeline.

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

In recent years, we have built additional R&D capabilities beyond tablets, capsules, liquids, ointments and creams to 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 injectables, transdermal patches, oral thin film, drug device combinations and nasal delivery systems. We have also started the development of multiple AB-rated respiratory programs.

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 drugs and our proprietary drugs. Our facilities include four large development centers: a center in Israel focusing on synthetic products and peptides, a center in Hungary specializing in fermentation and semi-synthetic products and centers in India and Croatia, both focusing on synthetic products. Three additional smaller sites are located in Italy, Mexico and the Czech Republic for development of high-potency APIs. Our substantial investment in API R&D generates a steady flow of API products, enabling 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.

Specialty

Our specialty R&D product pipeline is focused on novel small molecule and biologic products, biosimilar products, innovation of existing molecules as well as discovery of new small molecule and 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, multiple sclerosis and neuropsychiatry. Our respiratory projects are focused on asthma and COPD and include novel compounds and novel 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.

Our commitment to innovate existing molecules in our core therapeutic areas remains a significant channel to build our pipeline. These projects include NTEs as well as deuterated molecules. NTEs are known molecules that are formulated, delivered or used in a novel way to address unmet patient needs (such as adherence, compliance, efficacy and safety). In deuterated molecules, hydrogen atoms are selectively replaced with deuterium atoms to create carbon deuterium bonds that are potentially more resistant to metabolic breakdown than their corresponding carbon hydrogen bond. Deuteration can enable changes in metabolic properties that can potentially lead to improved clinical outcomes.

We continue to evaluate in-licensing, acquisition and partnership opportunities to supplement and expand our specialty pipeline (e.g., the Regeneron, Celltrion and Eagle transactions) to create and maintain a robust global pipeline. In parallel, we continue to evaluate and expand the development scope of our existing R&D pipeline products as well as our existing products for submission in additional markets.

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Operations

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

- global research and development facilities that enable us to have a leading global generic pipeline and a broad generic product line globally, as well as a strong pipeline of specialty products in our key therapeutic areas;
- 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;
- 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 69 finished dosage and packaging pharmaceutical plants in 35 countries, including 22 finished dosage manufacturing sites and two packaging sites acquired as part of the Actavis Generics acquisition. These plants manufacture solid dosage forms, sterile injectables, liquids, semi-solids, inhalers, transdermal patches and medical devices. In 2016, we produced approximately 88 billion tablets and capsules and 720 million sterile units. The FDA has approved 36 of our finished dosage manufacturing facilities and we have 30 finished dosage manufacturing facilities approved by EMA authorities.

Our two primary manufacturing technologies, solid dosage forms and injectables, are available in North America, Europe, Latin America and Israel. The manufacturing sites located in Israel, Germany, Hungary, Croatia, Bulgaria and the Czech Republic comprise the majority of our production capacity.

We continue to implement our ongoing Operational Excellence program to optimize our manufacturing efficiency, to maintain our goal of supplying high quality, cost-competitive products on a timely basis to our customers globally. In 2016, we closed our manufacturing facilities in Pomona, NY (U.S.), Sens and Nevers (France), as well as two API facilities in Guayama (Puerto Rico) and Humacao (Puerto Rico). We are in the process of closing additional facilities and, in light of the Actavis Generics acquisition, are reviewing other potential sites for restructuring. Additional facilities, specifically Iceland, Malta, Corona (California) and Singapore, are planned for closure throughout 2017 and early 2018. Our network restructuring plan aims at further optimizing and consolidating our manufacturing footprint, yielding higher efficiency and reducing costs and capital expenditures.

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.

During 2016, we continued to invest in our manufacturing capabilities, focusing on strategic growth areas, including building a modified release parenteral facility in Croatia and initiating construction of a biologics facility in Ulm, Germany. We continue to evaluate our capabilities and capacity utilization to ensure efficient alignment with our ability to deliver the highest quality products.

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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.

Our principal pharmaceutical manufacturing facilities in terms of number of employees in Teva Global Operations (TGO), as of December 31, 2016, are listed below:

Location	Total Number of TGO Employees	Principal Market(s) Served
Goa, Mumbai and Amendabad, India	2,959	North America, Europe and other markets
Debrecen, Hungary	1,594	Europe and other non-U.S. markets
Ulm, Germany	1,425	Europe and other non-U.S. markets
Sophia and Dupnitsa, Bulgaria	1,419	North America, Europe and other markets
Opava, Czech Republic	1,394	North America, Europe and other markets
Zagreb, Croatia	1,292	North America, Europe and other markets
Ramat Hovav, Israel (3 sites)	1,228	North America, Europe and other markets
Kfar Saba, Israel	1,225	North America, Europe and other markets
Takayama, Japan	1,154	Japan
Nerviano, Milano and Santhia, Italy (3 sites)	853	North America, Europe and other markets
Jerusalem, Israel	852	North America, Europe and other markets
Xochimilco, Toluca and Guadalajara, Mexico (3 sites)	836	Latin America
Davies, Florida, U.S.	780	North America
Bulebel and Hal Far, Malta	660	North America, Europe and other markets
Krakow, Poland	612	North America, Europe and other markets
Godollo, Hungary	609	Europe and other markets
Puerto Rico (2 sites)	556	North America
Salt Lake City, Utah, U.S. (2 sites)	554	North America, Europe and other markets
Santiago, Chile	481	Latin America
Canada (3 sites)	468	North America, Europe and other markets
Leskovac, Serbia	458	Europe and other non-U.S. markets
Waterford, Ireland	449	North America, Europe and other markets
Haarlem, Netherlands	408	North America, Europe and other markets
Zaragoza, Spain	393	Europe and other non-U.S. markets
Runcorn, U.K.	375	North America, Europe and other markets
Cincinnati, Ohio, U.S.	370	North America
Forest, Virginia, U.S.	368	North America
Jakarta, Indonesia	350	Europe and other non-U.S. markets
Lima, Peru	283	Latin America
Buenos Aires, Argentina	210	Latin America

Raw Materials for Pharmaceutical Production

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 take a global approach to managing our commercial relations with these suppliers.

We currently have 20 API production facilities, including one acquired as part of the Actavis Generics acquisition, producing approximately 300 APIs in various therapeutic areas. Our API intellectual property portfolio includes approximately 600 granted patents and pending applications worldwide.

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We have expertise in a variety of production technologies, including chemical synthesis, semi-synthetic fermentation, enzymatic synthesis, high-potency manufacturing, plant extract technology, and 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.

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 or other authorities as applicable.

Environment, Health and Safety

We are committed to business practices that promote socially and environmentally responsible economic growth. During 2016, we continued to make significant progress on our multi-year plan to move closer to our long-term environment, health and safety (EHS) vision of Target Zero : zero incidents, zero injuries and zero releases. Among other things, in 2016 we:

- completed the development and continued the implementation of our global EHS management system, which promotes proactive compliance with applicable environment, health and safety requirements, establishes minimum expectations throughout our global operations and helps drive continuous improvement in our EHS performance;
- provided EHS regulatory surveillance tools for all countries where we have significant operations;
- proactively evaluated EHS compliance through self-evaluation and an internal audit program, addressing non-conformities through appropriate corrective and preventative action whose progress is tracked; and
- established targets to reduce the environmental impact of our operations, through energy and water conservation, recycling and reuse of waste products.

Quality

We are committed not only to complying with quality requirements but to developing and leveraging quality as a competitive advantage. In 2016, we successfully completed numerous inspections by regulatory agencies of our finished dosage pharmaceutical plants, 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, as part of our corporate culture and behavior, ensuring that quality is reflected in all environments to enable reliable and high quality products.

Following an FDA inspection earlier this year, we voluntarily discontinued all manufacturing activities at our facility in Godollo, Hungary, in order to assess and remediate quality concerns. In May 2016, the FDA issued a U.S. import alert for all products from this facility, which can only be lifted after the FDA confirms regulatory compliance. On October 14, 2016, we received a warning letter from the FDA, which cites deficiencies in manufacturing operations, laboratory controls and data integrity. We have currently decided to reduce our operations from this facility.

Following the closing of the Rimsa transaction, we identified issues concerning Rimsa s pre-acquisition quality, manufacturing and other practices. Therefore, in September 2016, we filed a lawsuit alleging fraud and breach of contract against the sellers of Rimsa. Rimsa s sellers also filed a lawsuit seeking a declaratory judgment against Teva, which was dismissed in February 2017. We have conducted an assessment and are currently executing a remediation plan in order to resume operations at the Rimsa facility.

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Organizational Structure

Teva is organized into two commercial business units that work in coordination with each other: the Global Generic Medicines group and the Global Specialty Medicines group. This structure is designed to ensure full integration of our operating units in accordance with our global strategy.

The Global Generic Medicines group is responsible globally for all generic and OTC commercial activities. This includes generic R&D portfolio management and selection, product launch and commercial execution. Bringing all of our regional generic businesses under one organization highlights our strong focus on, and commitment to, our generic business.

The Global Specialty Medicines group continues to drive organic growth with a strong pipeline of patient-centric solutions and by introducing new brands through focused business initiatives. Building on existing expertise and incorporating innovative technology, the group works to continue to enhance patient experience in our leading therapeutic areas.

In addition, our activities are conducted by several global divisions: (i) Teva Global Operations, which includes Teva Global Quality, (ii) Teva Global R&D, and (iii) global support functions including Finance, Legal, Information Technology, the Business Development Strategy and Innovation Group, Human Resources and the Corporate Marketing and Communications Group.

Teva Global Operation s responsibilities include development, manufacturing and commercialization of APIs, manufacturing of pharmaceuticals, quality assurance, procurement and supply chain. Teva Global Quality is charged with ensuring the reliable supply of quality, cost-effective medicines from our global network of sites in compliance with all relevant standards.

Teva Global R&D is responsible for research and development of specialty products and includes regulatory affairs and pharmacovigilance.

Our worldwide operations are conducted through a network of global subsidiaries. We have direct operations in many countries around the world, including commercial activities, pharmaceutical manufacturing sites, API sites and R&D centers. The following sets forth our principal operating subsidiaries based on revenues, as of December 31, 2016:

Name of Subsidiary*	Country
Teva Pharmaceuticals USA, Inc.	United States
Actavis Pharma, Inc.	United States
Teva API Inc.	United States
Teva Santé SAS	France
ratiopharm GmbH	Germany
Teva GmbH	Germany
TEVA Pharmaceutical Works Private Limited Company	Hungary
Teva Italia S.r.l.	Italy
Teva Pharma S.L.	Spain
Teva API B.V.	The Netherlands
Teva UK Limited	United Kingdom
Teva Canada Limited	Canada
Teva Takeda Pharma Ltd.	Japan
Teva Takeda Yakuhin Ltd.	Japan
Teva Limited Liability Company	Russia

* All listed subsidiaries are 100% owned by Teva, except for Teva Takeda Pharma Ltd. in which Takeda has a 49% ownership interest, and TEVA Pharmaceutical Works Private Limited Company, which has a very small minority interest.

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Properties and Facilities

Listed below are our principal facilities and properties in various regions of the world and their size in square feet as of December 31, 2016:

Facility Location	Square Feet (in thousands)	Main Function
Israel		
Ramat Hovav	1,448	API manufacturing and R&D
Kfar Saba	738	Pharmaceutical manufacturing, research laboratories, warehousing, and offices
Jerusalem (3 sites)	546	Pharmaceutical manufacturing, research laboratories and offices
Shoham Logistics Center	538	Distribution center
Netanya (2 sites)	468	API manufacturing, pharmaceutical warehousing, laboratories, distribution center and offices
Petach Tikva	380	Corporate headquarters
Ashdod	153	Manufacturing of hospital supplies
Assia Petach Tikva	118	R&D laboratories
United States		
North Wales area, PA (4 sites)	847	Teva USA headquarters, warehousing and distribution center
Olive Branch, MS	499	Offices
Forest, VA	450	Manufacturing, packaging and offices
West Chester, PA (6 buildings)	392	Laboratories and offices
Gurnee, Ill.	370	Distribution
Irvine, CA (7 buildings)	362	Pharmaceutical manufacturing and R&D laboratories
Elizabeth, NJ	355	Distribution center
Salt Lake City, UT (3 buildings)	347	Offices, manufacturing and R&D laboratories
Salt Lake City, UT (4 buildings)	331	Manufacturing, warehouse, R&D, packaging
Cincinnati, OH	305	Pharmaceutical manufacturing, R&D laboratories and packaging
Weston, FL	240	Warehousing, manufacturing, offices
Fajardo, Puerto Rico	234	Distribution center
Mexico, MO	204	API manufacturing
Overland Park, KS	204	Offices
Corona, CA (3 buildings)	198	Manufacturing, warehouse, R&D
Frazer, PA	188	Offices
Miami, FL (5 buildings)	168	Manufacturing
Miami, FL (3 buildings)	157	Manufacturing, R&D laboratories, warehousing and offices
Groveport, OH	152	Distribution center
Parsippany, NJ	128	Offices
Canada		
Toronto, Ontario	448	Offices, pharmaceutical packaging, warehousing, distribution center and laboratories
Stouffville, Ontario	155	Pharmaceutical manufacturing and R&D laboratories
Markham, Ontario	127	Pharmaceutical manufacturing and warehousing

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Facility Location	Square Feet (in thousands)	Main Function
Europe		
Debrecen, Hungary (3 sites)	2,529	Pharmaceutical manufacturing, API manufacturing, R&D laboratories and warehousing
Godollo, Hungary (4 sites)	2,189	Pharmaceutical manufacturing, hospital supplies manufacturing, R&D laboratories, distribution center, packaging and warehousing
Ulm, Germany (3 sites)	1,510	Pharmaceutical manufacturing, warehousing and offices
Opava, Czech Republic	1,485	Pharmaceutical and API manufacturing, warehousing and distribution center
Krakow, Poland	939	Pharmaceutical manufacturing and warehousing
Dupnista, Bulgaria	685	Pharmaceutical manufacturing
Zagreb, Croatia (5 sites)	643	Pharmaceutical manufacturing, packaging and warehousing, API manufacturing and R&D laboratories
Weiler, Germany	521	Pharmaceutical manufacturing and packaging
Sofia, Bulgaria (4 sites)	485	Offices
Leskovac, Serbia	455	Manufacturing and warehousing
Savski Marof, Croatia	448	API manufacturing
Waterford, Ireland (3 sites)	433	Pharmaceutical manufacturing, warehousing and packaging
Schimitari, Greece	410	Pharmaceutical manufacturing
Haarlem, The Netherlands (3 sites)	327	Pharmaceutical manufacturing and offices
Zaragoza, Spain (3 sites)	325	Pharmaceutical manufacturing, R&D laboratories
Nerviano, Italy (2 sites)	320	Pharmaceutical manufacturing, R&D laboratories and office
Sajababony, Hungary	283	Mixed use
Troyan, Bulgaria	277	Pharmaceutical manufacturing
Runcorn, England (2 sites)	261	Pharmaceutical manufacturing, warehousing, laboratories and offices
Hafnarfjordur, Iceland (2 sites)	256	Pharmaceutical manufacturing and offices
Zejtun, Malta	256	Pharmaceutical manufacturing, warehousing and offices
Glasshoughton, England	255	Warehousing and distribution center
Barnstaple, England*	200	Manufacturing and offices
Santhiâ, Italy	177	API manufacturing, R&D laboratories and warehousing
Amsterdam, The Netherlands	176	Distribution center and offices
Eastbourne, England	163	Warehousing and packaging
Birzebbugia, Malta (2 sites)	159	Pharmaceutical manufacturing and warehousing
Asia		
Gajraula (U.P.), India	1,200	API manufacturing
Takayama, Japan	1,035	Pharmaceutical manufacturing
Hangzhou, China	609	API manufacturing
Goa, India (2 sites)	584	Pharmaceutical manufacturing, wearhousing and R&D laboratories

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Facility Location	Square Feet (in thousands)	Main Function
Ahmedabad, India	327	OTC manufacturing, packaging, warehousing and laboratories
Sanand, India	327	Pharmaceutical manufacturing
Ambernath, India (2 sites)	312	API manufacturing and R&D laboratories
Malanpur, India	302	API manufacturing
Koka, Japan	289	Pharmaceutical manufacturing
Nagoya, Japan (2 sites)	256	Offices
Bangalore, India (4 sites)	134	R&D laboratories
Latin America		
Guadalajara, Mexico	1,038	Manufacturing and distribution
Santiago, Chile (4 sites)	414	Pharmaceutical manufacturing, warehousing and R&D laboratories
Mexico City, Mexico	344	Pharmaceutical manufacturing, warehousing and R&D laboratories
Munro, Argentina	298	Pharmaceutical manufacturing, warehousing, R&D laboratories and packaging
Lima, Peru (3 sites)	273	Pharmaceutical manufacturing, offices, warehousing and R&D laboratories
Ramos Arizpe, Mexico	110	Pharmaceutical manufacturing

* This facility was sold in January 2017 as part of the divestment of certain assets and operations of Actavis Generics in the U.K. and Ireland, as part of our undertaking to the European Commission in connection with the Actavis Generics acquisition.

We lease certain of our facilities. In Israel, our principal executive offices and corporate headquarters in Petach Tikva are leased until December 2020. In North America, our principal leased properties are the facilities in North Wales and Frazer, Pennsylvania, which have lease terms expiring 2022. We own and lease various other facilities worldwide.

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 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 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.

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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, 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. 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.

The Best Pharmaceuticals for Children Act, signed into law in 2002, continues the so-called pediatric exclusivity program established by the FDA Modernization Act of 1997. This pediatric exclusivity program provides a six-month period of extended exclusivity, applicable to certain listed patents and to other regulatory exclusivities for all formulations of an active ingredient, if the sponsor performs and submits pediatric studies

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requested by the FDA within specified timeframes. An effect of this program has been to delay the launch of numerous generic products by an additional six months.

The Medicare Prescription Drug, Improvement and Modernization Act (the Medicare Modernization Act) of 2003 modified certain provisions of the Hatch-Waxman Act. Under the Medicare Modernization Act, the 180-day period of generic exclusivity rights may be forfeited under certain specified circumstances. In 2012, Congress passed legislation to create a generic drug user fee program (GDUFA) in order to augment the FDA s congressional appropriations. User fee funding is anticipated to be sufficient to eliminate the backlog of ANDAs pending with the FDA by the end of fiscal year 2017 as well as provide for improved review performance over the statute s five-year period. Additionally, generic drug user fees are intended to bring parity between the U.S. and foreign inspections by 2017 in order to ensure a consistent standard of quality for all drugs intended for the U.S. market. In July 2012, Congress also passed legislation that allowed the FDA to continue to collect user fees for brand products and new user fee programs for biosimilar products.

The passage of the Food and Drug Administration Amendments Act in 2007 strengthened the FDA s regulatory authority on post-marketing safety and granted the agency greater authority to control drug marketing and labeling, to require post-approval studies, to establish active surveillance systems, and to make clinical trial opportunities and results more available to the public. Another provision, as amended, provides for a 150 day period for the FDA to respond to citizen petitions submitted to the FDA that could delay the approval of generic applications. A key provision also allows the FDA to require a risk evaluation and mitigation strategy for drugs associated with greater safety risks.

The Generic Drug Enforcement Act of 1992 established penalties for wrongdoing in connection with the development or submission of an ANDA by authorizing the FDA to permanently or temporarily debar such companies or individuals from submitting or assisting in the submission of an ANDA, and to temporarily deny approval and suspend applications to market generic drugs. The FDA may suspend the distribution of all drugs approved or developed in connection with wrongful conduct and also has authority to withdraw approval of an ANDA under certain circumstances. The FDA may also significantly delay the approval of a pending NDA or ANDA under its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Policy. Manufacturers of generic drugs must also comply with the FDA s cGMP regulations or risk sanctions such as the suspension of manufacturing or the seizure of drug products and the FDA s refusal to approve additional ANDAs.

In November 2013, the FDA proposed a rule that would require generic manufacturers to participate in the Changes Being Effected process to initiate labeling changes for generic medicines without prior FDA approval. If adopted, the rule would allow different labels to be in use at the same time. Currently, generic and brand drug labeling must be the same except for exceptions explicitly designated by statute. If the rule were to become final as proposed, our potential product liability exposure could increase.

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 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. Of this portfolio, Tev-Tropin® and Granix® are sold in the United States, while others are distributed outside of the United States. 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.

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Healthcare Reform and Certain Government Programs

In 2010, the United States Congress enacted the Patient Protection and Affordable Care Act (the PPACA). The PPACA seeks to reduce the federal deficit and 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. The PPACA 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. Other components of healthcare reform include funding of pharmaceutical costs for Medicare patients in excess of the prescription drug coverage limit and below the catastrophic coverage threshold. Under the PPACA, pharmaceutical companies are obligated to fund 50% of the patient obligation for branded prescription pharmaceuticals in this gap, or donut hole. Additionally, commencing in 2011, an excise tax was levied against certain branded pharmaceutical products. The tax is specified by statute to be approximately $3 billion in 2012 through 2016, $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. In 2017, a new administration which had promised to repeal and replace the PPACA, took power. We cannot predict the form any such replacement of the PPACA may take, although it may have the impact of reducing the number of insured as well as coverage for pharmaceutical products. In addition, while no changes are expected in the Medicare coverage gap discount program, there may be changes to the pharmaceutical excise tax and the Medicaid rebate structure, as well as other regulations affecting the pharmaceutical industry.

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.

In addition, the PPACA 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, effective on October 1, 2016, 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.

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 2016, we continued to register products in the EU, 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.

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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 whole of the European market.

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, 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. Teva is working to ensure it has that the necessary infrastructure in place to ensure there is no disruption to its supply chain when the regulations take effect in 2019.

In connection with the Actavis Generics acquisition, we made a number of commitments to the European Commission to divest certain Actavis Generics assets and operations. Transfer of the marketing authorizations to the respective buyers is an important step in meeting these commitments, but regulatory submissions will also be required to transfer production of the finished product to the buyer in many cases. We are working with the regulators to separate certain marketing authorizations to be transferred to the buyers from other linked authorizations, which we are retaining, a process that is expected to take 3-5 years to complete.

European Union

The medicines regulatory framework of the EU 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 EU. 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 EU 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 EU may prevent companies from applying for marketing approval for a generic product for eight (or ten years for orphan medicinal products) from the date of the first market authorization of the original product in the EU. 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 EU 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 research and development work during the patent term for the purpose of developing and submitting registration dossiers.

Rest of the World Markets

Japan

The registration of existing or new generic drugs in Japan is subject to Pharmaceutical and Medical Device Agency approval and requires carrying out local bioequivalence studies, as well as upholding stringent quality, stability and stable supply requirements. Generic prices are regulated by the Ministry of Health, Labor and Welfare and are set at 40%-50% of the equivalent branded drug prices, depending on the number of competitors. Generic drug prices are company specific, reflecting the actual net selling price by a company and are subject to ongoing price reductions of approximately 8-10% every two years.

The Japanese government provides comprehensive healthcare coverage, and the majority of healthcare expenditure is funded by the government. In order to control growing healthcare costs, the Japanese regulator adopted a coordinated policy to promote the use of generic drugs by utilizing a series of targeted incentive programs. The government s stated goal is to reach at least 70% generic penetration by mid-2017. In every second year since April 2010, new financial incentive schemes are established, encouraging pharmacies to substitute branded drugs with generics and doctors to prescribe generic drugs. The next reform, currently scheduled for April 2018, is expected to further increase generic penetration.

Canada

The Canadian Federal Government, under the Food and Drugs Act and the Controlled Drug and Substances Act, regulates the therapeutic products that may be sold in Canada and the applicable level of control. The Therapeutic Products Directorate (TPD) is the national authority that evaluates and monitors the safety, effectiveness and quality of drugs, medical devices and other therapeutic products. The TPD requires companies to make an abbreviated new drug submission in order to receive approval to manufacture and market generic pharmaceuticals.

The issuance of a market authorization or Notice of Compliance is subject to the Food and Drug Regulations, which provide, among other things, up to eight and one-half years of data exclusivity for innovative new drugs not previously approved for sale in Canada. Issuance of a Notice of Compliance for generic drug products is also subject to the Patented Medicines (Notice of Compliance) Regulations under the Patent Act. The TPD will not issue a Notice of Compliance if there are any relevant patents listed on the Patent Register maintained by Health Canada, which were listed prior to the filing of the generic submission. Generic pharmaceutical manufacturers can serve a Notice of Allegation (NOA) upon the brand company and, as is frequently the case, the brand company may commence litigation in response to the NOA. In such cases a Notice of Compliance will not be issued until the earlier of the expiration of the automatic 24-month stay or resolution of the litigation in the generic company s favor.

Every province in Canada offers a comprehensive public drug program for seniors, persons on social assistance, low-income-earners, and those with certain specified conditions or diseases, and regulates the reimbursement price of drugs listed on their formularies. Formulary listings are also used by private payors to reimburse generic products. To be listed in a provincial formulary, drug products must have been issued a Notice of Compliance and must comply with each jurisdiction s individual review process. Most provinces in Canada have implemented price reforms aimed at reducing the reimbursement price of generic products. Canadian

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provinces have been working separately and collectively to effect price reforms on a select number of high volume generic products. Ontario and Quebec, which represent 60% of the Canadian market, have implemented regulations limiting trade allowances paid to pharmacy customers, and Quebec requires generic companies to report the details of all such transactions.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by Health Canada and the Health Products and Food Branch Inspectorate. In addition, Health Canada conducts pre-approval and post-approval reviews and plant inspections to determine whether systems are in compliance with the good manufacturing practices in Canada, Drug Establishment Licensing requirements and other provisions of the Food and Drug Regulations. Competitors are subject to similar regulations and inspections.

Russia

Implementation of the 2020 pharmaceutical sector strategy continues to be a priority of the Russian government. The strategy emphasizes localization of production and aims to harmonize the Russian pharmaceutical regulations with international principles and standards.

Russian pricing regulations impose price restrictions on pharmaceuticals listed on the Essential Drug List (EDL). In accordance with this legislation, EDL manufacturers cannot sell pharmaceuticals listed on the EDL unless their prices have been registered with the healthcare regulator. Since August 2015, pricing regulation has been supervised by the Federal Antimonopoly Service of the Russian Federation, which resulted in stricter scrutiny.

As part of the sector strategy, prescription of pharmaceuticals based on INN has been mandatory since 2013, and cGMP requirements have been mandatory since 2014.

To support local manufacturing, foreign-made products may be deemed ineligible under the Russian procurement system if at least two locally manufactured analogous products are available.

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 processing of personal data throughout 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 worldwide 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.

ITEM 4A: UNRESOLVED STAFF COMMENTS

None.

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ITEM 5: OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Introduction

Overview

We are a global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic medicines and a focused portfolio of specialty medicines. We operate worldwide, with a significant presence in the United States, Europe and many other markets around the world. Our key strengths include our world-leading generics expertise and portfolio, focused specialty portfolio, robust R&D capabilities, global infrastructure and scale and dedicated leadership and employees.

We believe we are strategically positioned to benefit from market, economic and regulatory trends in global healthcare. These trends include aging populations, the increasing prevalence of chronic diseases, economic pressure on governments and private payors to provide affordable healthcare solutions, legislative and regulatory reforms, scientific and technological advances, increased patient awareness and involvement, the impact of the digital revolution on consumer healthcare, increased spending on pharmaceuticals in emerging markets and the growing importance of OTC medicines.

Segments

We operate our business in two segments:

- **Generic medicines**, which includes chemical and therapeutic equivalents of originator medicines in a variety of dosage forms, such as tablets, capsules, injectables, inhalants, liquids, ointments and creams. We are the leading generic drug company in the United States and Europe, and we have a significant presence in certain ROW markets. This segment includes our OTC business, conducted primarily through PGT, our consumer healthcare joint venture with P&G, which we now include in the generics segment as a result of an analysis following the acquisition of Actavis Generics. Also included in this segment is our API manufacturing business.

- **Specialty medicines**, which includes our core therapeutic areas of CNS medicines such as Copaxone® and Azilect® and respiratory medicines such as ProAir® and QVAR®. Our specialty medicines segment also includes products in other therapeutic areas, such as Bendeka®/Treanda® in oncology and ParaGard® in women s health.

In addition to these two segments, we have other activities, primarily sales of third-party products for which we act as distributor in the United States, Israel and Hungary.

Strategy

Our strategy aims to capitalize on our strengths including the largest generic medicines business in the world, a focused specialty medicines business, a global OTC business, our robust R&D and API capabilities and global infrastructure and scale to better address patient needs. Fundamental to our strategy are our efforts to enhance our financial profile with diversified revenue sources and profit streams, backed by strong product development engines in both generics and specialty.

Underlying our strategy is our focus on cash generation and debt repayment. As we execute our disciplined strategy, we seek to continue generating significant cash flow, which we plan to use to pay down debt and maintain our current credit ratings.

The key elements of our strategy are:

- ***Driving continuous growth and improving profitability in our generics business.*** We are the leading generics company worldwide, delivering high quality generic medicines at competitive prices. Our

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strong legacy generics business, combined with the Actavis Generics business, has a world-leading product portfolio, comprehensive R&D capabilities, a robust product pipeline and an efficient global operational network. Our generics business includes:

- a wide-reaching commercial presence, as the market leader in the United States and a top-three leadership position in over 40 other countries;
- a global portfolio of more than 1,800 molecules, treating millions of patients every day around the world; and
- a world-leading generic pipeline that includes, as of December 31, 2016, 330 product applications awaiting FDA approval in the U.S., including 71 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. Nearly 70% of pending applications include a paragraph IV patent challenge, and we believe we are first to file with respect to 95 of these products, or 119 products including final approvals where launch is pending a settlement agreement or court decision. During 2016, we received 1,655 generic approvals in Europe, including two EMA approvals valid in 30 EU member states, and approximately 2,435 marketing authorization applications pending approval in 37 European countries, including one application pending with the EMA for four strengths in 30 countries. Our global pipeline of generic products positions us for an increasing number of first-to-file opportunities and other key generic launches, as well as further expanding our product portfolio.

This world-leading product pipeline, which includes a large number of smaller opportunities, will lessen our dependence on any single product and be critical to our growth while improving profitability in the face of the continuing price erosion expected in the generics market.

Achieving synergies from the Actavis Generics acquisition and driving efficiency and effectiveness throughout our organization. We seek to manage our business to extract the greatest benefit from synergies from the Actavis Generics acquisition. At the same time, we are expanding our cost reduction activities to continue improving the profitability of our business.

Delivering on the promise of our specialty pipeline. We seek leadership positions in our core therapeutic areas of CNS (including MS, neurodegenerative diseases, movement disorders, pain care and migraine) and respiratory (including asthma and COPD). We have taken significant steps to leverage the existing platforms in our core therapeutic areas to develop promising pipeline assets, addressing illnesses such as MS, Huntington disease, chronic pain, migraine and severe respiratory conditions.

Maintaining Copaxone® and other key specialty products. We enhanced our MS franchise through the introduction of our three-times-a-week Copaxone® 40 mg/mL product in the United States in 2014 and in additional countries since 2015. We also enhanced our oncology portfolio with the launch of Bendeka® in January 2016, which extended our bendamustine franchise. We will continue to support Copaxone® and our other key products by vigorously defending our intellectual property and through patient support programs and product enhancements.

Highlights

Significant highlights of 2016 included:

In August 2016, we completed our acquisition of Actavis Generics. The acquisition had a significant impact on our generic medicines segment, expanding our product portfolio and pipeline, R&D capabilities and global operational network.

Our revenues were $21.9 billion, compared to $19.7 billion in 2015, up 11%.

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Revenues of our generic medicines segment were $12.0 billion, up 14%, and profit was $3.3 billion, up 13%. Our higher revenues and profit in 2016 were mainly due to the inclusion of five months of Actavis Generics revenues in 2016 and our new business venture with Takeda, which commenced operations in April 2016, partially offset by losses of exclusivity and increased competition on certain products in the U.S.

Revenues of our specialty medicines segment were $8.7 billion, up 4%, and profit was $4.7 billion, up 7%. In local currency terms, revenues increased 5%. Our higher revenues and profit in 2016 were mainly due to higher net pricing of Copaxone®.

In January 2017, the U.S District Court for the District of Delaware held that four of our patents covering Copaxone® 40mg/mL that were challenged in paragraph IV litigation were invalid. We intend to appeal this decision; however, it is possible that certain competitors may receive FDA approval and launch competing 40mg/mL generic products before the appeal is decided.

Expenses related to impairments, restructuring and others were $699 million, compared to $1.1 billion in 2015, mainly due to a gain related to divestments of products in connection with the Actavis Generics acquisition and lower contingent consideration, partially offset by impairments of Revascor® and Zecuity® in 2016.

Legal settlements and loss contingencies were $899 million, compared to $631 million in 2015, mainly due to the FCPA settlement with the DOJ and SEC and the ciprofloxacin settlement.

Goodwill impairment was $900 million in 2016 in connection with the Rimsa acquisition as compared to none in 2015. Following the closing, we identified issues concerning Rimsa s pre-acquisition quality, manufacturing and other practices. We are currently executing a remediation plan in order to resume operations at the Rimsa facility and obtain re-approval of its product filings.

Operating income was $2.2 billion, down 36% compared to 2015, mainly due to the goodwill impairment and higher purchase of research and development in process, partially offset by lower impairments, restructuring and others.

Financial expenses were $1.3 billion, compared to $1.0 billion in 2015. The increase was mainly due to an impairment of our monetary assets related to Venezuela as well as an increase in interest expenses, partially offset by a decrease in other-than-temporary impairment of securities (primarily our Mylan shares).

Net income attributable to Teva was $329 million, compared to $1.6 billion in 2015.

Net income attributable to ordinary shareholders was $68 million in 2016, compared to $1.6 billion in 2015.

Exchange rate movements during 2016 in comparison with 2015 decreased revenues by $174 million and decreased operating income by $81 million. In addition, the Venezuelan bolivar exchange rates that we used and inflation-driven price increases in Venezuela increased revenues by $526 million and increased operating income by $23 million. In light of the economic conditions in Venezuela, we exclude the 2016 increases in revenues and operating profit in any discussion of currency effects.

Cash flow from operating activities was $5.2 billion, compared to $5.5 billion in 2015.

Significant transactions, in addition to the Actavis Generics acquisition, included:

In December 2016, we entered into a license agreement for research, development, manufacture and commercializing of Attenukine™ by a subsidiary of Takeda.

In November 2016, we entered into an agreement to sell our royalties and other rights in Ninlaro® (ixazomib) to a subsidiary of Takeda.

In October 2016, we completed the acquisition of Anda Inc., the fourth largest distributor of generic pharmaceuticals in the United States.

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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.

In September 2016, we entered into a collaborative agreement with Regeneron to develop and commercialize Regeneron s pain medication product, fasinumab.

In April 2016, we established a business venture with Takeda in Japan, combining our Japanese generics business with Takeda s portfolio of off-patent products.

In March 2016, we completed the acquisition of Rimsa, a pharmaceutical manufacturing and distribution company in Mexico. For more information regarding these and other transactions, see note 2 of our consolidated financial statements.

Changes in Senior Management

On February 6, 2017, Dr. Yitzhak Peterburg, who served as Chairman of the Board of Directors from January 2015 to February 2017, was appointed Interim President and Chief Executive Officer, succeeding Erez Vigodman, who stepped down as President and Chief Executive Officer and from our Board of Directors. As required by the Israeli Companies Law, Dr. Peterburg stepped down from his role as Chairman in order to serve as Interim Chief Executive Officer and was replaced by Dr. Sol J. Barer, who has been a member of the Board since January 2015.

Results of Operations

The following table sets forth, for the periods indicated, certain financial data derived from our U.S. GAAP financial statements, 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	
	2016	2015	2014	2016-2015	2015-2014
	%	%	%	%	%
Net revenues	100.0	100.0	100.0	11	(3)
Gross profit	54.1	57.8	54.5	4	3
Research and development expenses	9.6	7.8	7.3	38	2
Selling and marketing expenses	17.6	17.7	19.0	11	(10)
General and administrative expenses	5.6	6.3	6.0	*	2
Impairments, restructuring and others	3.2	5.8	3.2	(38)	74
Legal settlements and loss contingencies	4.1	3.2	(0.5)	42	n/a
Goodwill impairment	4.1			n/a	n/a
Operating income	9.8	17.0	19.5	(36)	(15)
Financial expenses net	6.1	5.1	1.6	33	219
Income before income taxes	3.7	11.9	17.9	(65)	(35)
Income taxes	2.4	3.2	2.9	(18)	7
Share in losses of associated companies net	*	0.6	*	n/a	n/a
Net loss attributable to non-controlling interests	*	*	(0.1)	(300)	n/a
Net income attributable to Teva	1.5	8.1	15.1	(79)	(48)

* Represents an amount less than 0.5%.

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Segment Information

Generic Medicines Segment

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

	Generic Medicines Year Ended December 31,					
	2016		2015		2014	
	U.S.$ in millions / % of Segment Revenues					
Revenues	$11,990	100.0%	$10,540	100.0%	$10,810	100.0%
Gross profit	5,696	47.5%	4,903	46.5%	4,601	42.6%
R&D expenses	659	5.5%	519	4.9%	521	4.8%
S&M expenses	1,727	14.4%	1,459	13.8%	1,734	16.0%
Segment profit*	$3,310	27.6%	$2,925	27.8%	$2,346	21.7%

* Segment profit consists of gross profit for the segment, less R&D and S&M expenses related to the segment. Segment profit does not include G&A expenses, amortization and certain other items. Beginning in 2015, expenses related to equity compensation are excluded from our segment results. Beginning in 2016, our OTC business is included in our generic medicines segment. The data presented have been conformed to reflect these changes for all relevant periods. See note 20 of our consolidated financial statements and Operating Income below for additional information.

Generic Medicines Revenues

Our generic medicines segment includes generic medicines and our OTC business as well as API products sold to third parties. Revenues from our generic medicines segment in 2016 were $12.0 billion, an increase of $1.5 billion, or 14%, compared to 2015.

Revenues of generic medicines in the United States, our largest generic market, were $4.6 billion, a decrease of $239 million, or 5%, compared to 2015. Revenues of generic medicines in Europe were $3.6 billion, an increase of $417 million, or 13%, compared to 2015. In local currency terms, European revenues increased 16%. Revenues from generic medicines in our ROW markets were $3.9 billion, an increase of $1.3 billion or 49%, compared to 2015. In local currency terms, ROW revenues increased 30%, taking into account a negative impact of $27 million due to exchange rate fluctuations. In addition, the Venezuelan bolivar exchange rates that we used and inflation-driven price increases in Venezuela increased revenues by $526 million. In light of the economic conditions in Venezuela, we exclude the 2016 increases in revenues and operating profit in any discussion of currency effects.

Our revenues from OTC products in 2016 were $1.4 billion, an increase of 34% compared to $1.0 billion in 2015. In local currency terms, revenues increased 7%, taking into account a negative impact of $31 million due to exchange rate fluctuations. In addition, the Venezuelan bolivar exchange rates that we used and inflation-driven price increases in Venezuela increased OTC revenues by $309 million. In light of the economic conditions in Venezuela, we exclude the 2016 increases in revenues and operating profit in any discussion of currency effects.

API sales to third parties in 2016 were $776 million, an increase of 4% compared to 2015. In local currency terms, sales increased 3%, mainly due to increases in sales in the United States and Europe.

Comparison of 2015 to 2014. In 2015, revenues from generic medicines were $10.5 billion, a decrease of 2% compared to $10.8 billion in 2014. In local currency terms, revenues increased 6%.

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The following table presents generic segment revenues by geographic area for the past three years:

	Year Ended December 31,			Percentage Change	
	2016	2015	2014	2016-2015	2015-2014
	U.S. $ in millions				
United States	$ 4,556	$ 4,795	$ 4,516	(5%)	6%
Europe	3,563	3,146	3,638	13%	(14%)
Rest of the World	3,871	2,599	2,656	49%	(2%)
Total Generic Medicines	$ 11,990	$ 10,540	$ 10,810	14%	(2%)

United States Generic Medicines Revenues

In 2016, we led the U.S. generic market in total prescriptions and new prescriptions, with approximately 613 million total prescriptions, representing 16.0% of total U.S. generic prescriptions according to IMS data. We seek to continue our U.S. market leadership based on our ability to introduce new generic equivalents for brand-name products on a timely basis, with a focus on complex generics and other high-barrier products that we believe will create more value for patients and customers, our strong emphasis on customer service, the breadth of our product line, our commitment to quality and regulatory compliance and our cost-effective production, including through our recent acquisition of Actavis Generics, which has substantially expanded our generics operations and pipeline.

Revenues from generic medicines in the United States in 2016 were $4.6 billion, a decrease of 5% compared to $4.8 billion in 2015. The decrease resulted mainly from the loss of exclusivity on esomeprazole (the generic equivalent of Nexium®) and aripiprazole (the generic equivalent of Abilify®), a decline in the sales of budesonide (the generic equivalent of Pulmicort®) due to increased competition, loss of revenues following our divestment of certain products in connection with the Actavis Generics acquisition and the decline in sales of capecitabine (the generic equivalent of Xeloda®). This decrease was partially offset by the inclusion of five months of Actavis Generics revenues of approximately $1.2 billion and revenues from products that were not sold in 2015. Starting with the first quarter of 2017 we will no longer track stand-alone revenues attributable to the Actavis Generics business, as the extent of integration makes it impractical to do so.

The most significant generic products we sold in the United States in 2016 were an authorized generic version of Concerta® (methylphenidate extended release tablets) and generic versions of Pulmicort® (budesonide inhalation), Adderall XR® (mixed amphetamine salts ER) and Abilify® (aripiprazole).

Comparison of 2015 to 2014. Total generic revenues in the United States in 2015 were $4.8 billion, compared to $4.5 billion in 2014. This increase was mainly due to launches of key products.

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Products. In 2016, we launched generic versions of the following branded products in the United States (listed by date of launch):

Generic Name	Brand Name	Launch Date	Total Annual U.S. Market at Time of Launch $ millions (IMS)*
Docetaxel injection, USP 20 mg/mL, 20 mg & 20 mg/mL, 80 mg	Taxotere®	February	62
Budesonide inhalation suspension 1 mg/2 mL	Pulmicort Respules®	February	97
Acamprosate calcium delayed-release tablets 333 mg	Campral®	March	14
Octreotide acetate injection 100 mcg/mL,100 mcg, 200 mcg/mL, 1000 mcg, 500 mcg/mL, 500 mcg & 1000 mcg/mL, 5000 mcg**	Sandostatin®	May	44
Fluvastatin sodium extended-release tablets 80 mg	Lescol® XL	June	31
Budesonide capsules (enteric coated) 3 mg	Entocort® EC	June	343
Eptifibatide injection, 2 mg/mL, 20 mg	Integrilin®	July	18
Sumatriptan injection, USP 4 mg/0.5 mL & 6 mg/0.5 mL	Imitrex®	July	194
Octreotide acetate injection, 50 mcg/mL, 50 mcg **	Sandostatin®	July	2
Cyclobenzaprine hydrochloride tablets, USP 7.5 mg	Flexeril®	August	10
Imatinib mesylate tablets, 100 & 400 mg	Gleevec®	August	2,331
Rosuvastatin tablets, 5, 10, 20 & 40 mg	Crestor®	August	6,702
Valganciclovir hydrochloride oral solution, 50 mg/mL	Valcyte®	August	35
Daptomycin injection 500 mg/vial***	Cubicin®	September	1,180
Methoxsalen capsules, USP 10 mg	Oxsoralen-Ultra®	September	12
Azacitidine injection, 100 mg/vial	Vidaza®	September	229
Abacavir and lamivudine tablets, USP 600 mg/300 mg	Epzicom®	September	459
Levalbuterol tartrate HFA inhalation aerosol 45 mcg/actuation	Xopenex HFA®	October	74
Nitrofurantoin oral suspension, USP 25 mg/5 mL	Furadantin®	October	29
Bleomycin for injection, USP 15 units/vial & 30 units/vial**	Blenoxane®	October	5
Hydromorphone HCl extended-release tablets CII 32 mg	Exalgo®	October	49
RAJANI (drospirenone, ethinyl estradiol and levomefolate calcium tablets and levomefolate calcium tablets) 3 mg/0.02 mg/0.451 mg; 0.451 mg	Beyaz®	October	136
Gemcitabine for injection, USP 2 gm/vial		October	1
Amlodipine and olmesartan medoxomil tablets 5 mg/20 mg, 5 mg/40 mg, 10 mg/20 mg & 10 mg/40 mg	Azor®	October	353
Risedronate sodium tablets, USP 150 mg	Actonel®	November	59
Olmesartan medoxomil, amlodipine, and hydrochlorothiazide tablets 20 mg/5 mg/12.5 mg, 40 mg/5 mg/12.5 mg, 40 mg/5 mg/25 mg, 40 mg/10 mg/12.5 mg & 40 mg/10 mg/25 mg	Tribenzor®	November	239
Desoximetasone ointment USP, 0.25%	Topicort®	November	14
Armodafinil tablets 50 mg, 150 mg, 200 mg & 250 mg	Nuvigil®	November	516
Clotrimazole cream, USP 1%	Lotrimin® AF	December	20
Tobramycin injection, USP 40 mg/mL, 80 mg & 40 mg/mL, 1.2 gm **.		December	6
Fluocinolone acetonide topical solution, USP 0.01%	Synalar®	December	14
Amantadine HCl tablets 100 mg		December	23

* For the twelve months ended in the calendar quarter closest to our launch or re-launch.
** Products were re-launched.
*** Authorized generic.

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We expect that our generic medicines revenues in the U.S. will continue to benefit from our world-leading generic pipeline that includes, as of December 31, 2016, 330 product applications awaiting FDA approval, including 71 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, these pending applications had U.S. sales for the year ended December 31, 2016 exceeding $110 billion according to IMS. Nearly 70% of pending applications include a paragraph IV patent challenge, and we believe we are first to file with respect to 95 of these products, or 119 products including final approvals where launch is pending a settlement agreement or court decision. Collectively, these first to file opportunities represent nearly $50 billion in U.S. brand sales for the year ended December 31, 2016 according to IMS. IMS 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.

The FDA requires companies to submit abbreviated new drug applications (ANDAs) for approval to manufacture and market generic forms of brand-name drugs. In most instances, FDA approval is granted upon the expiration of the underlying patents. However, companies may be rewarded with a 180-day period of marketing exclusivity, as provided by law, for being the first generic applicant to successfully challenge these patents. As part of our strategy, we actively review pharmaceutical patents and seek opportunities to challenge patents that we believe are either invalid or not infringed by our generic version. In addition to the commercial benefit of obtaining marketing exclusivity, we believe that our patent challenges ultimately improve healthcare by allowing consumers earlier access to more affordable, high-quality medications.

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In 2016 we received, in addition to 25 final generic drug approvals, 22 tentative approvals that remain tentative at December 31, 2016. 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. The outstanding tentative approvals received are for generic equivalents of the following products:

Generic Name	Brand Name		Total U.S. Annual Branded Market $ thousands (IMS)*
Amlodipine Besylate & Olmesartan Medoxomil & Hydrochlorothiazide Tablets	Tribenzor®	$	228,187
Arformoterol Tartrate Inhalation Solution, Eq. 0.015mg base/2mL	Brovana®	$	