TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 20-F
February 11, 2016
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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

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015

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

Fax: 972-3-914-8678

(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.

907,663,041 Ordinary Shares

781,355,149 American Depositary Shares

3,375,000 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 x 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 x

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 x 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 x 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 x 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:

þ 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.

¨ Item 17

¨ Item 18

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 x

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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 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;
- the anticipated results of acquisitions, including our pending Actavis Generics and Rimsa acquisitions;
- 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, 2015 and selected balance sheet data at December 31, 2015 and 2014 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, 2012 and selected balance sheet data at December 31, 2013, 2012 and 2011 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,				
	2015	2014	2013	2012	2011
	U.S. dollars in millions (except share and per share amounts)				
Net revenues	19,652	20,272	20,314	20,317	18,312
Cost of sales	8,296	9,216	9,607	9,665	8,797
Gross profit	11,356	11,056	10,707	10,652	9,515
Research and development expenses	1,525	1,488	1,427	1,356	1,095
Selling and marketing expenses	3,478	3,861	4,080	3,879	3,478
General and administrative expenses	1,239	1,217	1,239	1,238	932
Impairments, restructuring and others	1,131	650	788	1,259	430
Legal settlements and loss contingencies	631	(111)	1,524	715	471
Operating income	3,352	3,951	1,649	2,205	3,109
Financial expenses net	1,000	313	399	386	153
Income before income taxes	2,352	3,638	1,250	1,819	2,956
Income taxes	634	591	(43)	(137)	127
Share in losses of associated companies net	121	5	40	46	61
Net income	1,597	3,042	1,253	1,910	2,768
Net income (loss) attributable to non-controlling interests	9	(13)	(16)	(53)	9
Net income attributable to Teva	1,588	3,055	1,269	1,963	2,759
Accrued dividends on preferred shares	15				
Net income attributable to ordinary shareholders	1,573	3,055	1,269	1,963	2,759
Earnings per share attributable to ordinary shareholders:					
Basic ($)	1.84	3.58	1.49	2.25	3.10
Diluted ($)	1.82	3.56	1.49	2.25	3.09
Weighted average number of shares (in millions):					
Basic	855	853	849	872	890
Diluted	864	858	850	873	893

Balance Sheet Data

	As at December 31,				
	2015	2014	2013	2012	2011
	(U.S. dollars in millions)				
Financial assets (cash, cash equivalents and investment in securities)	8,404	2,601	1,245	3,089	1,748
Working capital (operating assets minus liabilities)	32	1,642	2,493	3,589	3,937
Total assets	54,258	46,420	47,508	50,609	50,142
Short-term debt, including current maturities	1,585	1,761	1,804	3,006	4,280

Long-term debt, net of current maturities	8,383	8,566	10,387	11,712	10,236
Total debt	9,968	10,327	12,191	14,718	14,516
Total equity	29,927	23,355	22,636	22,867	22,343

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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. Until April 2015, dividends were declared and paid in NIS, and then converted into U.S. dollars and paid by the depositary of our American Depositary Shares (ADSs) for the benefit of owners of ADSs. Commencing in April 2015, dividends are declared and paid in U.S. dollars.

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 will be paid in cash on March 15, June 15, September 15 and December 15 of each year commencing March 15, 2016, to and including December 15, 2018. So long as any mandatory convertible preferred shares remain outstanding, no dividends may 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 upon, or a sufficient sum of cash has been set apart for the payment of such dividends upon, 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 2015.

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

	2015	2014	2013	2012	2011
			In cents per share		
1st interim	34.0	34.7	32.0	26.3	23.2
2nd interim	34.0	35.3	32.2	25.0	23.5
3rd interim	34.0	32.1	32.6	25.7	21.9
4th interim	34.0	33.8	34.3	31.1	26.8

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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.

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

Our financial results depend upon our ability to develop and commercialize additional generic and specialty pharmaceutical products, particularly after the expiration of our patents covering the 20mg/mL version of our leading specialty medicine, Copaxone®, and patent challenges and expirations facing the 40mg/mL version of Copaxone® and 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 are increasingly focusing 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.

Our leading specialty medicine, Copaxone®, faces increasing competition, including from orally-administered therapies and a competing generic version.

Any substantial decrease in the revenues derived from our specialty medicines would have an adverse effect on our results of operations, several of which currently face, or will soon face, intense competition. Our multiple sclerosis franchise includes our Copaxone® products and laquinimod (a developmental compound for the treatment of MS). The profitability of 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 and non-recurring items. Our MS franchise profitability was $3.1 billion, $3.2 billion, and $3.3 billion in 2015, 2014 and 2013, respectively. Profitability of our multiple sclerosis franchise as a percentage of Copaxone® revenues was 77%, 75% and 76% in 2015, 2014 and 2013, respectively.

Although Copaxone® remains the leading therapy for multiple sclerosis to date, the market for MS treatments continues to change significantly as a result of new and emerging therapies. 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. The new oral treatments provide especially intense competition in light of their substantial convenience in comparison to injectables such as Copaxone®. As our U.S. Orange Book patents on Copaxone® 20mg/mL have expired, a competing generic version of this product was launched in the United States in June 2015. Copaxone® also continues to face competition from existing injectable products, such as the four beta-interferons Avonex®, Betaseron®, Extavia® and Rebif®, as well as from the two monoclonal antibodies Tysabri® and Lemtrada®.

Our business strategy for Copaxone® relies heavily on the continued migration of a substantial percentage of current daily Copaxone® patients to a new 40mg/mL, three-times-a-week version and the maintenance of

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patients on this new version. Four of our U.S. Orange Book patents for this new version are being challenged as well. The failure to achieve and maintain our objectives for Copaxone® 40mg/mL would likely have a material adverse effect on our financial results and cash flow.

We may fail to consummate the acquisition of Allergan plc s worldwide generic pharmaceuticals business (Actavis Generics). Even if we successfully consummate the acquisition, we may fail to realize all of 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.

Consummation of the Actavis Generics acquisition requires approval by certain governmental and regulatory authorities, including those required under the antitrust and competition laws of those in the U.S., the European Union and certain other foreign countries and authorities. Obtaining these approvals require certain divestitures and may entail restrictions on the conduct of the business of the combined company after the closing of the acquisition. Any one of these could jeopardize or delay the closing of the acquisition, could materially reduce the anticipated benefits of the transaction or could adversely affect our ability to integrate Actavis Generics with our operations. This could result in a failure to consummate the transaction or have a material adverse effect on the business and results of operations of the combined company. In addition, if the purchase agreement is terminated under certain circumstances by either Allergan or us due to failure to obtain necessary antitrust approvals, then we must pay Allergan $1 billion.

Our ability to realize the anticipated benefits of the Actavis Generics acquisition will depend, to a large extent, on our ability to integrate the Actavis Generics business. The combination of two independent businesses is a complex, costly and time-consuming process. The nature of a carve out acquisition makes it inherently more difficult to assume operations on closing day as well as to integrate activities, as certain systems, processes and people may not all transfer with the acquired business to support such activities. As a result, we will be required to devote significant management attention and resources, both prior to and following closing, to prepare for and then integrate our combined business practices and operations. The integration process may disrupt the businesses and, if implemented ineffectively, would restrict 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 transactions could cause an interruption of, or a loss of momentum in, the activities of the combined businesses and could adversely affect the results of operations of the combined businesses.

In addition, the overall 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 operations of the companies 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;
- 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;

challenges in attracting and retaining key personnel; and

coordinating a geographically dispersed organization.

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Many of these factors will be 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 the business, financial condition and results of operations of the combined company. In addition, even if the Actavis Generics operations are integrated successfully, the full benefits of the transactions and other pending acquisitions (such as the acquisition of Representaciones e Investigaciones Médicas, S.A. de C.V. (Rimsa)) may not be realized, including the synergies, cost savings or sales or growth opportunities that are expected. These benefits may not be achieved within the anticipated time frame, or at all. All of these factors could cause dilution to our earnings per share, decrease or delay the expected accretive effect of the transactions. As a result, it cannot be assured that the Actavis Generics acquisition will result in the realization of the full benefits anticipated from such transaction.

Following the completion of the Actavis Generics acquisition, we will be dependent to a much larger extent than previously on our generic pharmaceutical business.

In 2015, revenues from our generic medicines segment amounted to approximately $9.5 billion, or 49% of our total revenues. Gross profit from our generic medicines segment amounted to approximately $4.5 billion, or 39.6% of our total gross profit. Following the completion of the Actavis Generics acquisition, the percentage of our revenues and profits attributable to sales of generics is expected to increase substantially. Generic pharmaceuticals are, as a general matter, less profitable than specialty pharmaceuticals, and due to the size of the acquisition, it is unlikely that the proportion of revenues attributable to generic pharmaceuticals, which will move from less than half before the acquisition to nearly two-thirds afterward, will change significantly over the next few years. Accordingly, we will be more dependent on our generics business and increasingly subject to market and regulatory factors affecting generic pharmaceuticals worldwide.

If the Actavis Generics acquisition is consummated, we will incur a substantial amount of debt to finance the aggregate cash consideration portion and certain other amounts to be paid in connection with the acquisition, which will increase our expenses and could adversely affect our business, including by restricting our ability to engage in additional transactions or incur additional indebtedness or resulting in a downgrade or other adverse action with respect to our credit rating.

In connection with the Actavis Generics acquisition, we expect that one or more of our subsidiaries will borrow approximately $27 billion through various debt financings that we will guarantee. Following the completion of the acquisition, on a pro forma basis, giving effect to the incurrence of debt, our consolidated debt would have been approximately $37 billion as of December 31, 2015. As a result, our borrowing costs will increase significantly.

This substantial level of debt 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; and
- restricting us from pursuing certain business opportunities.

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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 announcement of the Actavis Generics acquisition, Standard and Poor s Financial Services LLC and Moody s Investor Service, Inc. downgraded our ratings to BBB+ and Baa1, respectively, and expect to further downgrade our ratings in connection with the consummation of the acquisition to BBB and Baa2, respectively. Any reduction in our credit ratings may limit our ability to borrow at interest rates consistent with the interest rates that have been available to us prior to the acquisition. If our credit ratings are 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.

We expect that, for a period of time following the consummation of the Actavis Generics acquisition, we will have significantly less cash on hand than prior to the closing. This reduced amount of cash could adversely affect our ability to grow.

We are expected to have, for a period of time following the consummation of the Actavis Generics acquisition, significantly less cash and cash equivalents on hand than the approximately $6.9 billion of cash and cash equivalents we had as of December 31, 2015. Although our management believes that it will have access to cash sufficient to meet our business objectives and capital needs, the lessened availability of cash and cash equivalents for a period of time following the consummation of the Actavis Generics acquisition could constrain our ability to grow our business. Our more leveraged financial position following the Actavis Generics acquisition could also make us vulnerable to general economic downturns and industry conditions, and place us at a competitive disadvantage relative to our competitors that have more cash at their disposal. In the event that we do not have adequate capital to maintain or develop our business, additional capital may not be available to us on a timely basis, on favorable terms, or at all.

We may be subject to material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing 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 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 our business practices currently under investigation, as described below) may expose us to 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.

For several years, we have been conducting a voluntary worldwide investigation into business practices that may have implications under the FCPA. We have engaged outside counsel to assist in the investigation, which was prompted by the receipt, beginning in 2012, of subpoenas and informal document requests from the SEC and the Department of Justice (DOJ) to produce documents with respect to compliance with the FCPA in certain countries. We have provided, and will continue to provide, documents and other information to the SEC and the DOJ, and are cooperating with these agencies in their investigations of these matters. In the course of our investigation, which is substantially complete, we have identified certain business practices and transactions in Russia, certain European countries, certain Latin American countries and other countries in which we conduct business, which likely constitute violations of the FCPA and/or local law. In connection with our investigation, we have also become aware that affiliates in certain countries under investigation provided to local authorities inaccurate or altered information relating to marketing or promotional practices. We have brought and continue to bring these issues to the attention of the SEC and the DOJ.

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Although our internal investigation is substantially complete, additional issues or facts could become known to management as the investigation continues, which may expand the scope or severity of the potential violations and/or extend to additional jurisdictions. Our investigation is expected to be completed in 2016, but may continue beyond that date.

We cannot predict at this time the impact on the Company as a result of these matters and accordingly cannot assure you that we will not be materially and adversely affected. The DOJ, SEC and other agencies and authorities have a broad range of civil and criminal penalties they may seek to impose (on the Company and/or individuals) for violations of the FCPA and other similar laws. We may be required to pay material fines and/or penalties and/or disgorge any profits earned from improper conduct. Our operations in the affected countries may be negatively impacted, and we may be subject to injunctions or limitations on future conduct, be required to modify our business practices and compliance programs and/or have a compliance monitor imposed on us, or suffer other criminal or civil penalties or adverse impacts, including lawsuits by private litigants or investigations and fines imposed by local authorities. 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 could have a material adverse effect on our reputation and our business, financial condition or results of operations.

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

We must invest significant resources to develop specialty medicines (including our strategic focus on developing new therapeutic entities, 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 20mg/mL version of our leading specialty medicine, Copaxone®, and patent challenges and expirations facing certain of our other specialty medicines, we have increased our investments in the acquisition and development of products to build our specialty pipeline, including through our recent acquisitions and in-licensing of Auspex Pharmaceuticals, Inc., Eagle Pharmaceuticals, Inc. and Labrys Biologics, 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.

Because of the amounts required to be invested in augmenting our pipeline of specialty and other products, we are also reliant on partnerships and joint ventures with third parties, and consequently face the risk that some of these third parties may fail to perform their obligations, or fail to reach the levels of success that we are relying on to meet our revenue and profit goals. 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.

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

As a key part of our strategy, we continue to evaluate or pursue potential acquisitions, collaborations and licenses, among other transactions. Our reliance 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:

- We may fail to identify transactions that would enable us to execute our business strategy.
- 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 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.
- 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.

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 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.

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. 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

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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.

Following the completion of the Actavis Generics acquisition, our manufacturing network will increase 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.

Our patent settlement agreements, which are important to our business, face increased government scrutiny in both the U.S. 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 U.S., 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 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.

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 2015, approximately 43% of our revenues came from sales outside the United States. 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. In 2015, foreign exchange fluctuations negatively affected our revenues by approximately $1.3 billion and our operating income by $95 million. We may also be exposed to credit risks in some of these markets. 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 assets in Venezuela, which suffers from hyperinflation, totaled $487 million at December 31, 2015. As a result, if there is a devaluation of the Venezuelan currency or if our use of the preferential CENCOEX rate in our financial statements can no longer be supported, we would incur an 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 2015 we recorded sales and expenses in various other currencies. Approximately 56% of our operating costs in 2015 were incurred in currencies other than the U.S. dollar, particularly in euros, Israeli shekels, Hungarian forints, Canadian dollars, Japanese yen and the British pound. 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 success of our specialty medicines depends on the effectiveness of our patents, confidentiality agreements and other measures to protect our intellectual property rights.

The success of our specialty medicines 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.

We are currently engaged in lawsuits challenging the validity and/or enforceability of the U.S. patents covering Copaxone® 40 mg/mL, Treanda® and Amrix®. For example, Treanda® faces numerous patent challenges, and if we are unable to enforce our patents, which expire between 2026 and 2031, generic competition could commence as early as May 2016. 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 known or be independently developed by our competitors or we may not be able to maintain the confidentiality of information relating to such products.

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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. 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, 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 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.

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 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 new companies selling such product and the timing of their approvals.

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

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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.

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 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 over 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.

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 U.S. or elsewhere.

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

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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. We could also experience business interruption, information theft 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.

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 increased focus on innovative and specialty pharmaceuticals 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.

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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 2015 accounted for 20% 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.

Decreased opportunities to obtain 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 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. The failure to continue to develop such opportunities could adversely affect our sales and profitability.

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 being the first generic product in the market.

However, the number of significant new generic products for which Hatch-Waxman exclusivity is available, and the size of those product opportunities, has decreased in recent years, and patent challenges have become more difficult. Additionally, increasingly we share the 180-day exclusivity period with other generic competitors, which diminishes the commercial value of the exclusivity.

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.

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 U.S., 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 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 U.S. 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.

The failure to recruit or retain key personnel, 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. 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. In addition, there is a risk that we will not strike the appropriate balance between retaining existing managerial talent and achieving the targets of the cost reduction program mentioned above.

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

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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.

The large amount of long lived assets recorded on our balance sheet is expected to significantly increase 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 increased approximately 31% in the past five years to $33.2 billion mainly as a result of our acquisitions, and is expected to significantly increase further following consummation of the Actavis Generics and other future acquisitions. For example, in 2015 we recorded impairment charges on long-lived assets of $361 million. 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 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, if adopted by individual countries, could adversely affect our provision for income taxes. It is hard to predict how the principles and recommendations developed by the OECD in the BEPS project will translate into specific national laws, and therefore we cannot predict at this stage the magnitude of the effect of such rules on our financial results.

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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 are likely to 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.

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 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.

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.

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ITEM 4: INFORMATION ON THE COMPANY

Introduction

Teva Pharmaceutical Industries Limited is 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 in pharmaceutical markets worldwide, with a significant presence in the United States, Europe and other markets. As a world leading pharmaceutical company, we are strategically positioned to benefit from ongoing changes in the global healthcare environment.

We operate our business in two segments:

Generic medicines, which include chemical and therapeutic equivalents of originator medicines in a variety of dosage forms, including 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 or growing presence in our ROW markets. We are also one of the world s leading manufacturers of Active Pharmaceutical Ingredients (APIs).

Specialty medicines, which include several franchises, most significantly our core therapeutic areas of CNS medicines such as Copaxone®, Azilect®, Nuvigil® and Zecuity® and of respiratory medicines such as ProAir® HFA and QVAR®. Our specialty medicines segment includes other therapeutic areas, such as oncology medicines, including Treanda®, women s health and selected other areas.

In addition to these two segments, we have other activities, primarily PGT Healthcare, our over-the-counter (OTC) consumer healthcare joint venture with P&G.

We seek to address unmet patient needs while capitalizing on evolving market, economic and legislative dynamics in global healthcare. These dynamics include the aging population, increased spending on pharmaceuticals in emerging markets, economic pressure on governments and private payors to provide accessible healthcare solutions, legislative and regulatory reforms, an increase in patient awareness and the growing importance of OTC medicines.

We believe that our dedicated leadership and employees, world-leading generics expertise and portfolio, focused specialty portfolio, global reach, robust R&D capabilities and global infrastructure and scale position us to take advantage of opportunities created by these dynamics. Our global strengths include the following:

As the world s leading generic medicines manufacturer, with a global portfolio of more than 1,000 molecules, we provide medicines that treat millions of patients every day, around the world.

Our generics business is ranked in leading positions in the United States and Europe. We also have a significant presence in Canada and Japan and a growing presence in Russia.

Our broad portfolio of generic products covers almost every major therapeutic area.

Our extensive technological capabilities enable us to provide a wide array of generic products, in a variety of dosage forms, including oral solid doses, injectables, inhalations and other delivery devices.

We are one of the world s leading manufacturers of APIs, with operations around the globe. We produce APIs not only for our own use but also for other pharmaceutical companies.

Our generics business is poised to grow significantly through our pending acquisition of Actavis Generics.

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We are a recognized leader in innovative and specialty pharmaceuticals, from drug development and delivery to monitoring and patient support services.

In specialty pharmaceuticals, we have a leading presence in central nervous system (CNS) and a significant presence in respiratory, which is supported by a strong pipeline of innovative products in these therapeutic areas.

We have a strong commercial presence in certain other therapeutic areas, including oncology and women s health.

We are leveraging our strength in generic and specialty R&D, our scalable production network, market access and knowledge to create opportunities for further sustainable growth.

We have a global OTC business, primarily through our joint venture with P&G, combining our production capabilities and market reach with P&G s marketing expertise and expansive global platform.

In 2015, 49% of our revenues were generated from generic medicines, including APIs sold to third parties, and 42% of our revenues were generated from specialty medicines.

In 2015, we generated 51% of our generic revenues in the United States, 28% in Europe (which for the purpose of this report includes all European Union (EU) member states, Norway, Switzerland, Albania and the countries of former Yugoslavia) and 21% in our ROW markets (primarily Japan, Canada, Venezuela and Russia).

For a three year 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

In 2014, we began a process of re-defining and re-focusing our business strategy to better leverage our strengths and differentiate ourselves in the pharmaceutical market. We seek to capitalize on our advantages including the largest generic medicines business in the world, a focused specialty business, a unique OTC business and our robust R&D and API capabilities to provide patients with integrated, outcome-focused solutions. Underlying our strategy is our heightened focus on profitable and sustainable business.

The key elements of our strategy consist of the following:

Solidifying our foundation and driving organic growth. We have solidified, and continue to strengthen, the core foundations of our generics and specialty businesses to create additional value from our existing operations. We implemented organizational and leadership changes, such as the creation of the Global Generics Medicines group, designed to achieve global integration and improve focus and effectiveness. We continue to drive organic growth and improve profitability in our generics business.

Transforming our generics business. Upon consummation of our acquisition of Actavis Generics, the Actavis Generics portfolio and pipeline, combined with our strong existing generics portfolio, will further enhance our goals of delivering the highest quality generic medicines at competitive prices. The combined generic business will have a commercial presence across 100 markets, including a top three leadership position in over 40 markets.

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Focusing on key growth markets. While we currently operate in numerous markets throughout the world, we intend to concentrate our efforts on a smaller number of growth markets where we believe we can establish or expand leadership positions. We are exploring both organic and inorganic initiatives to achieve leadership in these markets, including, for example, our pending acquisition of Rimsa, a leading pharmaceutical company in Mexico.

Maintaining Copaxone® and other key specialty products. We enhanced our multiple sclerosis (MS) franchise through the introduction of our three-times-a-week Copaxone® 40 mg/mL product in the United States, Europe and other countries in 2015. We also enhanced our oncology portfolio with the FDA s approval in December 2015 of Bendeka (bendamustine hydrochloride), which complements our Treanda® franchise. For many of our other specialty products, we are expanding into new markets, improving the products and taking further steps to protect the franchise while creating value for patients and payors.

Solidifying leadership positions in our core therapeutic areas. Our focus is on our core therapeutic areas of CNS (including MS, neurodegenerative diseases, movement disorders and pain care) and respiratory (including asthma and chronic obstructive pulmonary disease), where we seek to establish leadership positions. In the past year, we have taken significant steps, both internally and by pursuing business development initiatives, to significantly solidify our position in our core therapeutic areas, specifically with the acquisitions of Labrys and Auspex.

Pursuing strategic business development initiatives. We continue to pursue business development initiatives across all our activities. As part of these initiatives, we will continue to evaluate opportunities for joint ventures, collaborations and other activities that support our strategy.

Transaction highlights

Japanese business venture: On November 30, 2015, we agreed with Takeda Pharmaceutical Company Limited (Takeda) to form a new business venture for generic medicines in Japan, in which Teva will have a 51% stake and Takeda will have 49%. The venture will combine Takeda s leading brand reputation and strong distribution presence in Japan and Teva s expertise in supply chain, operational network and infrastructure and R&D. Subject to regulatory approval, the venture is expected to begin operations in the second quarter of 2016.

Rimsa acquisition: On October 1, 2015, we entered into a definitive agreement to acquire Representaciones e Investigaciones Médicas, S.A. de C.V. (Rimsa), a leading pharmaceutical company in Mexico, along with its portfolio of products, companies, intellectual property, assets and pharmaceutical patents, for an aggregate of $2.3 billion, in a cash free, debt free set of transactions. This acquisition is expected to add a portfolio of patent-protected drugs to our business in Latin America. Subject to satisfaction of the closing conditions, we expect the acquisition to close in the first quarter of 2016.

Actavis Generics acquisition: On July 27, 2015, we announced that we entered into a definitive agreement with Allergan plc to acquire Actavis Generics. We will pay consideration of $33.75 billion in cash and approximately 100 million Teva shares. Closing of the transaction is subject to certain conditions, including relevant regulatory approvals. We continue to work toward satisfying all conditions in order to close by the end of the first quarter of 2016; however, it is possible that closing may be slightly delayed. Upon consummation of the acquisition, Teva and Allergan will enter into a stockholders agreement, which will impose certain restrictions on Allergan, including prohibiting transfers of the Teva shares during a 12-month lockup period or to certain competitors of Teva and activist investors, as well as to customary standstill limitations. Allergan will agree to vote its Teva shares, subject to certain exceptions relating to significant corporate transactions, in accordance with the recommendation of Teva s board of directors and in favor of persons nominated and recommended to serve as directors by Teva s board of directors. Allergan will be entitled to customary demand and piggy-back registration rights.

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Auspex acquisition: In May 2015, we acquired Auspex Pharmaceuticals, Inc. (Auspex), an innovative biopharmaceutical company specializing in applying deuterium chemistry to known molecules to create novel therapies with improved safety and efficacy profiles, for net cash consideration of $3.3 billion. Auspex s lead investigational product, SD-809 (deutetrabenazine), which leverages Auspex s deuterium technology platform, is being developed for the potential treatment of chorea associated with Huntington s disease, tardive dyskinesia and Tourette syndrome.

Eagle license: In February 2015, we entered into an exclusive license agreement with Eagle Pharmaceuticals, Inc. (Eagle) for Eagle s EP-3102, a bendamustine hydrochloride rapid infusion product. In December 2015, the FDA approved the product, Bendeka (bendamustine hydrochloride), an injection for the treatment of patients with chronic lymphocytic leukemia (CLL) and for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Teva is responsible for all U.S. commercial activities for the product including promotion and distribution. Bendeka became commercially available in January 2016. Eagle received an upfront cash payment of $30 million, a first milestone payment of $15 million and may receive up to $65 million in additional milestone payments as well as royalties on net sales.

Other transactions: During 2015, we acquired stakes in Gecko Health Innovations, Inc., Immuneering Corporation and Microchips Biotech, Inc. for an aggregate of approximately $102 million and certain contingent payments.

Our Segments

Generic Medicines

Generic medicines are the chemical and therapeutic equivalents of originator medicines and are typically more affordable in comparison to the originator s product. 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.

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, Japan and Brazil, 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 continued expansion in the global generic market, as well as increased competition in this market.

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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. In contrast, in Russia, Ukraine, Kazakhstan, some Asian and Latin American countries as well as certain European markets, generic medicines are 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.

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.

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.

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, 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 approximately 370 generic products in more than 1,100 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 consolidation continues among purchasers, including large drugstore chains, wholesaling organizations and buying groups. Our growth strategy focuses on a portfolio of products that will provide added value to our customers, payors and patients, utilizing new and advanced technologies.

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. We believe we have a focused and competitive pricing strategy.

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A substantial majority 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 products offerings and our global network capabilities, have provided mutual strategic advantages to our customers. We are committed to the success of our customers and work closely with them as important business partners.

In the United States, our wholesale and retail selling efforts are supported by advertising in professional journals and on leading pharmacy websites, as well as participating in key medical and pharmaceutical conferences. We continue to strengthen consumer awareness of the benefits of generics through partnerships and digital marketing programs.

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

Europe

Europe, which we define as the 28 countries in the European Union, Norway, Switzerland, Albania and the countries of former Yugoslavia, is a diverse region with a population of over 500 million people.

We are the leading generic pharmaceutical company in Europe. We are among the top three companies in 20 markets, serving patients 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.

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. Teva is one of few companies with a pan-European footprint. Most competitors focus on a select few markets or business lines.

Our strategy for generics 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, we are able to understand and adapt to the local needs of our patients, customers and payors. In parallel, we are continuously enhancing 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.

Key markets highlights

Germany is the largest European pharmaceutical market. We are the second largest provider in the overall generic market, and our ratiopharm brand continues to be a leader in the retail generics segment. The German market has a hybrid nature, partially driven by prescriptions of physicians and partially by tenders with increasing price pressure. Teva is present and strong 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 the largest supplier by volume to the National Health Service, supplying one in every six 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 the pharmacy 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 limit 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 **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 the pharmacist has an increasing level of influence and ability to substitute.

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 advantage, being the preferred partner in the generic market and promoting generic substitution in pharmacies.

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 2015 by further government pricing and reimbursement reforms which increased generic utilization. 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 Japan, Canada, Venezuela and Russia. The countries in this category range from highly regulated, pure generic markets such as Canada, to hybrid markets such as Japan and Brazil, to branded generics markets such as certain Commonwealth of Independent States (CIS) and Latin American markets. Russia is characterized by rapid growth and relatively high sales of branded generics and OTC products. Some countries such as Canada and Israel have higher generic penetration rates and therefore lower growth rates.

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, Brazil and India and significantly 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 minimize or divest our generic operations.

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Key markets highlights

In November 2015, we signed an agreement with Takeda to form a business venture to provide generic medicines in **Japan**. Teva will have a 51% stake and Takeda will have 49% in the business venture. Subject to regulatory approval, the venture is expected to commence operations in the second quarter of 2016.

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

The Japanese pharmaceutical market is transforming from a branded generics market, driven by physicians choice of brands, to a pharmacy substitution market with an increased proportion of generic prescriptions. In addition, pharmacy chains are slowly emerging, which we expect will also drive increased generic penetration. We continue to establish strategic partnerships with key national and regional wholesalers in order to ensure distribution to all customer segments.

In **Canada**, we are one of the two leading generic pharmaceutical companies in terms of prescriptions and sales, offering a broad portfolio of medicines.

We market generic products to retail chains, retail buying groups and independent pharmacies, reaching approximately 8,800 outlets across Canada. We continue to see consolidation of independent retail pharmacies and increased expansion of retail chains and buying groups: the top five retail chains in Canada now represent approximately half 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 approximately 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. In addition, several of our customers continue to intensify their efforts to provide private label products, which may compete with our products.

We operate in **Venezuela**, with a comprehensive product portfolio in a wide range of therapeutic areas. Our products are mainly marketed as generic and branded generics medicines.

In **Russia**, which is primarily a branded generic market, we market a diverse portfolio of products. We are currently one of the largest pharmaceutical companies in Russia, playing a role in the commercial, retail, 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. We established a manufacturing facility in Yaroslavl, Russia in 2015 to take advantage of this policy, and we expect this facility to become fully operational during 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

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pain care) 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. We believe that our primary competitive advantages include our commercial marketing teams, global R&D function, 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 in 2015 amounted to $6.4 billion, comprising the most significant part of our specialty business. Our European specialty medicines revenues in 2015 amounted to $1.5 billion and in ROW amounted to $378 million. 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. In Europe and in ROW markets, we leverage existing synergies with our generics and OTC businesses through integrated in-market structures.

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. Teva currently operates Patient Support Programs in 30 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, Azilect® for the treatment of the symptoms of Parkinson s disease and Nuvigil® for the treatment of sleep disorders, as well as several novel therapies for the treatment of pain care, including Fentora®, Amrix® and Zecuity®.

Copaxone® (glatiramer acetate injection 20 mg/mL and 40 mg/mL) is the leading multiple sclerosis therapy in the United States and worldwide. Copaxone® is indicated for 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.

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In November 2015, Copaxone® 20 mg/mL was launched in Japan, pursuant to an agreement with Takeda to market this product in Japan.

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. To date, we have launched Copaxone® 40mg/mL in 14 European countries, with another six to eight European launches planned for early 2016. We received regulatory approval for Copaxone® 40 mg/mL in Russia in October 2015. We are in discussions with the marketing authorities in Australia and other markets globally, with approvals expected starting in early 2016. We expect to receive marketing approvals in other ROW markets during 2016.

Copaxone® 40 mg/mL is protected by three U.S. Orange Book patents that expire in 2030, which are being challenged in paragraph IV litigation and in patent office proceedings in the United States, and a fourth U.S. Orange Book patent expiring in 2030 that was issued in October 2015 and is also being challenged in paragraph IV litigation, but not in patent office proceedings. It is also protected by one European patent expiring in 2030, the validity of which was confirmed by the European Patent Office in December 2015, which rejected all invalidity claims.

Since the launch of Copaxone® 40 mg/mL three times a week in the United States, over 78% of the total U.S. Copaxone® prescriptions are now filled with the 40 mg/mL version. This was driven by patient and physician choice of the 40 mg/mL version supported by payor access and patient support activities.

Copaxone® accounted for $4.0 billion (including $3.2 billion in the U.S.), or 20% of our revenues in 2015, 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 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. In June 2015, Sandoz launched its generic version of Copaxone® 20 mg/mL, Glatopa™, in the United States. Copaxone® also continues to face competition from existing injectable products, such as the four beta-interferons Avonex®, Betaseron®, Extavia® and Rebif®, as well as from the two monoclonal antibodies Tysabri® and Lemtrada®.

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 expect generic competition commencing in early 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. Data exclusivity protection for Azilect® in the EU expired in 2015. In 2014, we signed an agreement with Takeda to market this product in Japan.

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

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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. Since November 2015, a number of generic products that compete with Azilect® have launched, or are in the process of launching, throughout Europe.

Nuvigil® (armodafinil), the R-isomer of modafinil, is indicated for the treatment of excessive sleepiness associated with narcolepsy and certain other disorders.

Several products, including methylphenidate products, compete with Nuvigil®.

Nuvigil® is protected by several patents, with a pediatric extension. In 2012, we reached an agreement with Mylan Pharmaceuticals, providing Mylan the ability to sell its generic version of Nuvigil® in the United States beginning in June 2016, or earlier under certain circumstances. We have entered into other agreements to permit the other generic filers to enter the market under license 180 days after Mylan s entry.

Fentora®/Effentora® (fentanyl buccal tablet) is indicated for the treatment of breakthrough pain in opioid-tolerant adult patients with cancer. Fentora®/Effentora® is protected by patents expiring between 2019 and 2028.

Zecuity® is a prescription transdermal system approved by the FDA for the acute treatment of migraine with or without aura in adults. Zecuity® is a disposable, single-use, iontophoretic transdermal system that actively delivers sumatriptan, the most widely prescribed migraine medication, through the skin. Zecuity® was launched in the United States in September 2015. Zecuity® is protected by seven U.S. Orange Book listed patents, expiring between 2023 and 2030.

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 ***Movement Disorders, Neurodegeneration and Multiple Sclerosis*** products includes:

Movement Disorders,

Neurodegeneration

and Multiple Sclerosis

Products	**Potential Indication(s)**	**Route of Administration**	**Development Phase (date entered Phase 3)**
SD-809 (deutetrabenazine)	Huntington disease	Oral	Submitted in U.S. (May 2015)
	Tardive dyskinesia		3 (October 2014)
	Tourette syndrome		2
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 acquired as part of the Auspex acquisition in May 2015.

SD-809 was granted Orphan Drug Designation by the FDA for the treatment of Huntington disease in November 2014. The SD-809 NDA submission for 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). In the placebo-

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controlled, randomized FIRST-HD study, SD-809 reduced chorea in patients with Huntington disease. Positive top-line data from the Phase 3, open-label ARC-HD study demonstrated that patients were able to safely convert from tetrabenazine, currently the only approved Huntington treatment, to SD-809 overnight with continued control of chorea.

SD-809 is currently in clinical development for the treatment of Tardive dyskinesia and Tourette syndrome. Results from the pivotal Phase 2 clinical study Aim to Reduce Movements in Tardive Dyskinesia (ARM-TD) showed that the study met its primary endpoint, demonstrated a positive trend in all secondary endpoints and showed a favorable safety and tolerability profile. Phase 3 clinical development for Tardive dyskinesia is in progress and will continue through the second half of 2016. Phase 3 clinical development for Tourette syndrome is planned in 2016.

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 acquired the exclusive rights to develop, register, manufacture and commercialize laquinimod worldwide from Active Biotech, in return for an upfront payment and possible future milestone payments and royalties.

In 2011, we conducted two Phase 3 studies. In both studies the observed safety and tolerability profile of laquinimod was considered favorable. A third Phase 3 safety and efficacy trial for laquinimod (CONCERTO) was initiated in February 2013 in patients with relapsing-remitting multiple sclerosis, the primary endpoint of impact on disability progression.

In 2012, we submitted a Marketing Authorization Application to the EMA and a New Drug Submission to Health Canada. In January 2014, the EMA announced that the risk-benefit profile of laquinimod is not favorable. This decision was re-examined and confirmed by the EMA in May 2014. The ongoing Phase 3 CONCERTO trial, testing laquinimod versus placebo using confirmed disability progression as the primary endpoint, is intended to further address the risk-benefit profile of laquinimod. In addition, studies are ongoing to address nonclinical findings noted by the Committee for Medicinal Products for Human Use (CHMP) and elucidation of the molecular mechanism of action.

Further clinical studies of laquinimod in patients with progressive forms of multiple sclerosis as well as patients with Huntington disease are ongoing.

In January 2016, we discontinued the highest doses of laquinimod in all studies, after the occurrence of cardiovascular events, none of which were fatal, in eight patients using the highest doses in the CONCERTO trial and in the other ongoing study in progressive forms of multiple sclerosis. All studies are continuing with the lower- and mid-dosages.

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), which we obtained from Neurosearch A/S in 2012. We initiated a Phase 2 clinical study to evaluate the safety and efficacy of pridopidine in patients with Huntington disease in February 2014, with results expected in the third quarter of 2016.

Pridopidine is protected by patents worldwide that expire in 2020.

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

Migraine and Pain Products	Potential Indication(s)	Route of Administration	Development Phase (date entered Phase 3)
Vantrela ER	Pain	Oral	Submitted US (October 2014)
TV-46763 (abuse deterrent)	Pain	Oral	3 (July 2015)
TV-46139 (abuse deterrent)	Pain	Oral	2
TEV-48125 (anti CGRP)	Chronic and episodic migraine	Subcutaneous	2
TV-45070 Topical	Neuropathic pain	Topical	2

Vantrela ER (CEP-33237 Extended Release Hydrocodone) is our formulation of hydrocodone, an opioid analgesic, utilizing our OraGuard® technology, with potential abuse-deterrent properties that has been evaluated for resistance to physical manipulations, chemical extractions and multi-step chemical extractions methods. A Phase 3 study was completed in August 2011, but did not demonstrate a statistically significant difference between the hydrocodone and placebo treatment groups. A re-designed Phase 3 study demonstrated significant improvement in the treatment of patients chronic low back pain.

Submission of the U.S. NDA was completed in December 2014.

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

TV-46763 and ***TV-46139*** are two pain products with potential abuse-deterrent properties, developed using our OraGuard® technology. TV-46763 is currently in Phase 3 development for safety and efficacy evaluation, which is expected to be completed in the first half of 2016. TV-46139 is in early clinical development.

TEV-48125 (anti CGRP) is a fully humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP). The product was obtained through the Labrys acquisition in June 2014. TEV-48125 is being developed for the prevention of chronic and high frequency episodic migraine. In the Phase 2b trial, TEV-48125 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 will be initiated in the first half of 2016.

TEV-48125 is protected by patents expiring in 2026 in Europe and in 2027 in the United States.

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 than placebo. TV-45070 is currently in Phase 2 development for neuropathic pain.

In a recent phase 2b clinical trial, TEV-45070 demonstrated a favorable safety and tolerability profile, with no drug-related serious adverse events. However, TV-45070 did not demonstrate a statistically significant difference from placebo in efficacy endpoints associated with pain due to osteoarthritis of the knee.

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

Respiratory Medicines

We are committed to maintaining a leading presence in the respiratory market, a 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 therapies for patients through novel delivery systems and therapies that address unmet needs.

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In recent years, we have continued to build upon our experience in the development, manufacture and marketing of inhaled respiratory drugs delivered by metered-dose and dry powder inhalers, primarily for bronchial asthma and COPD. In addition, we have invested in high quality manufacturing capability for press and breathe metered-dose inhalers, multi dose powder inhalers, nasal sprays and nebulized therapy.

In 2013, we acquired MicroDose Therapeutx and its proprietary inhalation technology tidal inhaler. This technology allows people suffering from asthma and 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® hydrofluoroalkane (HFA) inhalation aerosol with dose counter (albuterol sulfate) is indicated in 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, which is marketed only in the United States, is the leading quick relief inhaler. 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 beginning on December 19, 2016 and without quantity limitations after June 2018.

ProAir® Respiclick® (albuterol sulfate) is indicated for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 12 years of age and older. In April 2015 ProAir® Respiclick® was approved by the FDA. ProAir® Respiclick® is the first breath actuated dry powder inhaler with Albuterol sulfate as active ingredient approved in the United States. ProAir® Respiclick® is protected by various U.S. Orange Book listed patents expiring between 2017 and 2028.

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® is the fastest growing inhaled corticosteroid in the United States. We market QVAR®, which is manufactured by 3M, in the United States and in major European markets. QVAR® is protected by various Orange Book listed patents in the United States expiring in 2015 and 2017.

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 ß-agonist bronchodilator, and was approved for treatment of asthma and COPD in adults in the EU by the EMA in a centralized procedure. In 2014, we launched Duoresp Spiromax® in several EU countries, including Germany, the U.K. and Spain.

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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, which was also approved by the FDA for a pediatric indication in December 2014.

Respiratory Pipeline

The primary area of focus of respiratory R&D is the development of differentiated respiratory therapies for patients using novel delivery systems that address unmet needs. Our novel delivery systems include:

- An advanced breath-actuated inhaler (BAI) called Easi-Breathe;
- Spiromax® / RespiClick® (US), a novel inhalation-driven multi-dose powder inhaler (MDPI); and
- Tidal Inhaler (formerly Teva MicroDose), 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 Easi-Breathe BAI device is protected by applications and patents expiring between June 2021 and July 2031.
- The Spiromax® / 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 is described below:

Respiratory Products	Potential Indication(s)	Route of Administration	Development Phase (date entered Phase 3)
ProAir® RespiClick® US	Asthma, exercise induced bronchospasm	Oral Inhalation	Approved in U.S. in adults (March 2015). Submitted in U.S. for pediatrics (June 2015)
Reslizumab	Severe asthma with eosinophilia	Intravenous	Submitted in U.S. (March 2015), EU (June 2015)
		Subcutaneous	3 (August 2015)
Fluticasone Salmeterol Spiromax® EU	Asthma, COPD	Oral Inhalation	Submitted in EU (June 2015)
QVAR® BAI US	Asthma, COPD	Oral Inhalation	3 (December 2013)
Fluticasone Propionate MDPI US	Asthma	Oral Inhalation	3 (June 2014)

Fluticasone Salmeterol MDPI US	Asthma	Oral Inhalation	3 (June 2014)
Fluticasone Salmeterol (MDI) EU	Asthma, COPD	Oral Inhalation	1
TV-44649 (Budesonide Formoterol HFA MDI)	Asthma, COPD	Oral Inhalation	1
TV-44664 (Fluticasone Salmeterol DPI)	Asthma, COPD	Oral Inhalation	1

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ProAir® RespiClick US is a dry-powder inhaler formulation of albuterol in our multi-dose powder inhaler device that is designed to be an improvement to our ProAir® product. ProAir® RespiClick was approved by the FDA in March 2015 for use in adults and adolescents (12 years of age and older) to treat asthma and exercise-induced bronchospasm. The product was accepted for filing by the FDA on September 8, 2015 for pediatric use in patients aged 4 years and older.

The ProAir® RespiClick product is protected by the device patents and applications noted above.

Reslizumab is an investigational humanized monoclonal antibody (MAb) against interleukin-5 (IL-5). IL-5 has been shown to play a crucial role in the maturation, growth and chemotaxis (movement) of eosinophils, inflammatory white blood cells implicated in a number of allergic diseases.

The reslizumab BLA submission for the intravenous product was accepted by the FDA on June 15, 2015 based on Phase 3 study results from August 2014. Study results indicated the product met the primary endpoint of reduction in the frequency of clinical asthma exacerbations compared to placebo.

The Phase 3 clinical program for the subcutaneous reslizumab product was initiated in August 2015.

Reslizumab is protected by patents in the United States that expire in 2017. We expect the product to be entitled to 10 years regulatory exclusivity in Europe and 12 years biological exclusivity in the United States, beginning on the date of approval.

Fluticasone Salmeterol Spiromax® EU is being developed per EU guidance to achieve the same clinical outcomes as Seretide® Accuhaler®. Bioequivalence has been demonstrated for the high strength product and the product was submitted to EMA in June 2015. Further clinical development for the middle strength product is planned in 2016.

The Fluticasone Salmeterol Spiromax® EU product is protected by the device patents and applications noted above.

QVAR® BAI US (beclomethasone) is an oral aerosol corticosteroid in development for the treatment of asthma for ages four years and older. The product is delivered using our advanced breath-actuated inhaler. The Phase 3 clinical program was initiated in December 2013 and is expected to be completed in mid-2016. Results from the low strength safety and efficacy study in February 2015 confirmed the primary end points were achieved. NDA submission is planned in 2016.

The QVAR® BAI product is protected by Easi-Breathe BAI 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.

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

The Fluticasone Propionate MDPI US product is protected by the device patents and applications noted above.

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

Phase 3 clinical trial results in November 2015 demonstrated clinically relevant and greater benefit at all doses compared to placebo and vs. respective monotherapy (fluticasone propionate) in the improvement of lung function. Regulatory submission to the FDA is planned in 2016.

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Fluticasone Salmeterol (MDI) EU is designed to be comparable to Advair®/Seretide® HFA, delivered in a well-established press-and-breath device. Clinical studies were completed and submission plans are in development.

TV-44649 (Budesonide Formoterol HFA MDI) is a long acting ß2-agonist and an inhaled corticosteroid combined for the treatment of asthma in patients 12 years of age and older. TV-44649 is currently in phase 1 clinical development and initiation of pivotal clinical studies to demonstrate therapeutic equivalency to Symbicort® is planned in 2016.

TV-44664 (Fluticasone Salmeterol DPI) is a long acting ß2-agonist and an inhaled corticosteroid combined for the treatment of asthma in patients 4 years of age and older. TV-44664 is currently in phase 1 clinical development and initiation of pivotal clinical studies to demonstrate therapeutic equivalency to Advair® is planned in 2016.

Oncology

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

Treanda® (bendamustine hydrochloride injection) is approved in the United States for the treatment of patients with chronic lymphocytic leukemia (CLL) and patients with indolent B-cell non-Hodgkin s lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. In 2014, we launched a new, easier to use, liquid formulation of Treanda®. While we currently market the product only in the United States, we also hold rights to Treanda® in certain other countries, including Canada.

Treanda® 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.

Including the previously granted six months of pediatric exclusivity, regulatory exclusivity for the NHL indication is scheduled to expire in April 2016. Orphan drug exclusivity for the CLL indication expired in March 2015. We have 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. The 30-month stays against the ANDA filers will expire beginning in May 2016 and continuing into 2017, unless there are court decisions adverse to Teva before that date. We have reached final settlements with 11 of the 19 ANDA filers. Trial against five of the remaining ANDA filers began in December 2015.

Bendeka (bendamustine hydrochloride) injection was approved by the FDA in December 2015. Bendeka is a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride that we have licensed from Eagle to complement our Treanda® franchise. Bendeka is approved for the treatment of patients with CLL and patients with indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Bendeka became commercially available to prescribers in January 2016.

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.

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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 ROW 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. It was approved in Russia in July 2014 and is in registration in other countries around the world. Lonquex® is protected by patents expiring in 2024 in Europe, with extension to 2028 in several countries.

Competitors to Teva s filgrastim include 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 2016-2017 in the United States, and the first long-acting G-CSF biosimilars are also expected to begin launching in the United States in 2016.

Women s Health

Our women s health portfolio includes ParaGard®, Plan B One-Step® OTC/Rx (levonorgestrel), Zoely®, Seasonique® and Ovaleap®, along with a number of other products marketed in various countries.

Plan B One-Step® OTC/Rx (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 on the market. However, in June 2013, it became the first FDA-approved emergency contraceptive to be available without age or point of sales restrictions. Teva is 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.

ParaGard® T380 A (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®, Jaydess® in Europe and Skyla® in the United States by Bayer and patches and vaginal hormonal contraceptive rings like NuvaRing® by Merck.

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Other Specialty Products Pipeline

Our clinical pipeline of other specialty products includes:

Other Specialty Products	Potential Indication(s)	Route of Administration	Development Phase (date entered Phase 3)
CEP-41750 (Mesenchymal Precursor Cell)	Chronic Heart Failure	Intracardiac	3 (March 2014)
	Acute Myocardial Infarction	Injection	2
TEV-90110	HIV	Oral	1
TEV-90111			1
TEV-90112			1
TEV-90113			1

CEP-41750 (Mesenchymal Precursor Cell, Revascor®) consists of human stem cells, the immature cells that give rise to different types of mature cells that make up the organs and tissues of the human body. In December 2010, we entered into a strategic alliance with Mesoblast Ltd. to develop and commercialize Mesoblast s mesenchymal precursor cell therapeutics for hematopoietic stem cell transplantation in cancer patients, certain central nervous system disorders and certain cardiovascular conditions, including congestive heart failure and acute myocardial infarction.

In January 2011, interim results from the ongoing multi-center Phase 2 trial of Revascor® for patients with congestive heart failure were announced. The first of two Phase 3 pivotal studies were initiated in March 2014.

CEP-41750 is protected by patents in the United States that expire in 2021 with potential for patent term extension of up to 5 years.

TEV-90110, TEV-90111, TEV-90112 and TEV-90113 are fixed dose combination products containing antiretrovirals for the treatment of HIV all of which are in Phase 1 clinical development.

Changes to Other Pipeline Projects During 2015

During 2015, the following projects underwent changes to their status due to either clinical results or reprioritization within the Teva pipeline:

Laquinimod for Crohn s disease We cancelled the development for this indication due to our therapeutic area focus.

Albutropin (TV-1106) We decided to terminate the development of TV-1106 and stop all ongoing clinical activities in the area of growth hormones. Based on evolving data from ongoing and completed clinical studies, we reassessed the benefit/risk balance of TV-1106 and the likelihood of regulatory success for TV-1106. No new safety issues were identified with the administration of TV-1106.

Other Activities

Our other activities are comprised of our OTC business and other sources of revenues, which are not included in our generics and specialty segments described above.

Consumer Healthcare Joint Venture

PGT is our consumer healthcare joint venture with P&G. PGT manufactures and markets more than 200 consumer healthcare brands, including OTC medicines and vitamins, minerals and food supplements (VMS), in more than 70 countries around the world. Its portfolio includes leading cough and cold brand Vicks®, Germany s leading OTC brand, ratiopharm, and other leading brands.

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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, along with the pharmaceutical supply, regulatory and development capabilities of Teva. This facilitates expansion into new countries and categories, which enables PGT to quickly reach a significant number of consumers. PGT s strategy builds on improving and finding innovative ways to expand on its existing business.

PGT is focused on expanding in the following categories:

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.

Developing the existing local brands that have market leading potential in individual or groups of countries.

Others

We have other sources of revenues, primarily sales of third-party products for which we act as distributor, mostly in Israel and Hungary, as well as sales of medical products and other miscellaneous items.

Research and Development

Our research and development activities span the breadth of our business, including generic medicines (finished goods and API), specialty pharmaceuticals, new therapeutic entities (NTEs) and OTC medicines. All research and development activities, except for API, are integrated into a single unit, Teva Global R&D.

Generics and Technologies

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 in the United States, Israel, Europe, Latin America, Mexico, Japan and India, include product formulation, analytical method development, stability testing, management of bioequivalence and other clinical studies, and registration of generic drugs in all of the markets where we operate. We have more than one thousand generic products in our pipeline.

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

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

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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

Specialty R&D is focused on the development of small molecule, biologic and biosimilar products including discovery of new compounds, preclinical assessment (including toxicology, pharmacokinetics, pharmacodynamics and pharmacology studies), process development, clinical pharmacology and the design, execution and analysis of clinical trials, as well as regulatory strategy to support registration of our pipeline products.

Teva Global 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 and products that address unmet patient needs. We also pursue select projects in other therapeutic and disease areas that leverage R&D and commercial areas of expertise.

Teva continues to evaluate in-licensing, acquisition and partnership opportunities to supplement our specialty pipeline (e.g., Eagle, Auspex, Microchips Biotech, Gecko Health Innovations and Heptares) to create and maintain a robust and sustainable pipeline.

In parallel, we continue to evaluate and expand the development scope of our R&D pipeline products as well as marketed products to support submission to key markets beyond the United States and Europe.

Innovation Using Existing Molecules (New Therapeutic Entities; Deuteration)

A strategic area of focus of Teva Global R&D is innovation using existing molecules (IEM), which is a major channel to build our pipeline, with a focus on our core therapeutic areas (CNS and respiratory). These IEM projects include the development of 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, safety). Examples of NTEs include use of novel technology to reduce frequency of administration (especially for injectable drugs), enable early onset of action, deter abuse of opioids and other frequently-abused/misused-drugs, new fixed-dose-combinations, drugs with modified pharmacokinetic profiles to reduce side effects, and drugs that are repurposed for new indications. At the end of 2015, our pipeline included 21 NTE projects. These projects incorporate various technological abilities and formulation specialties such as abuse-deterrence, delayed release and rapid release, which form the basis for future development of NTEs.

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 have begun to incorporate deuterated projects into our pipeline with SD-809 (deutetrabenazine) for Huntington disease and tardive dyskinesia and SD-560 (deupirfenidone) for idiopathic pulmonary fibrosis (which is in early development). We anticipate adding more deuterated projects into our portfolio over time.

Because IEMs involve proven targets with known efficacy and safety profiles, we expect their development to involve reduced risks and costs, and shorter timelines compared to novel drugs. On the other hand, there are

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multiple avenues to exclusivity for IEMs, leveraging both regulatory and patent exclusivity to protect novel formulations, combinations and indications. Our IEM programs are in various stages of development, including formulation development, preclinical and clinical.

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 in the United States, as well as a strong pipeline of innovative 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 economies of scale;
- API manufacturing capabilities that offer a stable, high-quality supply of key APIs, as well as efficient vertically integrated 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 over 40 finished dosage pharmaceutical plants in 25 countries, including North America, Europe, Latin America, Asia and Israel. These plants manufacture solid dosage forms, sterile injectables, liquids, semi-solids, inhalers and medical devices. In 2015, Teva produced approximately 61 billion tablets and capsules and over 700 million sterile units. The FDA has approved 18 of our plants, and 26 of our plants are EMA approved. We also have 20 API sites and more than 20 pharmaceutical R&D centers.

Our two primary manufacturing technologies, solid dosage forms and injectables, are available in North America, Latin America, Europe and Israel. The main manufacturing sites for respiratory inhaler products are located in Ireland and Israel. The manufacturing sites located in Israel, Germany, Hungary, Croatia and the Czech Republic comprise a significant percentage of our production capacity.

We are implementing a global Operational Excellence program to optimize our manufacturing efficiency, in order to maintain our goal of supplying high quality, cost-competitive products on a timely basis to our customers globally. In 2015, we sold our manufacturing facilities in Kasukabe (Japan), Sellersville (U.S.) and Kunming (China) and closed our sites in Kutno (Poland) and San Miguel (Peru). We are in process of closing additional facilities and are reviewing other potential sites for restructuring. 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 2015, we continued to invest in our manufacturing capabilities, focusing on strategic growth areas, including the construction of a new oral solid dosage facility in Russia and a new OTC manufacturing facility in India. We invested in expanding our manufacturing facility in Japan, our inhaler activities in Israel and Ireland,

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and our global sterile manufacturing centers in Hungary and Croatia. We constantly review these capabilities and our capacity utilization to ensure efficient alignment with our ability to timely deliver the highest quality products.

Our policy is to maintain multiple supply sources for our strategic products and APIs to the extent possible, so that we are not dependent on a single supply source. However, our ability to do so may be limited by regulatory or other requirements.

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

Location	Total Number of TGO Employees[1]	Principal Market(s) Served
India (5 sites)	2,089	Europe and other non-U.S. markets
Debrecen, Hungary (including one other site)	1,683	Europe and other non-U.S. markets
Zagreb, Croatia (including one other site)	1,434	North America, Europe and other markets
Ulm, Germany	1,366	Europe and other non-U.S. markets
Kfar Saba, Israel	1,296	North America, Europe and other markets
Opava, Czech Republic	1,213	North America, Europe and other markets
Takayama, Japan	1,164	Asia
Neot Hovav, Israel	987	North America, Europe and other markets
Jerusalem, Israel	904	North America and Europe
Canada (3 sites)	716	North America, Europe and other markets
Godollo, Hungary	669	North America, Europe and other markets
Krakow, Poland	598	North America and Europe
Forest, VA, U.S.	428	North America, Europe and other markets
Waterford, Ireland	357	North America, Europe and other markets
Haarlem, Netherlands	353	North America, Europe and other markets
Runcorn, U.K.	346	North America, Europe and other markets
Cincinnati, OH, U.S.	303	North America
Irvine, CA, U.S.	275	North America
Hangzhou, China	252	North America, Europe and other markets

(1) Figures refer to operations employees as of December 31, 2015 (pharmaceutical manufacturing, API manufacturing and API R&D).

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 all over the world. We produce approximately 300 APIs in various therapeutic areas. Our API intellectual property portfolio includes approximately 600 granted patents and pending applications worldwide.

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

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Our API facilities meet all 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. During 2015, inspections of our API facilities worldwide found our manufacturing practices to be in compliance.

Environment

We are committed to business practices that promote socially and environmentally responsible economic growth. During 2015, we continued to make significant progress versus 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. Some highlights include:

- Continued development and implementation of our global EHS management system to promote proactive compliance with all applicable environment, health and safety requirements; to establish minimum global expectations; and drive continuous improvement in our EHS performance.
- Provided EHS regulatory surveillance tools for all countries where we have significant operations.
- Implemented an internal regulatory surveillance EHS audit program to self-identify non-conformities and trigger appropriate corrective and preventative action.
- Continue to assess the environmental footprint of our operations and take action to optimize our processes and operations and reduce our impact through more efficient use of natural resources.

Quality

We are committed to not just complying with quality requirements but to developing and leveraging quality as a competitive advantage. Throughout 2015, we successfully completed numerous inspections of our facilities by regulatory agencies and continued discussions with authorities about drug shortages and participated in several industry-wide task forces. We continue to focus on building 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.

Organizational Structure

Our commercial structure is aligned with our strategy to ensure an integrated Teva.

Teva is led by two commercial business units that work in full synchronization with each other: the Global Specialty Medicines group, formed in April 2013, and the Global Generic Medicines group, formed in July 2014.

The Global Generic Medicines group is responsible globally for all generic commercial activities. This includes portfolio management and selection, product launch and commercial execution. Bringing all of our regional generic businesses under one roof 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 three global divisions: Teva Global Operations, which includes Teva Global Quality and Teva Global R&D, and by global support functions including Finance, Legal, Information Technology, the Business Development, Strategy and Innovation Group, Human Resources and the Corporate Marketing Excellence and Communications Group.

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TGO s responsibilities include development, manufacturing and commercialization of APIs, manufacturing of pharmaceuticals, quality assurance, procurement and supply chain.

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

Our worldwide operations are conducted through a network of global subsidiaries. We have direct operations in many countries around the world, including pharmaceutical manufacturing sites, API sites and R&D centers. The following sets forth our principal operating subsidiaries in terms of aggregate total revenues, as of December 31, 2015:

Name of Subsidiary*	Country
Teva Pharmaceuticals USA, Inc.	United States
Teva Santé SAS	France
Teva UK Limited	United Kingdom
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 Canada Limited	Canada
Teva Limited Liability Company	Russia
Teva Pharma Japan Inc. (Teva Seiyaku)	Japan

* All listed subsidiaries are 100% owned by Teva, except 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, 2015:

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
Forest, VA	450	Manufacturing, packaging and offices
Irvine, CA (7 sites)	362	Pharmaceutical manufacturing and R&D laboratories
West Chester, PA	356	Laboratories
Salt Lake City, UT	347	Offices, manufacturing and R&D laboratories
Cincinnati, OH	305	Pharmaceutical manufacturing, R&D laboratories and packaging
Mexico, MO	204	API manufacturing
Frazer, PA	188	Offices
Pomona, NY	182	Pharmaceutical manufacturing and R&D laboratories
Guayama, Puerto Rico	170	API manufacturing
Miami, FL (3 sites)	157	Manufacturing, R&D laboratories, warehousing and offices
Overland Park, KS	154	Offices
Montvale, NJ	143	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
Europe		
Debrecen, Hungary (3 sites)	2,549	Pharmaceutical manufacturing, API manufacturing, R&D laboratories and warehousing
Ulm, Germany (2 sites)	1,740	Pharmaceutical manufacturing, warehousing and offices
Opava, Czech Republic	1,466	Pharmaceutical and API manufacturing, warehousing and distribution center

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Facility Location	Square Feet (in thousands)	Main Function
Krakow, Poland	939	Pharmaceutical manufacturing and warehousing
Zagreb, Croatia (5 sites)	909	Pharmaceutical manufacturing, packaging and warehousing, API manufacturing and R&D laboratories
Savski Marof, Croatia	577	API manufacturing
Weiler, Germany	521	Pharmaceutical manufacturing and packaging
Waterford, Ireland (3 sites)	413	Pharmaceutical manufacturing, warehousing and packaging
Sajababony, Hungary	374	Mixed use
Zaragoza, Spain (3 sites)	325	Pharmaceutical manufacturing, R&D laboratories
Runcorn, England (2 sites)	284	Pharmaceutical manufacturing, warehousing, laboratories and offices
Glasshoughton, England	255	Warehousing and distribution center
Haarlem, The Netherlands	232	Laboratories
Gödöllõ, Hungary	211	Pharmaceutical manufacturing, hospital supplies manufacturing, R&D laboratories, distribution center, packaging and warehousing
Santhiâ, Italy	177	API manufacturing, R&D laboratories and warehousing
Amsterdam, The Netherlands	176	Distribution center
Eastbourne, England	163	Warehousing and packaging
Asia		
Gajraula (U.P.), India	1,200	API manufacturing
Takayama, Japan	1,009	Pharmaceutical manufacturing
Hangzhou, China	609	API manufacturing
Ahmedabad, India	327	OTC manufacturing, packaging, warehousing and laboratories
Malanpur, India	302	API manufacturing
Goa, India	285	Pharmaceutical manufacturing and R&D laboratories
Koka, Japan	151	Pharmaceutical manufacturing
Nagoya, Japan (2 sites)	141	Offices
Latin America		
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 (4 sites)	297	Pharmaceutical manufacturing, warehousing and R&D laboratories
Ramos Arizpe, Mexico	110	Pharmaceutical manufacturing

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 between 2016 and 2022. We own and lease various other facilities worldwide.

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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.

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.

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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 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 (FDAAA) 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 provides for a 180-day period for the FDA to respond to citizen petitions submitted to the FDA that could delay the approval of generic applications. That 180-day period was reduced to 150 days as part of legislation passed in July 2012. 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.

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On November 13, 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, Teva s 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. As part of these efforts we filed a BLA for our G-CSF product (Granix®) in 2009, which was approved by the FDA in 2012, and was launched in November 2013. 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 issued three substantial draft guidance documents in February 2012 that are intended to provide a roadmap for development of biosimilar products. These draft guidance documents address quality considerations, scientific considerations and questions and answers regarding commonly posed issues.

Healthcare Reform and Certain Government Programs

In early 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 now 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.

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. CMS has proposed, but not yet finalized, a regulation implementing aspects of the PPACA in the Medicaid drug rebate program.

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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 2015, we continued to register products in the EU, primarily using both the mutual recognition procedure (submission of applications in other member states following approval by a so-called reference member state) and the decentralized procedure (simultaneous submission of applications to chosen member states). We continue to use, on occasion, the centralized procedure to register our generic equivalent version of reference products that originally used this procedure.

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.

The requirements and demands of the European pharmacovigilance legislation continue to increase as the guidance on Good Vigilance Practice continues to evolve, and with it increased expectations of the pharmacovigilance inspection authorities. While these developments are in the interest of patient safety and transparency, they are an increasing administrative burden, which inevitably drives an increase in our costs. The new pharmacovigilance fees initiated in the fourth quarter of 2014 have now been fully implemented, and include (i) per license fees that are intended to support the maintenance of the European Pharmacovigilance System; and (ii) per activity fees, for the assessment of pharmacovigilance safety evaluation reports and study protocols for post authorization safety studies and referrals. Further, the requirement for local implementation of risk management materials for an increasing number of products is creating additional burdens and costs for the local markets.

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

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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.

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 50%-60% of the equivalent branded drug prices (which was revised in April 2014 from 60%-70%), 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 60% generic penetration in 2018. In April 2010 and 2012, new financial incentive schemes were established, encouraging pharmacies to substitute generic drugs for branded ones and doctors to prescribe generic drugs. The next reform, which is currently scheduled for April 2016, is likely to further increase generic penetration.

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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 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 task of the Russian government. The strategy emphasizes localization of production and aims to harmonize the Russian pharmaceutical regulations with international principles and standards.

Russian 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 is supervised by the Federal Antimonopoly Service of the Russian Federation, which is expected to result in stricter scrutiny.

As part of the sector strategy, prescription of pharmaceuticals based on INN has been mandatory since 2013, and cGMP requirements became effective in January 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.

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Miscellaneous Regulatory Matters

We are subject to various national, regional and local laws of general applicability, such as laws regulating working conditions. 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.

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 in pharmaceutical markets worldwide, with a significant presence in the United States, Europe and other markets. As a world-leading pharmaceutical company, we are strategically positioned to benefit from ongoing changes in the global healthcare environment.

We seek to address unmet patient needs while capitalizing on evolving market, economic and legislative dynamics in global healthcare. These dynamics include the aging population, increased spending on pharmaceuticals in emerging markets, economic pressure on governments and private payors to provide accessible healthcare solutions, legislative and regulatory reforms, an increase in patient awareness and the growing importance of OTC medicines.

We believe that our dedicated leadership and employees, world-leading generics expertise and portfolio, focused specialty portfolio, global reach, robust R&D capabilities and global infrastructure and scale position us to take advantage of opportunities created by these dynamics.

Segments

We operate our business in two segments:

- **Generic medicines**, which include chemical and therapeutic equivalents of originator medicines in a variety of dosage forms, including 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 or growing presence in our ROW markets. We are also one of the world s leading manufacturers of APIs.

- **Specialty medicines**, which include several franchises, most significantly our core therapeutic areas of CNS medicines such as Copaxone®, Azilect®, Nuvigil® and Zecuity® and of respiratory medicines such as ProAir® HFA and QVAR®. Our specialty medicines segment includes other therapeutic areas, such as oncology medicines, including Treanda®, women s health and selected other areas.

In addition to these two segments, we have other activities, primarily PGT Healthcare, our OTC consumer healthcare joint venture with P&G.

Strategy

In 2014, we began a process of re-defining and re-focusing our business strategy to better leverage our strengths and differentiate ourselves in the pharmaceutical market. We seek to capitalize on our advantages including the largest generic medicines business in the world, a focused specialty business, a unique OTC business and our robust R&D and API capabilities to provide patients with integrated, outcome-focused solutions. Underlying our strategy is our heightened focus on profitable and sustainable business.

The key elements of our strategy consist of:

- ***Solidifying our foundation and driving organic growth***. We have solidified, and continue to strengthen, the core foundations of our generics and specialty businesses to create additional value from our existing operations. We continue to drive organic growth and improve profitability in our generics business.

- ***Transforming our generics business***. Upon consummation of our acquisition of Actavis Generics, the Actavis Generics portfolio and pipeline, combined with our strong existing generics portfolio, will

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further enhance our goals of delivering the highest quality generic medicines at competitive prices. The combined generic business will have a commercial presence across 100 markets, including a top three leadership position in over 40 markets.

Focusing on key growth markets. While we currently operate in numerous markets throughout the world, we intend to concentrate our efforts on a smaller number of growth markets where we believe we can establish leadership positions. We are exploring both organic and corporate development initiatives to achieve leadership position in these markets, including, for example, our pending acquisition of Rimsa, a leading pharmaceutical company in Mexico.

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, Europe and other countries in 2015. We also enhanced our oncology portfolio with the FDA s approval in December 2015 of Bendeka (bendamustine hydrochloride), which complements our Treanda® franchise. For many of our other specialty products, we are expanding into new markets, improving the products and taking further steps to protect the franchise while creating value for patients and payors.

Solidifying leadership positions in our core therapeutic areas. We focus on our core therapeutic areas of CNS (including MS, neurodegenerative diseases, movement disorders and pain care) and respiratory (including asthma and chronic obstructive pulmonary disease), where we seek to establish leadership positions. In the past year, we have taken significant steps, both internally and by pursuing business development initiatives, to significantly solidify our position in our core therapeutic areas, specifically with the acquisitions of Labrys and Auspex.

Pursuing strategic business development initiatives. We continue to pursue business development initiatives across all our activities. As part of these initiatives, we will continue to evaluate opportunities for joint ventures, collaborations and other activities that support our strategy.

Highlights

Significant highlights of 2015 included:

Our revenues amounted to $19.7 billion, compared to $20.3 billion in 2014, down 3%, but up 4% in local currency terms.

Our generic medicines segment generated revenues of $9.5 billion, down 3%, and profit of $2.7 billion, an increase of 24%. In local currency terms, revenues increased 5%. The increase in profit resulted from lower S&M expenses and higher gross profit.

On July 27, 2015, we announced an agreement with Allergan plc to acquire Actavis Generics for $33.75 billion in cash and approximately 100 million Teva shares. We continue to work toward satisfying all conditions in order to close by the end of the first quarter of 2016; however, it is possible that closing may be slightly delayed. Following closing of the acquisition, our generics segment is expected to comprise a much larger percentage of our revenues.

Our specialty medicines segment generated revenues of $8.3 billion and profit of $4.4 billion, down 3% and 5%, respectively. In local currency terms, revenues increased 2%. Profit was negatively impacted by lower gross profit and higher R&D expenses, partially offset by lower S&M expenses.

Expenses related to impairments, restructuring and others amounted to $1.1 billion, compared to $650 million in 2014, mainly due to contingent consideration expenses, related primarily to successes in the development of the products acquired in the Labrys and Eagle transactions.

Legal settlements and loss contingencies amounted to an expense of $631 million, compared to a gain of $111 million in 2014, mainly due to additional reserves related to the settlement of the modafinil antitrust litigation, partially offset by insurance proceeds relating to the settlement of the pantoprazole patent litigation.

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Operating income amounted to $3.4 billion, a decrease of 15% compared to 2014, mainly due to legal settlements and loss contingencies as well as impairments, restructuring and others.

Financial expenses amounted to $1.0 billion, compared to $313 million in 2014. The increase was mainly due to a $623 million loss on our Mylan shares recognized in the third quarter of 2015. An additional expense of $105 million on our Mylan shares were recorded under impairments, restructuring and others during the second quarter of 2015. As of December 31, 2015, unrealized gain of $312 million on our Mylan shares was recorded in other comprehensive income.

Net income attributable to Teva amounted to $1.6 billion, compared to $3.1 billion in 2014.

Exchange rate differences had a negative impact of $1.3 billion on revenues, but only a $95 million negative impact on operating income.

Cash flow from operating activities amounted to $5.5 billion, an increase of $415 million compared to 2014.

In anticipation of the closing of the Actavis Generics acquisition, in December 2015, we closed public offerings consisting of 54 million ADSs at $62.50 per ADS and 3,375,000 of our 7.00% mandatory convertible preferred shares at $1,000 per share, and then in January 2016, we sold an additional 5.4 million ADSs and 337,500 mandatory convertible preferred shares. The net proceeds from the offerings were approximately $7.24 billion.

In October 2015, we agreed to acquire Rimsa, a leading pharmaceutical company in Mexico, for an aggregate of $2.3 billion in cash. This acquisition is expected to add a portfolio of patent-protected drugs to our business in Latin America.

In May 2015, we acquired Auspex, an innovative biopharmaceutical company specializing in applying deuterium chemistry to known molecules to create novel therapies with improved safety and efficacy profiles, for net cash consideration of $3.3 billion.

In February 2015, we entered into an exclusive license agreement with Eagle for Bendeka™, for the treatment of CLL and indolent B-cell NHL.

For more information regarding these and other transactions in 2015 and 2014, see note 2 of our consolidated financial statements.

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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	
	2015	2014	2013	2015-2014	2014-2013
	%	%	%	%	%
Net revenues	100.0	100.0	100.0	(3)	*
Gross profit	57.8	54.5	52.7	3	3
Research and development expenses	7.8	7.3	7.0	2	4
Selling and marketing expenses	17.7	19.0	20.1	(10)	(5)
General and administrative expenses	6.3	6.0	6.1	2	(2)
Impairments, restructuring and others	5.8	3.2	3.9	74	(18)
Legal settlements and loss contingencies	3.2	(0.5)	7.5	n/a	n/a
Operating income	17.0	19.5	8.1	(15)	140
Financial expenses net	5.1	1.6	2.0	219	(22)
Income before income taxes	11.9	17.9	6.1	(35)	191
Income taxes	3.2	2.9	(0.2)	7	n/a
Share in losses of associated companies net	0.6	**	0.2	n/a	(88)
Net loss attributable to non-controlling interests	0.1	(0.1)	(0.1)	n/a	(19)
Net income attributable to Teva	8.1	15.1	6.2	(48)	141

* Represents an amount less than 0.5%.
** Represents an amount less than 0.05%.

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,					
	2015		2014		2013	
	U.S.$ in millions / % of Segment Revenues					
Revenues	$ 9,546	100.0%	$ 9,814	100.0%	$ 9,902	100.0%
Gross profit	4,499	47.1%	4,253	43.3%	4,083	41.2%
R&D expenses	513	5.4%	512	5.2%	488	4.9%
S&M expenses	1,304	13.6%	1,575	16.0%	1,915	19.3%
Segment profit**	$ 2,682	28.1%	$ 2,166	22.1%	$ 1,680	17.0%

* The data presented have been conformed to reflect the revised classification of certain of our products for all periods.
** Segment profit is comprised 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. The data presented have been conformed to reflect the exclusion of equity compensation expenses for all periods. See note 20 of our consolidated financial statements and Operating Income below for additional information.

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Revenues

Our generic medicines segment includes generic medicines as well as API products sold to third parties. Revenues from our generic medicines segment in 2015 amounted to $9.5 billion, a decrease of $268 million, or 3%, compared to 2014. In local currency terms, sales increased 5%.

Revenues of generic medicines in the United States, our largest generic market, amounted to $4.8 billion, an increase of $375 million, or 8%, compared to 2014. Revenues of generic medicines in Europe amounted to $2.7 billion, a decrease of $442 million, or 14%, compared to 2014. In local currency terms, European sales decreased 1%. Revenues from generic medicines in our ROW markets amounted to $2.0 billion, a decrease of 9% compared to 2014. In local currency terms, ROW sales increased 6%.

API sales to third parties in 2015 amounted to $748 million, an increase of 3% compared to 2014. In local currency terms, sales increased 5%, mainly due to an increase in sales across all regions.

Comparison of 2014 to 2013. In 2014, revenues from generic medicines amounted to $9.8 billion, a decrease of 1% compared to $9.9 billion in 2013. In local currency terms, revenues increased 1%.

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

	Year Ended December 31,			Percentage Change	
	2015	2014	2013	2015-2014	2014-2013
	U.S. $ in millions				
United States	$ 4,793	$ 4,418	$ 4,172	8%	6%
Europe*	2,706	3,148	3,362	(14%)	(6%)
Rest of the World	2,047	2,248	2,368	(9%)	(5%)
Total Generic Medicines	$ 9,546	$ 9,814	$ 9,902	(3%)	(1%)

* All members of the European Union, Switzerland, Norway, Albania and the countries of former Yugoslavia.

United States Generic Medicines Revenues

In 2015, we led the U.S. generic market in total prescriptions and new prescriptions, with approximately 473 million total prescriptions, representing 13.1% 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 pending acquisition of Actavis Generics.

Revenues from generic medicines in the United States in 2015 amounted to $4.8 billion, up 8% compared to $4.4 billion in 2014. The increase resulted mainly from the 2015 exclusive launch of esomeprazole (the generic equivalent of Nexium®) and the launch of aripiprazole (the generic equivalent of Abilify®), as well as products that were sold in 2015 that were not sold in 2014. This increase was partially offset by lower sales of the generic versions of Pulmicort® (budesonide inhalation), Xeloda® (capecitabine), Niaspan® (niacin ER) and Lovaza® (omega-3-acid ethyl esters).

Among the most significant generic products we sold in the United States in 2015 were generic versions of Nexium® (esomeprazole), Pulmicort® (budesonide inhalation), Abilify® (aripiprazole), Xeloda® (capecitabine), Adderall XR® (mixed amphetamine salts ER), Lovaza® (omega-3-acid ethyl esters) and Detrol® (tolterodine tartrate ER).

Comparison of 2014 to 2013. Total generic revenues in the United States in 2014 amounted to $4.4 billion, up from $4.2 billion in 2013. This increase was mainly due to launches of key products.

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Products. In 2015, 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)*
Linezolid injection 600mg/300mL	Zyvox®	January	$ 464
Valsartan tablets 40, 80, 160 & 320mg	Diovan®	January	$ 1,903
Dexmethylphenidate HCl ER capsules 10mg	Focalin XR®	February	$ 169
Leucovorin calcium for injection 100mg/vial**		February	$ 3
Methylprednisolone acetate injectable suspension 40mg/mL**	Depo-Medrol®	February	$ 41
Esomeprazole magnesium DR capsules 20 & 40mg	Nexium®	February	$ 5,873
Amlodipine and valsartan tablets 5/160, 10/160, 5/320 & 10/320 mg	Exforge®	March	$ 415
Mesna injection 1 g/10 mL, 100 mg/mL**	Mesnex®	April	$ 8
Argatroban injection in 0.9% sodium chloride 1 mg/mL, 250 mg***		April	
Aripiprazole tablets 2, 5, 10, 15, 20 & 30mg	Abilify®	April	$ 7,901
Ondansetron injection 2 mg/mL, 40mg**	Zofran®	May	$ 39
Risedronate sodium DR tablets 35mg	Atelvia®	May	$ 72
Junel® Fe 24 (norethindrone acetate and ethinyl estradiol tablets USP and ferrous funarate tablets) 1 mg/0.02 mg	Lomedia® 24 Fe	May	$ 53
Risedronate sodium tablets, USP 5, 30 & 35 mg	Actonel®	June	$ 112
Guanfacine ER tablets, 1, 2, 3 & 4 mg	Intuniv®	June	$ 798
Dexmethylphenidate HCl ER capsules, 20 mg	Focalin XR®	June	$ 177
Linezolid tablets 600 mg	Zyvox®	June	$ 468
Aspirin/extended-release dipyridamole capsules 25 mg/200 mg	Aggrenox®	July	$ 436
Almotriptan malate tablets 6.25 & 12.5mg	Axert®	July	$ 30
Ifosfamide injection 50 mg/mL, 1 gm & 50 mg/mL, 3 gm**		August	$ 1
Dutasteride capsules 0.5 mg.	Avodart®	October	$ 457
Oxycodone hydrochloride ER tablets 10, 20, 40 & 80 mg	OxyContin®	October	$ 1,810
Fentanyl citrate lozenges 200, 400, 600, 800, 1200 & 1600 mcg	ACTIQ®	December	$ 59
Eptifibatide injection 0.75 mg/mL, 75 mg	Integrilin®	December	$ 103
Tri-Lo-Sprintec® (norgestimate and ethinyl estradiol tablets, USP) 0.18 mg/0.025 mg	Ortho Tri-Cyclen® Lo	December	$ 489

* For the twelve months ended in the calendar quarter closest to our launch or re-launch.
** Products were re-launched.
*** Approved via 505(b)(2) regulatory pathway; not equivalent to a brand product.

We expect that our generic medicines revenues in the U.S. will continue to benefit from our strong generic pipeline, which, as of January 22, 2016, had 107 product registrations awaiting FDA approval, including 28 tentative approvals. Collectively, these 107 products had U.S. sales in 2015 exceeding $72 billion. Of these applications, 76 were Paragraph IV applications challenging patents of branded products. We believe we are first to file with respect to 34 of these products, the branded versions of which had U.S. sales of more than $25 billion in 2015. IMS reported brand sales are one of the many indicators of future potential value of a launch,

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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.

In 2015 we received, in addition to 23 final generic drug approvals, four tentative approvals which remain tentative at December 31, 2015. A tentative approval letter 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 $ millions (IMS)*
Amlodipine/olmesartan tablets 5/20 mg, 5/40 mg, 10/20 mg & 10/40 mg	Azor®	$	339
Ezetimibe tablets 10 mg	Zetia®	$	2,245
Efavirenz tablets 600 mg	Sustiva®	$	169
Clozapine ODT 12.5 mg	Fazaclo®	$	53

* For the twelve months ended in the calendar quarter closest to the receipt of tentative approval.

Europe Generic Medicines Revenues

Teva defines its European region as the 28 countries in the European Union, Norway, Switzerland and Albania and the countries of the former Yugoslavia. It is a diverse region that has a population of over 500 million people. Revenues presented include those from all 36 countries currently in our European region.

Revenues from generic medicines in Europe in 2015 amounted to $2.7 billion, a decrease of 14% compared to 2014. In local currency terms, revenues decreased 1%, mainly due to our focus on profitable business. All major European region currencies weakened significantly against the U.S. dollar in 2015, especially the euro (16%), British pound (7%) and Hungarian forint (17%).

As in previous years, European regulatory measures aimed at reducing healthcare and drug expenditures have led to slower growth in the generic medicines market, and have adversely affected our revenues in some markets. In Germany, Italy and France, governmental measures (such as tenders and price-referencing) have reduced prices. We have adjusted our strategy to address these changes, shifting from a market share-driven approach to a model emphasizing profitable and sustainable growth. Despite the decrease in revenues, the selective approach to our portfolio and price structuring, as well as our strong focus on cost reduction contributed to significantly improved segment profitability.

As of December 31, 2015, Teva had 969 generic approvals in Europe relating to 96 compounds in 224 formulations, including one EMA approval valid in all EU member states. In addition, Teva had 1,793 marketing authorization applications pending approval in 31 European countries, relating to 156 compounds in 325 formulations, including one application pending with the EMA.

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Listed below are generic revenues highlights for 2015 in our most significant European operations in terms of size:

Germany: Generic revenues in 2015 decreased 11%, but increased 5% in local currency terms. The increase in local currency terms was primarily due to new product launches, partially offset by reduced prices and lower volumes in existing products driven by governmental measures.

United Kingdom: Generic revenues in 2015 decreased 12%, or 5% in local currency terms. The decrease was primarily due to price declines in existing products, partially offset by new product launches.

Italy: Generic revenues in 2015 decreased 8%, but increased 9% in local currency terms. The increase in local currency terms was primarily due to improvements in our supply management.

Switzerland: Generic revenues in 2015 decreased 1%, but increased 4% in local currency terms. The increase was primarily due to higher volumes sold of existing products and new product launches.

France: Generic revenues in 2015 decreased 27%, or 13% in local currency terms, due primarily to increasing competition, the impact of regulatory changes in pharmacy discounting rules and our focus on profitable business.

Spain: Generic revenues in 2015 decreased 31%, or 19% in local currency terms. The decrease was due mainly to the impact of the implementation of new commercial policies, and the increasing scope of the tendering system in the Andalucía region, in which we chose not to participate.

Comparison of 2014 to 2013. Total generic revenues in Europe in 2014 amounted to $3.1 billion, down from $3.4 billion in 2013. In local currency terms, revenues decreased 7%.

ROW Generic Medicines Revenues

Our ROW markets include all countries other than the United States and those in our European region. Our key ROW markets are Japan, Canada, Venezuela and Russia. The countries in this category range from highly regulated, pure generic markets such as Canada, to hybrid markets such as Japan and Brazil, to branded generics markets such as Russia, certain Commonwealth of Independent States markets and Latin American markets.

In our ROW markets, generics revenues amounted to $2.0 billion, a decrease of 9% compared to 2014. In local currency terms, revenues increased 6%. The increase in local currency terms was mainly due to higher revenues in Venezuela, partially offset by lower revenues in Canada and Japan.

Listed below are generic revenues highlights for 2015 in our main ROW markets:

In **Japan**, generic revenues in 2015 decreased 18%, or 7% in local currency terms, compared to 2014, mainly due to a reduction in our contract manufacturing business. The Japanese generics market as a whole is expected to continue to grow, bolstered by new government incentives to increase generic penetration. As described above, we entered into a business venture agreement with Takeda and, subject to regulatory approval, expect the venture to commence operations in the second quarter of 2016.

In **Canada**, where we are one of the two leading generic pharmaceutical companies, generic revenues decreased 35% in 2015, or 25% in local currency terms, compared to 2014. The decrease was primarily due to a negative court ruling related to pricing of a product sold in previous years and lower volumes and prices of other existing products, partially offset by new product launches.

In **Venezuela**, generic revenues increased 60% in 2015, compared to 2014. This increase is primarily due to inflation and higher volumes. Venezuela is a hyperinflationary economy with several official exchange rates. For further information, see below under Impact of Currency Fluctuations on Results of Operations.

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In **Russia**, generic revenues in 2015 decreased 22%, but increased 24% in local currency terms, compared to 2014. The increase in local currency terms was mainly attributable to inflation-related price increases. We maintained our leading position in the Russian generic pharmaceutical market.

Comparison of 2014 to 2013. In 2014, generic medicines revenues in our ROW markets were $2.2 billion, a decrease of 5% compared to 2013. In local currency terms, revenues increased 4%. The increase in local currency terms was mainly due to higher revenues in certain Latin American markets and Canada, partially offset by lower revenues in Japan.

Generic Medicines Gross Profit

In 2015, gross profit from our generic medicines segment amounted to $4.5 billion, an increase of $246 million, or 6%, compared to $4.3 billion in 2014. The higher gross profit was mainly a result of higher revenues from new products launched in the United States during 2015, lower other production expenses and higher gross profit from API sales to third parties. These increases were partially offset by lower gross profit in our ROW markets and lower gross profit in Europe.

Gross profit margin for our generic medicines segment in 2015 increased to 47.1%, from 43.3% in 2014. This increase in gross margin was mainly the result of higher profitability of our European (1.9 points) and United States (1.4 points) markets and lower other production expenses (0.7 points).

Comparison of 2014 to 2013. Generic medicines segment gross profit amounted to $4.3 billion in 2014, compared to $4.1 billion in 2013. Gross profit margin was 43.3% in 2014, compared to 41.2% in 2013.

Generic Medicines R&D Expenses

Research and development expenses relating to our generic medicines in 2015 amounted to $513 million, flat compared to 2014. In local currency terms, generic R&D expenses increased 4% mainly due to higher investment in our U.S. portfolio and development of complex generics for various markets. As a percentage of segment revenues, generic R&D expenses were 5.4% in 2015, compared to 5.2% in 2014.

Our R&D activities for the generic medicines segment include both (a) direct expenses relating to product formulation, analytical method development, stability testing, management of bioequivalence and other clinical studies, regulatory filings and other expenses relating to patent review and challenges prior to obtaining tentative approval, and (b) indirect expenses such as costs of internal administration, infrastructure and personnel involved in generic R&D.

Generic Medicines S&M Expenses

Selling and marketing expenses related to our generic medicines in 2015 amounted to $1.3 billion, a decrease of 17% compared to $1.6 billion in 2014. In local currency terms, S&M expenses decreased 6%, mainly due to lower royalty payments in the United States in connection with our generic version of Pulmicort® (budesonide inhalation) as well as lower expenses in Europe, partially offset by higher S&M expenses in certain ROW markets.

As a percentage of segment revenues, selling and marketing expenses decreased to 13.6% in 2015 from 16.0% in 2014.

Comparison of 2014 to 2013. Generic medicines S&M expenses in 2014 amounted to $1.6 billion, compared to $1.9 billion in 2013.

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Generic Medicines Profit

The profit of our generic medicines segment is comprised of the gross profit for the segment, less selling and marketing expenses and research and development expenses related to this segment. Segment profit does not include general and administrative expenses, amortization and certain other items. Beginning in 2015, expenses related to equity compensation are excluded from our segment results. See note 20 of our consolidated financial statements and Operating Income below for additional information.

Profit of our generic medicines segment amounted to $2.7 billion in 2015, compared to $2.2 billion in 2014. The increase was due to factors previously discussed, primarily lower S&M expenses and higher gross profit.

Generic medicines profit as a percentage of generic medicines revenues was 28.1% in 2015, up from 22.1% in 2014. The increase was mainly due to higher gross margin (increase of 3.8 points) and lower S&M expenses (decrease of 2.4 points), partially offset by higher R&D expenses (increase of 0.2 points).

Comparison of 2014 to 2013. Generic medicines profit amounted to $2.2 billion in 2014, up from $1.7 billion in 2013. In 2014, segment profit as a percentage of revenues amounted to 22.1%, up from 17.0% in 2013.

Specialty Medicines Segment

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

	Specialty Medicines* Year Ended December 31,					
	2015		2014		2013	
	U.S.$ in millions / % of Segment Revenues					
Revenues	$ 8,338	100.0%	$ 8,560	100.0%	$ 8,388	100.0%
Gross profit	7,200	86.3%	7,457	87.1%	7,274	86.7%
R&D expenses	918	11.0%	872	10.2%	877	10.5%
S&M expenses	1,921	23.0%	1,990	23.2%	1,856	22.1%
Segment profit**	$ 4,361	52.3%	$ 4,595	53.7%	$ 4,541	54.1%

* The data presented have been conformed to reflect the revised classification of certain of our products for all periods.

** Segment profit is comprised 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. The data presented have been conformed to reflect the exclusion of equity compensation expenses for all periods. See note 20 of our consolidated financial statements and Operating Income below for additional information.

Revenues

Specialty medicines revenues in 2015 amounted to $8.3 billion, a decrease of 3% compared to 2014, but increased 2% in local currency terms. In the United States, our specialty medicines revenues amounted to $6.4 billion, an increase of 5% from 2014. Specialty medicines revenues in Europe amounted to $1.5 billion, a decrease of 20%, or 5% in local currency terms, compared to 2014. ROW revenues were $378 million, a decrease of 32%, or 16% in local currency terms, compared to 2014.

Comparison of 2014 to 2013. In 2014, specialty medicines revenues amounted to $8.6 billion compared to $8.4 billion in 2013. United States revenues amounted to $6.1 billion, an increase of 1% from 2013. Specialty medicines revenues in Europe amounted to $1.9 billion, an increase of 2% in both U.S. dollar and local currency terms, over 2013. Specialty medicines revenues in our ROW markets in 2014 amounted to $552 million, an increase of 8%, or 23% in local currency terms, over 2013.

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The following table presents revenues by therapeutic area and key products for our specialty medicines segment for the past three years:

Specialty Medicines Revenues Breakdown

	Year Ended December 31,			Percentage Change	
	2015	2014	2013	2015-2014	2014-2013
	U.S. $ in millions				
CNS	*$ 5,213*	*$ 5,575*	*$ 5,545*	*(6%)*	*1%*
Copaxone®	4,023	4,237	4,328	(5%)	(2%)
Azilect®	384	428	371	(10%)	15%
Nuvigil®	373	388	320	(4%)	21%
Respiratory	*1,129*	*957*	*964*	*18%*	*(1%)*
ProAir®	549	478	429	15%	11%
Qvar®	392	286	328	37%	(13%)
Oncology	*1,201*	*1,180*	*1,005*	*2%*	*17%*
Treanda®	741	767	709	(3%)	8%
Women s Health	*461*	*504*	*510*	*(9%)*	*(1%)*
Other Specialty	*334*	*344*	*364*	*(3%)*	*(5%)*
Total Specialty Medicines	**$ 8,338**	**$ 8,560**	**$ 8,388**	**(3%)**	**2%**

The data presented have been conformed to reflect the revised classification of certain of our products for all periods.

Central Nervous System (CNS)

Our CNS specialty product line includes Copaxone®, Azilect®, Nuvigil®, Fentora®, Amrix®, Zecuity® and several other medicines. In 2015, our CNS sales amounted to $5.2 billion, a decrease of 6%, or 2% in local currency terms, compared to 2014, primarily due to lower Copaxone®, Azilect® and Provigil® revenues.

Copaxone®. In 2015, Copaxone® (glatiramer acetate injection) continued to be the leading multiple sclerosis therapy in the U.S. and globally. Since we launched Copaxone® 40 mg/mL three times a week in the United States and daily Copaxone® 20 mg/mL users migrated to this new version, 78% of the total Copaxone® prescriptions are now filled with the 40 mg/mL version. Sales of Copaxone® amounted to $4.0 billion, a 5% decrease compared to 2014. To date, we have launched Copaxone® 40mg/mL in Russia and 14 European countries, with additional launches expected during 2016.

Copaxone® revenues in the United States in 2015 increased 4% to $3.2 billion, mainly due to higher volumes, partially offset by net pricing declines. Our U.S. market shares in terms of new and total prescriptions were 26.5% and 30.0%, respectively, according to December 2015 IMS data.

Revenues in the United States accounted for 81% of global Copaxone® revenues in 2015, an increase from 73% of global sales in 2014.

Our Copaxone® revenues outside the United States amounted to $783 million during 2015, 30% lower than in 2014. In local currency terms, revenues decreased 16%, primarily due to lower tender orders in Russia, as well as lower volumes sold in Europe.

Copaxone® accounted for 20% of our revenues in 2015, and a significantly higher percentage contribution to our profits and cash flow from operations during such period.

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Copaxone® faces competition from an increasing number of oral treatments, a generic version of Copaxone® 20mg/mL and other existing treatments. For further discussion on Copaxone®, see Item 4- Specialty Medicines Central Nervous System Medicines Copaxone®

Comparison of 2014 to 2013. In 2014, global sales of Copaxone® were approximately $4.2 billion, a decrease of 2% compared to 2013. U.S. revenues in 2014 accounted for 73% of global sales of Copaxone®, a decrease from 75% in 2013.

Azilect® global in-market sales, which represent sales by Teva and Lundbeck to third parties, amounted to $514 million in 2015 compared to $549 million in 2014, a decrease of 6%. Our sales of Azilect® amounted to $384 million in 2015, a decrease of 10% compared to 2014. The decrease in sales reflects the impact of generic competition in Europe as well as a slowdown in sales to Lundbeck prior to the transfer of the product back to Teva in early 2016, partially offset by an increase in U.S. revenues. We expect generic competition in the United States commencing in early 2017.

Comparison of 2014 to 2013. In 2014, global in-market sales of Azilect® amounted to $549 million, an increase of 11% compared to 2013. Our sales of Azilect® in 2014 amounted to $428 million, an increase of 15% compared to 2013.

Nuvigil® global sales in 2015 amounted to $373 million, compared to $388 million in 2014, mainly due to a general market decline. Nuvigil® s market share in terms of total prescriptions of the U.S. wake category was 41.8% at the end of 2015, compared to 42.5% at the end of 2014.

Comparison of 2014 to 2013. In 2014, sales of Nuvigil® amounted to $388 million, an increase of 21% compared to 2013.

Respiratory

Our respiratory portfolio includes ProAir® HFA, ProAir® Respiclick®, QVAR®, DuoResp Spiromax® and Qnasl®. Revenues from our specialty respiratory products increased 18% in 2015 to $1.1 billion, primarily due to higher sales in the U.S. Sales in Europe were flat, as increased volumes, primarily from DuoResp Spiromax®, were offset by negative foreign currency effects.

ProAir® HFA revenues in 2015 amounted to $549 million, an increase of 15% compared to 2014, mainly due to volume growth. ProAir® maintained its leadership in the Short Acting Beta Agonist market, with a market share of 57.1% in terms of total number of prescriptions during the fourth quarter of 2015, an increase of 0.1 points compared to the fourth quarter of 2014.

QVAR® global revenues in 2015 amounted to $392 million, an increase of 37% compared to 2014, due to pricing variances and volume increases. QVAR® maintained its second-place position in the inhaled corticosteroids category in the United States, with a market share of 38.1% in terms of total number of prescriptions during the fourth quarter of 2015, an increase of 2.1 points compared to the fourth quarter of 2014.

Comparison of 2014 to 2013. In 2014, revenues of our respiratory products amounted to approximately $1.0 billion, a decrease of 1% compared to 2013.

Oncology

Our oncology portfolio includes Treanda®, Granix®, Trisenox®, Synribo® in the United States and Lonquex®, Myocet®, Eporatio®, Tevagrastim®/Ratiograstim® and Trisenox® outside the United States. Sales of these products amounted to $1.2 billion in 2015, flat compared to 2014, mainly due to our higher sales of G-CSF products, Granix® and Lonquex® in the United States and Europe, offset by lower sales of Treanda® and other products.

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Treanda® revenues amounted to $741 million in 2015, compared to $767 million in 2014, mainly due to lower volumes caused by wholesalers inventory management in the fourth quarter of 2014.

In December 2015, the FDA approved **Bendeka** , a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride that we have licensed from Eagle, which complements our Treanda® franchise. Bendeka became commercially available in January 2016.

Comparison of 2014 to 2013. In 2014, sales of our oncology products were $1.2 billion, an increase of 17% from $1.0 billion in 2013.

Women s Health

Our women s health portfolio includes ParaGard®, Plan B One-Step® OTC/Rx (levonorgestrel), Zoely®, Seasonique® and Ovaleap® along with a number of other products marketed in various countries.

Revenues from our global women s health products amounted to $461 million in 2015, a decrease of 9% from $504 million in 2014, mainly due to lower sales of several products in Europe, partially offset by higher U.S. sales of Paragard® and Plan B One-Step®.

Comparison of 2014 to 2013. In 2014, sales of our women s health products amounted to $504 million, a decrease of 1% from $510 million in 2013.

Specialty Medicines Gross Profit

In 2015, gross profit from our specialty medicines segment amounted to $7.2 billion, a decrease of 3% compared to $7.5 billion in 2014. The lower gross profit was mainly a result of a different product mix.

Gross profit margin for our specialty medicines segment in 2015 was 86.3%, compared to 87.1% in 2014. The decrease in gross margin was mainly a result of lower sales of Copaxone® and higher sales of respiratory and oncology products with slightly lower gross margins.

Comparison of 2014 to 2013. Specialty medicines segment gross profit amounted to $7.5 billion in 2014, compared to $7.3 billion in 2013. Specialty medicines segment gross profit margin was 87.1% in 2014, compared to 86.7% in 2013.

Specialty Medicines R&D Expenses

Our specialty R&D activities focus primarily on product candidates in the CNS and respiratory therapeutic areas, with additional activities in selected areas. Research and development expenses relating to our specialty medicines in 2015 were $918 million, up 5% compared to $872 million in 2014. In local currency terms, specialty R&D expenses increased 7%, mainly due to development costs related to assets acquired through the Auspex and Labrys acquisitions, partially offset by lower investments in our non-core therapeutic areas. As a percentage of segment revenues, R&D spending was 11.0% in 2015, compared to 10.2% in 2014.

Specialty R&D expenditures include certain upfront and milestone payments for products in the development phase, the costs of discovery research, preclinical development, early- and late-clinical development and drug formulation, clinical trials and product registration costs and are reported net of contributions received from collaboration partners. Our specialty R&D spending takes place throughout the development process, including (a) early-stage projects in both discovery and preclinical phases; (b) middle-stage projects in clinical programs up to phase 3; (c) late-stage projects in phase 3 programs, including where an NDA is currently pending approval; and (d) life cycle management and post-approval studies for marketed products. Furthermore, our R&D activities in innovation using existing molecules are managed and reported as part of our specialty R&D expenses.

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We consider phase 3, or late-stage development, to be our most significant R&D programs, as they could potentially affect revenues and earnings in the relatively near future. In addition, we incur indirect expenses that support our overall specialty R&D efforts but are not allocated by product or to specific R&D projects, such as the costs of internal administration, infrastructure and personnel. Our specialty segment R&D expenses include such unallocated expenses.

The following table presents the composition of our specialty R&D expenditures and the number of projects by stage of development:

	2015 Expenditure U.S.$ in millions	No. of Projects as of Dec. 31, 2015	2014 Expenditure U.S.$ in millions	No. of Projects as of Dec. 31, 2014	2013 Expenditure U.S.$ in millions	No. of Projects as of Dec. 31, 2013
Early stage*: discovery and pre-clinical	$ 65	N/A	$ 71	N/A	$ 57	N/A
Middle stage: clinical up to phase 3	203	22	130	21	148	16
Late stage: phase 3, registration and post-approval regulatory requirements	346	37	420	27	415	16
Unallocated R&D**	321		302		276	
Total gross R&D expenses***	935		923		896	
Total net R&D expenses	$ 918		$ 872		$ 877	

* Including early stage innovation using existing molecules.
** Unallocated R&D expenses are indirect expenses that support our overall specialty R&D efforts but are not allocated by product or to specific R&D projects, such as the costs of internal administration, infrastructure and personnel.
*** Gross R&D expenses include the full cost of programs that are partially funded by third parties.

We changed the classification of certain of our products, which impacted the classification of related expenses. The data presented have been conformed to reflect the revised classification.

Specialty Medicines S&M Expenses

S&M expenses related to our specialty medicines in 2015 amounted to $1.9 billion, compared to $2.0 billion in 2014. In local currency terms, S&M expenses increased 2%, mainly due to new respiratory and pain product launches.

As a percentage of segment revenues, selling and marketing expenses decreased to 23.0% in 2015 from 23.2% in 2014.

The decrease was primarily due to foreign exchange effects in our European and ROW markets.

Comparison of 2014 to 2013. Specialty medicines S&M expenses in 2014 amounted to $2.0 billion, compared to $1.9 billion in 2013. The increase was mainly due to higher expenditures related to launches of new products.

Specialty Medicines Profit

The profit of our specialty medicines segment is comprised of the gross profit for the segment, less selling and marketing expenses and research and development expenses related to this segment. Segment profit does not

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include general and administrative expenses, amortization and certain other items. Beginning in 2015, expenses related to equity compensation are excluded from our segment results. See note 20 of our consolidated financial statements and Teva Consolidated Results Operating Income below for additional information.

Profit of our specialty medicines segment amounted to $4.4 billion in 2015, compared to $4.6 billion in 2014, a decrease of 5%. This is a result of the factors discussed above, specifically lower gross profit as well as higher R&D expenses, partially offset by lower S&M expenses.

Specialty medicines profit as a percentage of segment revenues was 52.3% in 2015, down from 53.7% in 2014, a decrease of 1.4 points. The decline was mainly attributed to higher R&D expenses as a percentage of specialty medicines revenues (0.8 points) and lower gross profit as a percentage of specialty medicines revenues (0.7 points), partially offset by lower S&M expenses as a percentage of specialty medicines revenues (0.2 points), as discussed above.

Comparison of 2014 to 2013. Specialty medicines profit amounted to $4.6 billion in 2014, compared to $4.5 billion in 2013, an increase of 1.2%. Specialty medicines profit as a percentage of segment revenues was 53.7%, compared to 54.1% in 2013.

Our multiple sclerosis franchise includes our Copaxone® products and laquinimod (a developmental compound for the treatment of MS). The profit of our multiple sclerosis franchise is comprised of Copaxone® revenues and cost of goods sold as well as S&M and R&D expenses related to our MS franchise. It does not include G&A expenses, amortization and certain other items. Our MS franchise profit was $3.1 billion, $3.2 billion and $3.3 billion in 2015, 2014 and 2013, respectively. Profit of our multiple sclerosis franchise as a percentage of Copaxone® revenues was 77%, 75% and 76% in 2015, 2014 and 2013, respectively.

Other Activities

In addition to our generic and specialty medicines segments, we have other activities, primarily PGT Healthcare, our OTC joint venture with P&G, distribution services, primarily in Israel and Hungary, and sales of medical devices.

OTC

Our revenues from OTC products in 2015 amounted to $994 million, flat compared to $996 million in 2014, primarily due to an increase of PGT sales in Venezuela, offset by loss of revenues from our U.S. OTC plants, which were sold back to P&G in July 2014 and a decrease of PGT sales in Russia and certain European countries. Our revenues related to PGT amounted to $992 million, an increase of 11%, compared to $897 million in 2014.

PGT s in-market sales in 2015 amounted to $1.5 billion. This amount represents sales of the combined OTC portfolios of Teva and P&G outside North America.

Comparison of 2014 to 2013. In 2014, our OTC revenues were $996 million, a decrease of 15% compared to 2013, primarily due to the divestment of the U.S. OTC plants in July 2014, previously purchased from P&G as noted above.

Others

Other sources of revenue include sales of third party products for which we act as distributors (mostly in Israel and Hungary) and medical products, as well as miscellaneous items.

Our revenues from other sources in 2015 amounted to $774 million, a decrease of 14% compared to sales of $902 million in 2014. The decrease was mainly due to the loss of a large distribution contract in Israel.

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Comparison of 2014 to 2013. In 2014, revenues amounted to $902 million, an increase compared to $859 million in 2013.

Teva Consolidated Results

Revenues

Revenues in 2015 amounted to $19.7 billion, a 3% decrease compared to 2014. In local currency terms, revenues increased 4%. In local currency terms, our revenues were positively affected by higher revenues of our generic medicines and of our specialty medicines as well as higher OTC revenues. Please see Generic Medicines Revenues, Specialty Medicines Revenues and Other Activities OTC above. Exchange rate movements during 2015 in comparison to 2014 negatively impacted overall revenues by approximately $1.3 billion.

Comparison of 2014 to 2013. Revenues in 2014 amounted to $20.3 billion, flat compared to 2013.

Gross Profit

In 2015, gross profit amounted to $11.4 billion, an increase of 3% compared to 2014.

The higher gross profit was mainly a result of factors previously discussed under Generic Medicines Gross Profit and Specialty Medicines Gross Profit above. Gross profit was further affected mainly by lower charges related to the amortization of purchased intangible assets.

Gross profit as a percentage of revenues was 57.8% in 2015, compared to 54.5% in 2014.

The increase in gross profit as a percentage of revenues primarily reflects the higher profitability of our generic medicines segment (an increase of 2.0 points), the lower amortization of purchased intangible assets (an increase of 1.0 point), higher income from OTC and other activities (an increase of 0.4 points), the cessation of U.S. OTC manufacturing (an increase of 0.2 points), a decrease of costs related to regulatory actions taken in facilities (an increase of 0.2 points) and a decrease in accelerated depreciation (an increase of 0.1 point), partially offset by lower profitability of our specialty medicines segment (a decrease of 0.6 points).

Comparison of 2014 to 2013. Gross profit amounted in 2014 to $11.1 billion, an increase of 3% compared to 2013. Gross profit as a percentage of revenues was 54.5% in 2014, compared to 52.7% in 2013.

Research and Development (R&D) Expenses

Net research and development expenses for 2015, including the purchase of in-process R&D, were $1.5 billion, an increase of 2% compared to 2014. Specialty R&D expenses were $918 million and generic R&D expenses were $513 million in 2015, compared to $872 million and $512 million, respectively, in 2014. As a percentage of revenues, R&D spending was 7.8% in 2015, compared to 7.3% in 2014.

In 2015, our R&D expenses were primarily the result of the factors previously discussed under Generic Medicines R&D Expenses and Specialty Medicines R&D Expenses above as well as higher expenses related to cancellation of R&D projects due to focusing on our core therapeutic areas in 2014.

Comparison of 2014 to 2013. In 2014, R&D expenses amounted to $1.5 billion, an increase of 4% compared to 2013.

Selling and Marketing (S&M) Expenses

S&M expenses in 2015 amounted to $3.5 billion, a decrease of 10% compared to 2014. As a percentage of revenues, S&M expenses were 17.7% in 2015, compared to 19.0% in 2014.

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In 2015, we decreased our S&M spending, as discussed under Generic Medicines S&M Expenses and Specialty Medicines S&M Expenses above.

Comparison of 2014 to 2013. S&M expenses in 2014 amounted to $3.9 billion, a decrease of 5% compared to 2013. As a percentage of revenues, S&M expenses decreased from 20.1% in 2013 to 19.0% in 2014.

General and Administrative (G&A) Expenses

G&A expenses in 2015 amounted to $1.2 billion, an increase of $22 million compared to 2014. As a percentage of revenues, G&A expenses were 6.3%, compared to 6.0% in 2014. The increase was mainly due to higher expenses related to our joint venture with P&G and higher legal costs, which were partially offset by income from the divestiture of certain assets.

Comparison of 2014 to 2013. G&A expenses in 2014 amounted to $1.2 billion, a decrease of $22 million compared to 2013. As a percentage of revenues, G&A expenses were 6.0% in 2014 compared to 6.1% in 2013.

Impairments, Restructuring and Others

Charges for impairments, restructuring and others amounted to $1.1 billion in 2015, compared to $650 million for 2014.

Impairments

Impairment of long-lived assets in 2015 amounted to $361 million, comprised of:

1. Identifiable intangible assets impairments of $265 million were recorded, comprised of impairment of $133 million, following a decrease in sales projections of Synribo®, and other product rights impairments of $132 million due to current market conditions and supply chain challenges in various Teva markets. In 2014 and 2013, impairments of identifiable intangible assets were $224 million and $393 million, respectively.

2. Property, plant and equipment $96 million, based on management decisions regarding their expected use as a result of our planned plant rationalization, which triggered a reassessment of fair value. In 2014 and 2013, property, plant and equipment impairment was $163 million and $61 million, respectively.

As of December 31, 2015, the carrying value of our in-process R&D asset Revascor® (mesynchymal precursor cells) was $258 million. This drug candidate is in a phase 3 trial for congestive heart failure. Adverse trial results may lead us to reevaluate the fair value of the asset, which may lead to impairment. Such a loss may also lead us to reassess the current carrying value of our equity interest in Mesoblast Ltd., which was $75 million.

Contingent consideration

In 2015, we recorded $399 million of contingent consideration expenses, mainly due to a $311 million charge following the positive phase 2b results of TEV-48125 in both chronic and episodic migraine prevention and a $63 million charge following the FDA approval of Bendeka™, compared to income of $20 million in 2014.

Comparison of 2014 to 2013. Contingent consideration in 2014 amounted to a gain of $20 million, compared to an expense of $36 million in 2013. The change is mainly related to a 2014 reversal of contingent consideration, following an impairment of a related product.

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Acquisition costs

In 2015, we recorded $211 million of acquisition expenses, comprised mainly of expenses related to the Actavis Generics and Rimsa acquisitions as well as $105 million reflecting an other-than-temporary decline in fair value of our Mylan shares as of June 30, 2015, compared to $13 million for 2014.

Comparison of 2014 to 2013. Acquisition expenses in 2014 amounted to $13 million, compared to $27 million in 2013.

Restructuring

In 2015, we recorded $183 million of restructuring expenses, compared to $246 million in 2014. These expenses were primarily incurred following various initiatives as part of our cost reduction program.

Comparison of 2014 to 2013. Restructuring expenses in 2014 amounted to $246 million, compared to $201 million in 2013. The increase in 2014 was mainly due to our cost-savings plan announced by management in October 2013.

Legal Settlements and Loss Contingencies

Legal settlements and loss contingencies for 2015 amounted to an expense of $631 million, compared to a gain of $111 million in 2014. The 2015 amount is comprised mainly of additional reserves related to the settlement of the modafinil antitrust litigation, partially offset by insurance proceeds relating to the settlement of the pantoprazole patent litigation.

Comparison of 2014 to 2013. Legal settlements and loss contingencies in 2014 amounted to a gain of $111 million, compared to an expense of $1.5 billion in 2013. The change is mainly related to the settlement of the pantoprazole patent litigation in 2013.

Operating Income

Operating income was $3.4 billion in 2015, a decrease from $4.0 billion in 2014. As a percentage of revenues, operating income was 17.0% compared to 19.5% in 2014.

The decrease in operating income was due to factors previously discussed, mainly due to income in 2014 from legal settlements, compared to expenses in 2015 in connection with legal settlements, higher impairments, restructuring and others expenses and lower profit of our specialty segment as well as higher G&A expenses, partially offset by higher profit of our generic segment, lower amortization expenses and higher profit of other activities as well as lower other unallocated expenses.

The decrease of 2.5 points in operating income as a percentage of revenues was mainly due to income in 2014 compared to expenses in 2015 in connection with legal settlements (3.7 points), higher impairments, restructuring and others expenses (2.6 points) and lower profit of our specialty segment (0.5 points) as well as higher G&A expenses (0.3 points), partially offset by higher profit of our generic segment (2.9 points), lower amortization expenses (0.8 points), higher profit of other activities (0.5 points) as well as lower other unallocated expenses (0.4 points).

Comparison of 2014 to 2013. Operating income in 2014 amounted to $4.0 billion, compared to $1.6 billion in 2013. As a percentage of revenues, operating income increased to 19.5% in 2014 from 8.1% in 2013.

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The following table presents a reconciliation of our segments profits to Teva s consolidated operating income for the past three years:

	Year ended December 31,		
	2015	2014	2013
	(U.S.$ in millions)		
Generic medicines profit	$ 2,682	$ 2,166	$ 1,680
Specialty medicines profit	4,361	4,595	4,541
Total segment profit	7,043	6,761	6,221
Profit of other activities	318	226	243
Total profit	7,361	6,987	6,464
Amortization	838	1,036	1,180
General and administrative expenses	1,239	1,217	1,239
Impairments, restructuring and others	631	(111)	1,524
Legal settlements and loss contingencies	1,131	650	788
Other unallocated amounts	170	244	84
Consolidated operating income	$ 3,352	$ 3,951	$ 1,649

Financial Expenses-Net

In 2015, financial expenses amounted to $1.0 billion, compared to $313 million in 2014. The increase is mainly due to an other-than-temporary impairment of securities (primarily our Mylan shares) as well as expenses in connection with the debt tender offer and the termination of related swap agreements, partially offset by lower interest expenses, higher income from hedging and derivatives activities as well as higher income from investments.

Comparison of 2014 to 2013. In 2014, financial expenses amounted to $313 million, compared to $399 million in 2013.

Venezuela has experienced hyperinflation in recent years and has several official exchange rates, which deviate significantly among themselves as well as from unofficial market rates. In addition, remittance of cash outside of Venezuela is limited. As further described below, we currently prepare our financial statements using the official preferential industry exchange rate of 6.3 bolivars per U.S. dollar. If such exchange rate is no longer able to be used as a result of a devaluation, we are exposed to a potential loss of our net monetary assets in Venezuela, which, as of December 31, 2015, amounted to approximately $487 million using the official exchange rate.

Tax Rate

In 2015, income taxes amounted to $634 million, or 27% of pre-tax income of $2.4 billion. In 2014, income taxes amounted to $591 million, or 16% of pre-tax income of $3.6 billion. In 2013, the tax benefit amounted to $43 million, or 3% of pre-tax income of $1.3 billion. The increase in our annual effective tax rate compared to 2014 resulted primarily from the mix of products sold in different geographies and the effect of the loss on our Mylan shares.

The statutory Israeli corporate tax rate was 26.5% in 2015. However, our effective consolidated tax rates have historically been lower than the statutory rate because of tax incentives we benefit from in Israel and other countries. Most of our investments in Israel were granted Approved Enterprise status, which confers certain tax benefits. These benefits included a long-term tax exemption for undistributed income generated by such projects, effective until 2013, and lower tax rates in 2014 and onwards, as described in Item 10 Additional Information Israeli Taxation. We also benefit from other investment-related and R&D-related tax incentives in many of our facilities around the world.

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In the future, our effective tax rate is expected to fluctuate as a result of various factors, including changes in the product mix and geographical distribution of our income, the effect of mergers and acquisitions, and the effects of statutes of limitations and legal settlements which may affect provisions for uncertain tax positions.

Share in Losses of Associated Companies Net

Share in losses of associated companies net amounted to $121 million, compared to $5 million in 2014.

As a result of an other-than-temporary loss in value of our investment in Mesoblast due to adverse changes in market conditions, an impairment of $171 million was recorded in 2015 under Share in losses of associated companies net .

In addition, a $24 million currency translation adjustment was reclassified from accumulated other comprehensive loss to Share in losses of associated companies net , due to dilution of our equity holdings in Mesoblast.

The amounts mentioned above were recorded net of income tax of $71 million.

Net Income

Net income attributable to Teva in 2015 was $1.6 billion, compared to $3.1 billion in 2014. This decrease was due to the factors previously discussed, primarily higher financial expenses and lower operating income, as well as higher share in losses of associated companies net.

Comparison of 2014 to 2013. Net income attributable to Teva in 2014 amounted to $3.1 billion, compared to $1.3 billion in 2013.

Diluted Shares Outstanding and Earnings Per Share

On December 8, 2015, we sold 54 million ADSs at $62.50 per ADS and 3,375,000 of our 7.00% mandatory convertible preferred shares at $1,000 per share. In addition, on January 6, 2016, we sold an additional 5.4 million ADSs and 337,500 mandatory convertible preferred shares pursuant to the exercise of the underwriters over-allotment option. The net proceeds from the offerings were approximately $7.24 billion, after estimated underwriting discounts, commissions and offering expenses.

During 2015, we repurchased approximately eight million shares at a weighted average price of $57.09 per share, for an aggregate purchase price of $0.4 billion. These purchases were made pursuant to our share repurchase program.

The average weighted diluted shares outstanding used for the fully diluted share calculation for 2015, 2014 and 2013 were 864 million, 858 million and 850 million shares, respectively.

The increase in number of shares outstanding compared to 2014 was mainly due to the issuance of ordinary shares in December 2015 and the issuance of shares for employee options exercised and vested RSUs, in addition to higher amounts of dilutive options, RSUs and convertible senior debentures, following an increase in our share price. The increase was partially offset by the impact of the shares repurchased during the first quarter of 2015. For additional information, see Item 16E Purchases of Equity Securities by the Issuer and Affiliated Purchasers below.

At December 31, 2015, 2014 and 2013, the fully diluted share count for calculating Teva s market capitalization was approximately 991 million, 884 million and 857 million shares, respectively. The 2013 and 2014 share counts for calculating Teva s market capitalization were adjusted to fully diluted figures to be comparable to the 2015 fully diluted share count, which takes into account the issuance of our mandatory convertible preferred shares in December 2015. In calculating these share amounts, we used the outstanding number of shares (i.e., not including treasury shares) plus shares that would be outstanding upon the exercise of options and vesting of RSUs and PSUs, as well as the conversion of our convertible senior debentures and mandatory convertible preferred shares, in each case at period end. These share counts accordingly differ from those used for calculating earnings per share, which are based on the weighted share count for the applicable period.

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Diluted earnings per share amounted to $1.82 in 2015, a decrease of 49% compared to diluted earnings per share of $3.56 in 2014. Diluted earnings per share amounted to $1.49 in 2013.

Impact of Currency Fluctuations on Results of Operations

In 2015, approximately 43% of our revenues came from sales outside of the United States. Because our results are reported in U.S. dollars, we are subject to significant foreign currency risks and accordingly, changes in the rate of exchange between the U.S. dollar and the local currencies in the markets in which we operate (primarily the euro, Israeli shekel, Russian ruble, Canadian dollar, British pound, Japanese yen and Hungarian forint) impact our results. During 2015, all the main currencies relevant to our operations decreased in value against the U.S. dollar: the euro by 16%, the Russian ruble by 38%, the Canadian dollar by 13%, the Hungarian forint by 17%, the Japanese yen by 13%, the British pound by 7% and the Israeli shekel by 8% (each on an annual average compared to annual average basis).

As a result, exchange rate movements during 2015 in comparison with 2014 negatively impacted overall revenues by approximately $1.3 billion. However, operating income was reduced by $95 million only.

Venezuela. Our Venezuelan operations use the U.S. dollar as the functional currency due to the hyperinflationary state of the Venezuelan economy. The government of Venezuela currently has three official exchange rates: the CENCOEX rate of 6.3 bolivars per U.S. dollar; the SICAD rate of 13.5; and the SIMADI rate of approximately 200. We use the preferential CENCOEX rate to report our Venezuelan financial position, results of operations and cash flows, since the nature of our business operations in Venezuela, which include the importation, manufacture and distribution of pharmaceutical products, would qualify for the most preferential rates permitted by law.

We cannot predict whether there will be a devaluation of the Venezuelan currency or whether our use of the CENCOEX rate will continue to be supported by the facts and circumstances.

As of December 31, 2015, our net monetary assets in Venezuela that are subject to revaluation totaled approximately $487 million (at the CENCOEX rate).

Comparison of 2014 to 2013. Exchange rate movements during 2014 in comparison with 2013 negatively impacted 2014 revenues by approximately $346 million and reduced our operating income for the year by $114 million.

Liquidity and Capital Resources

Total balance sheet assets amounted to $54.3 billion at December 31, 2015, compared to $46.4 billion at December 31, 2014. The increase resulted mainly from an increase in cash and cash equivalents and investment in securities as well as an increase in intangible assets following the Auspex acquisition, partially offset by foreign exchange fluctuations and lower inventory balances.

Inventory balances at December 31, 2015 amounted to $4.0 billion, compared to $4.4 billion at December 31, 2014. The decrease resulted mainly from foreign exchange fluctuations.

Accounts receivable at December 31, 2015, net of sales reserves and allowances (SR&A), amounted to negative $1.3 billion, compared to negative $0.4 billion at December 31, 2014, mainly due to increases in sales reserves and allowances, primarily customer rebates.

We monitor macro-economic risks in certain emerging markets that are experiencing economic stress, focusing on Latin America and Eastern Europe, and have taken action to limit our exposure in these regions.

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Accounts payables and accruals increased to $3.6 billion at December 31, 2015 compared to $3.2 billion at December 31, 2014.

Our working capital balance, which includes accounts receivable, inventories, deferred taxes and other current assets net of SR&A, accounts payable and other current liabilities, was $32 million at December 31, 2015, compared to $1.6 billion at December 31, 2014. The decrease in working capital is mainly due to the increase in SR&A, increase in accounts payable and accruals, as well as a decrease in inventory.

Investment in property, plant and equipment in 2015 amounted to $0.8 billion, compared to $0.9 billion in 2014. Depreciation amounted to $449 million in 2015, compared to $464 million in 2014.

Cash and cash equivalents and short term and long term investments at December 31, 2015 amounted to $8.4 billion, compared to $2.6 billion at December 31, 2014. The increase was mainly due to $6.6 billion in proceeds received from the issuance of ADSs and our mandatory convertible preferred shares in December 2015, $4.9 billion generated from operating activities net of cash used for capital investments in 2015 and $2.1 billion in proceeds from the issuance of 2.0 billion senior notes in March 2015, partially offset by $3.3 billion used for acquisitions (mainly Auspex), $2.5 billion debt repayment (including $1.3 billion for the debt tender offer in February 2015), $1.2 billion of dividends paid and $0.4 billion decline in the fair market value of our Mylan shares.

As of December 31, 2015, we held net monetary assets of approximately $487 million in Venezuela, which are subject to significant risk of devaluation and for which repatriation is limited.

Following the announcement of the Actavis Generics acquisition, Standard and Poor s Financial Services LLC and Moody s Investor Service, Inc. downgraded our ratings from A-/A3 to BBB+/Baa1 with a Negative/Under Review outlook, respectively.

In November 2015, both Standard and Poor s and Moody s announced that they likely expect a further one notch downgrade to BBB/Baa2 with a stable outlook upon completion of the Actavis Generics acquisition.

2015 Debt Movements

At December 31, 2015, our debt was $10 billion, a decrease of $0.3 billion compared to $10.3 billion at December 31, 2014, mainly due to debt repayments during the year, partially offset by the issuance of 2.0 billion senior notes in March 2015.

In January 2015, we repaid at maturity a 122 million European Investment Bank loan. The loan had borne interest determined on the basis of three months EURIBOR +1.0%.

In February 2015, we consummated a cash tender offer for certain of our outstanding senior notes. We paid $1.3 billion in aggregate consideration to redeem $1.2 billion aggregate principal amount of senior notes.

In March 2015, we issued senior notes in an aggregate principal amount of 2.0 billion, comprised of: 1.3 billion due in March 2023 bearing interest of 1.25% and 0.7 billion due in March 2027 bearing interest of 1.88%.

In June 2015, we repaid at maturity $1.0 billion 3.0% fixed rate senior notes issued in June 2010.

2014 Debt Movements

In March 2014, we repaid $750 million comprised of $500 million of LIBOR + 0.5% floating rate senior notes and $250 million of 1.7% senior notes, both issued in March 2011.

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Aggregate Debt

Our debt at December 31, 2015 is effectively denominated in the following currencies: 44% in U.S. dollars, 39% in euros, 12% in Japanese yen and 5% in Swiss francs.

The portion of total debt classified as short term at December 31, 2015 was 16%, down from 17% at December 31, 2014.

Our financial leverage decreased to 25% at December 31, 2015 from 31% at December 31, 2014.

Our average debt maturity increased from 6.4 years at December 31, 2014 to 6.5 years at December 31, 2015, as a result of the issuance of 2.0 billion senior notes in March 2015 and repayment of short term debt.

In November 2015, we entered into a $3 billion five-year unsecured credit facility (which will increase to $4.5 billion upon closing of the Actavis Generics acquisition), replacing the $3.0 billion unsecured credit facility entered into in 2012. As of December 31, 2015 the credit facility remained unutilized.

Shareholders Equity

Total shareholders equity was $29.9 billion at December 31, 2015, compared to $23.4 billion at December 31, 2014. The increase resulted primarily from $6.6 billion equity issuance in anticipation of the acquisition of Actavis Generics, net income attributed to Teva of $1.6 billion, $0.5 billion of unrealized gain from available-for-sale securities and unrealized gain from derivative financial instruments, $0.4 billion of proceeds from exercise of options and a $0.1 billion increase in non-controlling interests, partially offset by dividend payments of $1.2 billion, the negative impact of foreign exchange fluctuations of $1.1 billion and share repurchases of $0.4 billion.

Exchange rates also had a significant impact on our balance sheet, as approximately 20% of our net assets (including both non-monetary and monetary assets) were in currencies other than the U.S. dollar. When compared with the end of 2014, changes in currency rates had a negative impact of $1.1 billion on our equity as of December 31, 2015, mainly due to the change in value against the U.S. dollar of: the euro by 10%, the Russian ruble by 24%, the Canadian dollar by 16%, the Polish zloty by 10%, the Chilean peso by 15%, the Peruvian nuevo sol by 12%, and the Hungarian forint by 10%. All comparisons are on the basis of end of year rates.

Cash Flow

Cash flow generated from operating activities for 2015 amounted to $5.5 billion, an increase of $0.4 billion compared to 2014. The increase was mainly due to an improvement in the efficiency of our working capital management.

During 2015, we paid $970 million related to the modafinil settlement with the FTC and received $178 million insurance proceeds related to the pantoprazole settlement.

Cash flow generated from operating activities in 2015, net of cash used for capital investments, amounted to $4.9 billion, compared to $4.3 billion in 2014. The increase resulted mainly from higher cash flow generated from operating activities and lower capital expenditures.

Dividends

We announced a dividend for the fourth quarter of 2015 of $0.34 per share. The dividend payment is expected to take place on March 14, 2016, to holders of record as of February 29, 2016.

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Commitments

In addition to financing obligations under short-term debt and long-term senior notes and loans, debentures and convertible debentures, our major contractual obligations and commercial commitments include amounts payable in connection with the closing of the Actavis Generics and Rimsa acquisitions, leases, royalty payments, contingent payments pursuant to acquisition agreements and participation in joint ventures associated with research and development activities.

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 will be paid in cash on March 15, June 15, September 15 and December 15 of each year commencing March 15, 2016, to and including December 15, 2018.

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

In connection with certain development, supply and marketing, and research and collaboration or services agreements, we are required to indemnify, in unspecified amounts, the parties to such agreements against third-party claims relating to (1) infringement or violation of intellectual property or other rights of such third party; or (2) damages to users of the related products. Except as described in our financial statements, we are not aware of any material pending action that may result in the counterparties to these agreements claiming such indemnification.

Certain of our loan agreements and debentures contain restrictive covenants, mainly the requirement to maintain certain financial ratios. We are currently in compliance with all applicable financial ratios.

To help finance the Actavis Generics acquisition, we entered into a bridge loan credit agreement (currently for $22 billion) and term loan agreement (for $5 billion) with a syndicate of banks. Any loan under the bridge facility would bear an interest rate of LIBOR plus a margin ranging from 0.30% to 1.65%, so long as we maintain an investment-grade credit rating. The term loan is split into two tranches of $2.5 billion each, with the first tranche maturing in full after three years and bearing an interest rate of LIBOR plus a margin ranging from 1.000% to 1.375% based on our credit rating from time to time and the second tranche maturing in five years with payment installments each year and bearing an interest rate of LIBOR plus a margin ranging from 1.125% to 1.5% based on our credit rating from time to time. To date, we have not drawn any funds under the bridge loan or the term facilities. We expect to offer various tranches of debt securities, either in lieu of drawing under the bridge loan facility or to repay amounts borrowed thereunder.

Our principal sources of short-term liquidity are our existing cash investments, liquid securities, and available credit facilities; primarily our $3 billion syndicated revolving line of credit (to increase to $4.5 billion following consummation of the Actavis Generics acquisition), as well as internally generated funds, which we believe are sufficient to meet our on-going operating needs. Our cash in hand is generally invested in bank deposits as well as liquid securities that bear fixed and floating rates.

Supplemental Non-GAAP Income Data

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

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

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