TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 20-F
February 09, 2015
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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, 2014

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.

851,871,888 Ordinary Shares

729,850,138 American Depositary 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 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 development and launch of our products, including product approvals and results of clinical trials;
- projected markets and market size;
- anticipated results of litigation;
- 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, 2014 and selected balance sheet data at December 31, 2014 and 2013 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, 2011 and selected balance sheet data at December 31, 2012, 2011 and 2010 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,				
	2014	2013	2012	2011	2010
	U.S. dollars in millions (except per share amounts)				
Net revenues	20,272	20,314	20,317	18,312	16,121
Cost of sales	9,216	9,607	9,665	8,797	7,056
Gross profit	11,056	10,707	10,652	9,515	9,065
Research and development expenses	1,488	1,427	1,356	1,095	951
Selling and marketing expenses	3,861	4,080	3,879	3,478	2,968
General and administrative expenses	1,217	1,239	1,238	932	865
Impairments, restructuring and others	650	788	1,259	430	408
Legal settlements and loss contingencies	(111)	1,524	715	471	2
Operating income	3,951	1,649	2,205	3,109	3,871
Financial expenses net	313	399	386	153	225
Income before income taxes	3,638	1,250	1,819	2,956	3,646
Income taxes	591	(43)	(137)	127	283
Share in losses of associated companies net	5	40	46	61	24
Net income	3,042	1,253	1,910	2,768	3,339
Net income (loss) attributable to non-controlling interests	(13)	(16)	(53)	9	8
Net income attributable to Teva	3,055	1,269	1,963	2,759	3,331
Earnings per share attributable to Teva:					
Basic ($)	3.58	1.49	2.25	3.10	3.72
Diluted ($)	3.56	1.49	2.25	3.09	3.67
Weighted average number of shares (in millions):					
Basic	853	849	872	890	896
Diluted	858	850	873	893	921

Balance Sheet Data

	As at December 31,				
	2014	2013	2012	2011	2010
	(U.S. dollars in millions)				
Financial assets (cash, cash equivalents and marketable securities)	2,601	1,245	3,089	1,748	1,549
Working capital (operating assets minus liabilities)	1,642	2,493	3,589	3,937	3,835
Total assets	46,420	47,508	50,609	50,142	38,152
Short-term debt, including current maturities	1,761	1,804	3,006	4,280	2,771
Long-term debt, net of current maturities	8,566	10,387	11,712	10,236	4,110
Total debt	10,327	12,191	14,718	14,516	6,881
Total equity	23,355	22,636	22,867	22,343	22,002

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Dividends

We have paid dividends on a regular quarterly basis since 1986. Our dividend policy is regularly reviewed by the Board of Directors based upon conditions then existing, including our earnings, financial condition, capital requirements and other factors. Our ability to pay cash dividends may be restricted by instruments governing our debt obligations. Dividends are declared and paid in NIS. Dividends are converted into U.S. dollars and paid by the depositary of our American Depositary Shares (ADSs) for the benefit of owners of ADSs, and are subject to exchange rate fluctuations between the NIS and the U.S. dollar between the declaration date and the date of actual payment. Commencing in April 2015, our dividends will be declared and paid in U.S. dollars.

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 2014.

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

	2014	2013	2012	2011	2010
	In cents per share				
1st interim	34.7	32.0	26.3	23.2	18.8
2nd interim	35.3	32.2	25.0	23.5	18.1
3rd interim	32.1	32.6	25.7	21.9	19.3
4th interim	33.8	34.3	31.1	26.8	21.8

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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 U.S. Orange Book patents covering our leading specialty medicine, Copaxone®. 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 potential generic versions.

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 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 non-recurring items. Our MS franchise profitability was $3.2 billion, $3.3 billion, and $3.0 billion in 2014, 2013 and 2012, respectively. Profitability of our multiple sclerosis franchise as a percentage of Copaxone® revenues was 75%, 76%, and 74% in 2014, 2013 and 2012, 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. Copaxone® also faces 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®. The new oral treatments provide especially intense competition in light of their substantial convenience in comparison to injectables such as Copaxone®. Also, our U.S. Orange Book patents on Copaxone® expired in May 2014 and, subject to further judicial review, in September 2015. As a result, a generic version of our 20mg/20mL product could be sold in the United States if FDA approval is obtained. In addition, our business strategy for Copaxone® relies heavily on the continued migration of a substantial percentage of current daily Copaxone® patients to a new three-times-a-week version and the maintenance of patients on this new version. The failure to achieve our objectives for the new version would likely have a material adverse effect on our financial results and cash flow.

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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 subject to increasing focus and activity by regulatory authorities in recent years. Actions by our employees, or 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 continuing, we have identified certain business practices and transactions in Russia, certain Eastern 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.

Our internal investigation is not complete and 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 continue through the end of 2015, and 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.

Research and development efforts invested in our pipeline of specialty and other products may not achieve expected results.

We must invest increasingly 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. 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.

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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 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.

We may not be able to reduce operating expenses to the extent and during the timeframe intended by our cost reduction program.

In October 2013, we accelerated the goals of our previously announced cost reduction program to $2.0 billion by the end of 2017, with half of that to be achieved by the end of 2014 and 70% by the end of 2015. As part of the acceleration, we planned to reduce our employee headcount by approximately 10% by the end of 2014. This program, the first of its magnitude in our history, is a significant pillar of our strategy, with much of the expected savings targeted for reinvestment in our business. The announced plan for headcount reductions has generated intense governmental and union opposition in Israel and may generate similar opposition in European countries and other locations where we have significant numbers of unionized employees. If such opposition limits our ability to carry out workforce-related aspects of our cost savings program or causes us to grant significant financial concessions, our ability to achieve planned cost reductions will be further impacted. If we are unable to achieve our cost reduction targets during the expected timeframes, our results of operations will be negatively affected and our ability to execute other aspects of our strategy may be slowed or undermined.

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 be engaged in various stages of evaluating or pursuing 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 may result 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 increasing numbers of transactions may divert management s attention from our existing business operations, resulting in the loss of key customers and/or personnel and exposing us to unanticipated liabilities.
- We may fail to integrate acquisitions successfully in accordance with our business strategy or achieve expected synergies and other results.

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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 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 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.

Our patent settlement agreements, which are important to our business, are facing 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 may commence an action against us alleging violations of the antitrust laws. See Competition Matters in note 14 to our consolidated financial statements.

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.

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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.

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 2014, approximately 48% of our revenues came from sales outside the United States. As a result, we are currently subject to significant foreign currency risks, including repatriation restrictions in certain countries, and may face heightened risks as we enter new markets. An increasing proportion of our sales, particularly in Latin America, Central and Eastern European countries and Asia, is recorded in local currencies, which exposes us to the direct risk of devaluations, hyperinflation or exchange rate fluctuations. For example, in 2014, decreases in the value of the Russian ruble resulted in a negative effect of approximately $122 million on our revenues. 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.

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 2014 we recorded sales and expenses in 40 other currencies. Approximately 59% of our operating costs in 2014 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®, Fentora® and Treanda®. For example, Treanda® faces patent challenges from 17 ANDA filers and one 505(b)(2) filer, and if we are unable to enforce our patents, which expire between 2026 and 2031, generic competition could commence as early as September 2015. While we intend to defend the validity of these

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patents vigorously, and will seek to use all appropriate methods 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.

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 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. 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 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.

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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, Pricing and Other Investigations in note 14 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 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, 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.

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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 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 generic pharmaceutical companies (so-called authorized generics). No significant regulatory approvals are required for authorized generics, and brand companies do not face any other significant barriers to entry into such market. Brand companies may seek to delay introductions of generic equivalents through a variety of commercial and regulatory tactics. These actions may increase the costs and risks of our efforts to introduce generic products and may delay or prevent such introduction altogether.

Our 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 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.

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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.

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

A significant proportion of our sales is 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 2014 accounted for 18% 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

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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 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 the fact that litigation with the company that sells the brand versions was still pending at the time. In 2013, we settled the pantoprazole litigation and recorded aggregate charges of
$1.6 billion in 2012 and 2013 related to this matter.

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, 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.

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

The U.S. laws and regulations regarding Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. The subjective decisions and complex methodologies used in making calculations under these programs are subject to review and challenge, and it is possible that such reviews could result in material changes. A number of state attorneys general and others have filed lawsuits alleging that we and other pharmaceutical companies reported inflated average wholesale prices, leading to excessive payments by Medicare and/or Medicaid for prescription drugs. Such allegations could, if proven or settled, result in additional monetary penalties (beyond the lawsuits we have already settled) and possible exclusion from Medicare, Medicaid and other programs. In addition, we are notified from time to time of governmental investigations regarding drug reimbursement or pricing issues. See Government Investigations and Litigation Relating to Pricing and Marketing in note 14 to our consolidated financial statements.

The large amount of long lived assets recorded on our balance sheet 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 an impairment may have occurred. The amount of goodwill, identifiable intangible assets and property, plant and equipment on our consolidated balance sheet has increased approximately 50% in the past five years to $30.5 billion as a result of our acquisitions, and may increase further following future acquisitions. For example, in 2014 we recorded impairment charges on long-lived assets of $387 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.

We have significantly increased our leverage in recent years and more frequently engage in refinancing activities, making us increasingly reliant on access to the capital markets at favorable terms.

Our short- and long-term indebtedness has approximately doubled over the past five years. As a result, our principal and interest payment obligations have increased, as have our costs relating to financing activities. The degree to which we are leveraged could affect our ability to obtain additional financing for acquisitions, refinancing of existing debt, working capital, or other purposes and could make us more vulnerable to industry downturns and competitive pressures as well as interest rate and other refinancing risks. In addition, capital markets have been more volatile in recent years. Such volatility may adversely affect our ability to obtain financing on favorable terms at a time when we need to access the capital markets regularly. Our ability to refinance existing debt and meet our debt service obligations will be dependent upon our future performance and access to the capital markets, which will be subject to financial, business and other factors affecting our operations (including our long-term unsecured credit ratings), many of which are beyond our control.

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.

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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 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, as is the case in Israel from 2014 and on, the applicable tax rates may increase;
- 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 pharmaceutical products. As the world s leading generic medicines company with a strong specialty medicines portfolio, 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® and Nuvigil® and of respiratory medicines such as ProAir® HFA and QVAR®. Our specialty medicines segment includes other therapeutic areas, such as oncology, 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) 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, integrated 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 and certain Latin American countries.

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

Our extensive technological capabilities enable us to provide a very 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 many other pharmaceutical companies.

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

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

We are leveraging our strength in integrated 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 2014, 48% 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 2014, we generated 45% of our generic revenues in the United States, 32% 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 23% in our ROW markets (primarily Japan, Canada 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 integrated 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 are solidifying the core foundations of our generics and specialty businesses to create additional value from our existing operations. In 2014, 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 seek to drive organic growth in our generics business by emphasizing markets where we have or are pursuing leadership positions, and by shifting our generic pipeline and portfolio to include a larger proportion of complex products, with high barriers to entry.

Focusing on key growth markets. While we currently operate in numerous markets throughout the world, in 2015 we intend to concentrate our efforts on a smaller number of large 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.

Maintaining Copaxone® and other key specialty products. We have enhanced our multiple sclerosis (MS) franchise through the introduction of our three-times-a-week Copaxone® 40 mg/mL product in the United States, and will launch Copaxone® 40 mg/mL in Europe and other countries in 2015. 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 plan to focus on our core therapeutic areas of CNS (including MS, neurodegenerative diseases and pain) and respiratory

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(including asthma and chronic obstructive pulmonary disease), establishing leadership positions in such areas. In so doing, we will leverage our focused R&D efforts, new product submissions and strong execution of product launches. In addition, in women s health and oncology, where we have a significant commercial presence, we strive to maintain the existing franchises and may consider business development opportunities to maximize sustainable profitability.

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 commercially-oriented activities.

Executing on our cost reduction program. We are focused on the continued execution of our sustainable efficiency program, which includes improvements in the operational efficiency of our production plants, in our global procurement activities, and others.

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 generics for brand-name pharmaceuticals 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.

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

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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 integrated global R&D function, as well as our API R&D and manufacturing activities, which provide significant vertical integration for our own products. APIs used in pharmaceutical products are subject to regulatory oversight by national health authorities. We produce approximately 300 APIs for our own use and for sale to third parties in many therapeutic areas. 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.

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

Below is a description of our generic medicine 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 375 generic products in more than 1,100 dosage strengths and packaging sizes, including oral, injectables 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 carefully selected 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.

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.

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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.

Europe

Europe, which we define as the 28 countries in the European Union, Norway, Iceland, 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 gradually 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 maintain 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 independent retail pharmacies.

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.

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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 **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 2014 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.

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 comparably 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 and in addition to achieve number two position 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.

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 Russia, Japan and Canada. 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 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 Russia, China, Brazil and India. We intend to further focus our entry to new markets such as Indonesia and significantly enhance our existing presence in other high growth markets such as Mexico, South Korea, Australia and Turkey. In other markets, we will optimize our existing assets and minimize or divest our generic operations.

Key markets highlights

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.

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The Russian government seeks to encourage the use of generic products in order to reduce the cost of pharmaceuticals and increase patient access, which is influencing our portfolio strategy. The government is further seeking to encourage local pharmaceutical production by providing incentives, and we have recently established a manufacturing facility in Yaroslavl, Russia.

Our presence in **Japan** was established and strengthened through the acquisition of several generic companies. In April 2012, we integrated our generic operations into a single entity, Teva Seiyaku (Teva Pharma Japan, Inc.).

Japan is one of the largest pharmaceutical markets in the world. The generic pharmaceutical market constitutes approximately 40% of the total market in volume and about 10% of the total market value. The generic market is expected to continue growing 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 result in increased generic penetration. We continue to establish strategic partnerships with key national and regional wholesalers and top hanshas 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 regulation on pricing, selling and marketing. 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 have the potential to compete with our products.

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, and 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 business also includes our New Therapeutic Entity (NTE) activity, which focuses on enhancing known molecules through new delivery methods, unique combinations or device innovations to address specific patient needs.

Our specialty medicines business faces intense competition from both specialty and generic pharmaceutical companies. We believe that our primary competitive advantage is our integrated 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 and marketing capabilities, which are tailored to our product offerings and to our market and stakeholders needs.

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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.

In the United States, our specialty medicines revenues in 2014 amounted to $6.1 billion, comprising the most significant part of our specialty business. In 2014 specialty medicines revenues in Europe amounted to $1.9 billion and in ROW amounted to $552 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 in the United States to help patients adhere to their treatments, improve patient outcomes, ensure timely delivery of medicines and assist in securing reimbursement. These programs, known as Patient Services and Solutions, reflect the importance we place on supporting patients and are a critical part of our success in this market. We have begun expanding this capability to other regions and 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 and products:

Central Nervous System

Our CNS portfolio, one of our two core therapeutic areas, includes Copaxone® for the treatment 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.

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. Both preclinical and clinical research indicates that Copaxone® may reduce brain volume loss and increase the production of factors that enhance neuronal repair. Copaxone® provides a proven mix of efficacy, safety and tolerability.

Our U.S. Orange Book patents covering Copaxone® 20 mg/mL expired in May 2014 and, subject to further judicial review, in September 2015. As a result, a generic version of our 20 mg/mL product in the United States could be sold in the United States if FDA approval is obtained. We have patents on Copaxone® 20 mg/ml expiring in May 2015 in most of the rest of the world. In 2013, we entered into an agreement with Takeda to market this product in Japan and Takeda has submitted an NDA pursuant to this agreement.

In January 2014, we launched Copaxone® 40 mg/mL, a higher dose of Copaxone® with a three times a week dosing regimen for patients with RRMS, in the United States following approval by the FDA. This formulation

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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 and we received a positive outcome in the decentralized procedure for Copaxone® 40 mg/mL following a Positive Assessment Report from the United Kingdom s Medicines and Healthcare Products Regulatory Agency (MHRA), the Reference Member State (RMS), and all Concerned Member States (CMS) in Europe who were involved in the procedure. We expect to begin launching Copaxone® 40 mg/mL in certain European countries during 2015.

We also filed and are in discussions with marketing authorities in Russia, Australia and other markets globally, with approvals expected over the next several months.

Since the launch of Copaxone® 40 mg/mL three times a week in the United States, over 60% of the total 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.

Our strategy for Copaxone® includes:

- Patients ongoing switch from current daily Copaxone® 20 mg/mL to the new Copaxone® 40 mg/mL version;

- Our specialized Patient Services and Solutions program in the United States, which helps patients comply with their treatments, ensures timely delivery of medicines and assists them in securing reimbursement;

- The GLatiramer Acetate low frequenCy safety and patIent ExpeRience (GLACIER) study, which assessed the safety, tolerability and patient experience of Copaxone® 40 mg/mL compared to Copaxone® 20 mg/mL. This study showed that Copaxone® 40 mg/mL achieved a 50% reduction in injection related adverse events as compared to Copaxone® 20 mg/mL, highlighting the patient benefit of taking Copaxone® 40 mg/mL three times a week relative to 20 mg/mL injected daily;

- In addition to the Orange Book patents, we asserted U.S. Patent No. 5,800,808, which is set to expire on September 1, 2015, against Momenta/Sandoz, Mylan/Natco, and Synthon. In March 2014, the U.S. Supreme Court granted our petition for certiorari, and oral argument took place on October 15, 2014. On September 18, 2014, we dismissed the complaint against Synthon without prejudice with respect to the 808 patent. On January 20, 2015, the Supreme Court issued an opinion vacating the Federal Circuit Court s judgment of invalidity of the 808 patent and remanding the case to the Federal Circuit for further review. On January 22, 2015, we filed new complaints against Dr. Reddy s and Synthon with respect to their ANDAs for glatiramer acetate, 20 mg, alleging infringement of the 808 patent. On January 23, 2015, we filed a request that the lower court restore the original injunction against Momenta/Sandoz and Mylan/Natco that should expire on September 1, 2015.

- In 2013, we filed an application for reissue of the 808 patent with the United States Patent and Trademark Office, adding a new claim. The Patent Office has issued a final rejection of the two claims, which we have appealed to the Patent Trial and Appeal Board of the Patent Office.

- Given the inability of state-of-the-art analytical techniques to fully characterize the active ingredients of Copaxone®, as well as published results showing significant differences in gene expression between Copaxone® and a purported generic version, the regulatory pathway for their approval is uncertain. We believe that any purported generic version should be studied in pre-clinical testing and full-scale, placebo-controlled clinical trials with measured clinical endpoints (such as relapse rate) in RRMS patients to establish safety, efficacy and immunogenicity. Furthermore, because of the chemical complexity of Copaxone®, we believe that it can only be safely manufactured using a series of proprietary methods that have been perfected by Teva for more than 20 years.

We have filed a series of citizen s petitions in the United States requesting that the FDA refuse to approve any ANDA for a purported generic version of Copaxone® without sufficient scientific data.

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Our most recent citizen s petition, filed in July 2014, included the results of a new gene expression analysis demonstrating significant differences between the biological impact of Copaxone® and purported generic versions of Copaxone®, which may have unknown safety and efficacy ramifications for patients.

Copaxone® was responsible for $4.2 billion (including $3.1 billion in the U.S.), or 21% of our revenues in 2014, 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 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. Copaxone® also faces 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.

Azilect® was launched in Israel in March 2005, followed by a rolling launch in various European markets, and became available in the United States in 2006. We market Azilect® jointly with Lundbeck in certain key European countries. We exclusively market Azilect® in the United States, Germany and certain other markets, while Lundbeck exclusively markets Azilect® in the remaining European countries and certain other international markets. By the end of 2015, the initial period of our agreement with Lundbeck ends for all European markets and all marketing rights will revert to us. In 2014, we signed an agreement with Takeda to market this product in Japan.

Azilect® is protected in the United States by several patents that will expire between 2016 and 2027. We hold European patents covering Azilect® which are protected by Supplementary Protection Certificates in a number of European countries until 2019. Azilect® has data exclusivity protection in EU countries until 2015. Azilect® has been subject to various patent challenges mainly in the United States in which certain generic competitors are permitted under a settlement agreement to launch their generic versions just prior to expiry of the patent expiring in February 2017.

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

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

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

In early 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. Nuvigil® is protected by several patents, with a pediatric extension. We have entered into other agreements to permit the other generic filers to enter the market under license 180 days after Mylan s entry.

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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.

Provigil® (modafinil) is indicated for the treatment of excessive sleepiness associated with narcolepsy, obstructive sleep apnea and shift work disorder in the United States. Provigil® began to face generic competition in the United States in March 2012 and, as a result, sales decreased substantially.

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. We plan to launch Zecuity® in the United States in 2015.

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.

Respiratory

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.

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.

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 and 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 after June 2018, after which the quantity limitations cease.

Three major brands compete with ProAir® HFA 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

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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.

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 the second half of 2014, we launched Duoresp Spiromax® in several EU countries, including Germany, the U.K. and Spain.

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.

Oncology

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

Treanda® (bendamustine hydrochloride for 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.

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.

In November 2013, the FDA granted orphan drug exclusivity for Treanda®, for the NHL indication through October 2015. With the previously granted six months of pediatric exclusivity, regulatory exclusivity for this indication is now extended through April 2016. Treanda® also has orphan drug exclusivity for the CLL indication through March 2015, extended to September 20, 2015 based on the previously granted pediatric exclusivity. 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 17 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.

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 novel 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 the potential for patent term extensions.

Competitors to Teva s filgrastim include Neupogen®, and in Europe, also Zarzio® and Nivestim®, which are also G-CSF products.

Women s Health

Our women s health portfolio includes ParaGard®, Plan B One-Step® OTC/Rx (levonorgestrel), and Zoely® along with a number of other local products that are marketed in the United States, Europe and ROW.

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 other 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.

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. The joint venture includes our OTC medicines and vitamins, minerals and food supplements (VMS). PGT manufactures and markets more than 200 consumer healthcare brands 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 we have a strong presence, to increase our 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 our portfolio and expand to new markets.
- Expanding our VMS products globally, in collaboration with Swisse Wellness, Australia s market-leading wellness brand.
- Expanding PGT s digestive product brands, such as Metamucil®, to markets outside the United States, such as Australia, Latin America and Europe.

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 devices 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, 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 operates independently from Teva Global R&D, and focuses on the development of processes for the manufacturing of API, including intermediates, chemicals and biologicals (fermentation), for

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both our generic drugs and our proprietary drugs. Our facilities include a large center in Israel focusing on synthetic products and peptides, a large center in Hungary specializing in fermentation and semi-synthetic products, a facility in India and additional sites in Italy, Croatia, 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.

New Therapeutic Entities

A strategic area of focus of Teva Global R&D is the development of new therapeutic entities with a focus on our key therapeutic areas. NTEs are known molecules that are formulated, delivered or used in a novel way to address unmet patient needs. Examples of NTEs include fixed-dose-combinations that improve adherence and therefore efficacy, drugs with prolonged half-lives to reduce frequency of administration, drugs with modified pharmacokinetic profiles to reduce side effects, drugs that are administered orally instead of by injection, drugs that are delivered in ways that address the needs of special patient populations (for example, children and the elderly), and drugs that are approved for new indications.

Because NTEs 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 multiple avenues to exclusivity for NTEs, leveraging both regulatory and patent exclusivity to protect novel formulations, combinations and indications. At the end of 2014, 15 NTE products are part of the Teva pipeline. These products incorporate various technological abilities and formulation specialties such as tamper-deterrence, delayed release and rapid release, which form the basis for future development of NTEs. The programs are in various stages of development, including formulation development, preclinical and clinical.

Specialty

Another major area of focus for Teva Global R&D is the development of novel specialty products in our key therapeutic areas of CNS and respiratory, with select projects in additional areas. These specialty R&D activities include the discovery of new compounds, preclinical studies (including toxicology, pharmacokinetics, pharmacodynamics and pharmacology studies), process development, clinical pharmacology and the design, execution and analysis of clinical trials, as well as the regulatory work to develop and register the products from our pipeline. We conduct these activities for both small molecules and biologics.

During 2014, we conducted a strategic review of our core therapeutic areas. We defined the core therapeutic areas on which we will focus as CNS (including multiple sclerosis, neurodegenerative diseases and pain care) and respiratory (including asthma and chronic obstructive pulmonary disease). In other therapeutic areas, such as women s health and oncology, where we have a significant commercial presence, we will focus on market-ready or close-to-market assets to maximize sustainable profitability. In addition, we will continue to evaluate opportunities for commercially-oriented activities and collaborations. In parallel, we continue to extend our existing pipeline to additional ROW markets. We intend to continue to supplement our specialty pipeline, by in-licensing or acquiring products including small molecules and biologics, to create a robust and sustainable pipeline.

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CNS and Pain

Our clinical pipeline of CNS and pain projects is described below:

CNS and Pain Projects	Potential Indication	Route of Administration	Development Phase (month and year entering Phase 3)
CEP-33237 ER Hydrocodone (potential abuse deterrent properties)			
	Chronic Pain	Oral	Submitted U.S. (October 2014)
Laquinimod	Multiple Sclerosis (Relapsing Remitting and Progressive Forms)	Oral	3 (RRMS, February 2013)
			2 (PFMS)
	Huntington s Disease	Oral	2
Pridopidine	Huntington s Disease	Oral	2
TV-45070 Topical	Osteoarthritis & Neuropathic pain	Topical	2
TEV-48125 (CGRP MAb)	Chronic and episodic migraine	Subcutaneous	2
TV-46763 (abuse deterrent)	Pain	Oral	1
TV-46139 (abuse deterrent)	Pain	Oral	1

CEP-33237 ER 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 newly designed Phase 3 study was initiated in March 2013 and positive results were received in April 2014 which demonstrated a significant improvement in the treatment of patients chronic low back pain as measured by both weekly average Worst Pain Intensity (primary endpoint) and weekly Average Pain Intensity scores.

We initiated a rolling submission of the U.S. NDA in October 2014. Full submission was completed in December 2014.

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 of which the observed safety and tolerability profile of laquinimod was considered favorable. A third Phase 3 study of laquinimod, CONCERTO, was initiated in February 2013, with the primary endpoint of impact on disability progression. Further clinical studies of laquinimod as add-on therapy in patients with relapsing-remitting multiple sclerosis and as monotherapy in patients with progressive forms of MS are in progress.

In 2012, we submitted a Marketing Authorization Application to the EMA and a New Drug Submission to Health Canada. In January 2014, EMA announced that the risk-benefit profile of laquinimod is not favorable. This decision was re-examined and confirmed by EMA in May 2014. The ongoing Phase 3 CONCERTO trial, testing 0.6 and 1.2 mg 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.

Laquinimod is also being evaluated in an ongoing Phase 2 clinical trial for Huntington s disease.

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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 s disease), which we licensed from Neurosearch A/S in 2012. Phase 2 clinical development was initiated in February 2014.

Pridopidine is protected by patents worldwide that expire in 2020.

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 pain-related indications including osteoarthritis and neuropathic pain. The first Phase 2 study of the topical product for osteoarthritis was initiated in March 2014.

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

TEV-48125 (CGRP MAb) is a fully humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP). The product was obtained through the acquisition of Labrys Biologics, Inc. in June 2014. TEV-48125 (CGRP MAb) is being developed for the prevention of chronic and high frequency episodic migraine and is currently in Phase 2 clinical development.

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

TV-46763 and ***TV-46139*** are two pain products with potential abuse-deterrent properties, developed using our OraGuard® technology. The Phase 1 clinical program for TV-46763 was initiated in April 2014 and will be initiated for TV-46139 in early 2015.

Respiratory

The primary area of focus of our respiratory R&D is the development of products that are based on our proprietary delivery systems, which include:

- An advanced breath-actuated inhaler (BAI);
- Spiromax® EU / mDPI US, a novel inhalation-driven multi-dose powder inhaler (mDPI);
- Tidal Inhaler (formerly Teva MicroDose), a unique nebulization device; and
- Steri-Neb®, our advanced sterile formulations for nebulizers.

This strategy is intended to result in device consistency, allowing physicians to choose which device best matches a patient s needs both in terms of ease of use and effectiveness of delivery of the prescribed molecule.

The Easi-Breathe BAI device is protected by patents and applications expiring between June 2021 and June 2030. Our Spiromax® EU / mDPI US device is protected by patents and applications expiring between June 2021 and October 2034. The actuator with dose counter used in connection with ProAir® HFA and QVAR® is protected by patents and applications expiring between December 2017 and July 2030.

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Our clinical pipeline of respiratory projects is described below:

Respiratory Projects	Potential Indication	Route of Administration	Development Phase (month and year entering Phase 3)
ProAir® mDPI US	Asthma, exercise induced bronchospasm	Oral Inhalation	Submitted US (May 2014)
Reslizumab	Severe Asthma with eosinophilia	Intravenous Subcutaneous	3 (February 2010) 1
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 Spiromax® EU	Asthma, COPD	Oral Inhalation	1
Fluticasone Salmeterol (MDI) EU	Asthma, COPD	Oral Inhalation	1

ProAir® mDPI 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® HFA. The clinical development program has demonstrated the safety and efficacy of ProAir® mDPI US in adults and adolescents (12 years of age and older) with asthma and exercise-induced bronchospasm. The NDA was submitted in May 2014.

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.

Phase 3 study results from August 2014 for the IV product met the primary endpoint of reduction in the frequency of clinical asthma exacerbations compared to placebo. We also statistically demonstrated success in secondary efficacy measures associated with improvements in lung function (Forced Expiratory Volume or FEV1), asthma specific quality of life, and symptoms assessed using Asthma Control Questionnaire and symptom utility index. We expect to submit an NDA for the product in early 2015.

Reslizumab is delivered intravenously, and a Phase 3 clinical program for the subcutaneous product will be initiated in early 2015.

Reslizumab is protected by patents in Europe that expire in 2015 and 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.

QVAR® BAI (beclomethasone) is an oral aerosol corticosteroid in development for the treatment of asthma delivered using our advanced breath-actuated inhaler. The Phase 3 clinical program was initiated in December 2013 and will be completed in early 2015. NDA submission is planned for 2015.

Fluticasone Propionate mDPI US is a new formulation of this combination 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. Phase 2 trials were completed in 2013. The Phase 3 clinical program was initiated in June 2014.

Fluticasone Salmeterol mDPI US is a new formulation of this combination 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 Advair® Diskus. Phase 2 trials were completed in 2013. The Phase 3 clinical program was initiated in June 2014.

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. A middle strength study was initiated in August 2014 and results are expected in early 2015.

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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 the MAA submission is planned for 2015.

Other Specialty Projects

Our clinical pipeline of other specialty projects is described below:

Other Specialty Projects	Potential Indication (per Ext. Pipeline)	Route of Administration	Development Phase (month and year entering Phase 3)
CEP-41750 (Mesenchymal Precursor Cell, Revascor®)	Chronic Heart Failure	Intracardiac Injection	3 (January 2015)
	Acute Myocardial Infraction		2
Albutropin	Growth Hormone Deficiency	Subcutaneous	2
Laquinimod for Crohn s Disease (CD)	Crohn s Disease	Oral	2
TEV-90110	HIV	Oral	1
TEV-90112	HIV	Oral	1
Seasonique® EU	Contraception	Oral	Submitted EU (March 2013)

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, as well as 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 was initiated in March 2014. Interim analysis results, expected in early 2016, will follow the initial cohort, completing six months of follow-up.

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.

Albutropin is a long-acting Somatropin being evaluated for the treatment of Growth Hormone Deficiency in Adults and Adolescents. The Phase 2 clinical program was initiated in March 2013 and will be completed in 2015.

Albutropin is protected by patents worldwide that expire in 2015.

Laquinimod is also being evaluated for Crohn s Disease. A Phase 2 study showed laquinimod may have benefit for patients with Crohn s. We are exploring options for further development.

TEV-90110 & TEV-90112 are two fixed dose combination products containing antiretrovirals for the treatment of HIV in Phase 1 clinical development.

Seasonique® EU is a 91-day oral contraceptive with an 84-day regimen of levonorgestrel and ethinyl estradiol followed by a 7-day regimen of ethinyl estradiol alone. The ethinyl estradiol tablets are used during the seven days, instead of a placebo interval, allowing women to have four scheduled menstrual periods a year and potentially lessening the withdrawal symptoms that result from a sudden, sharp decrease in hormones. Seasonique® is backed by extensive clinical trials and has been available in the United States since 2006.

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Seasonique® was submitted in Europe in March 2013 and received a positive opinion from the CHMP in July 2014.

Seasonique® is protected by patents expiring in Europe in 2022.

Changes to Other Projects During 2014

During 2014, the following projects underwent changes to their status due to either clinical results or reprioritization within the Teva pipeline:

- ***Balugrastim*** for neutropenia no further development is planned;
- ***LAMA Breath Actuated Inhaler*** for the treatment of chronic obstructive pulmonary disease, has been terminated;
- ***LeCette® (Desogestrel and Ethinyl Estradiol)*** for contraception, has been terminated;
- ***Milprosa® (Progesterone Vaginal Ring)*** for luteal support for in vitro fertilization no further development or commercialization is planned;
- ***MDT-637 (Tidal inhaler)*** The tidal inhaler platform device proof of concept study was successful in confirming the functionality of the device as a product delivery platform. However, MDT-637 for respiratory syncytial virus infection did not reach statistically significant positive results for the primary end point in the Phase 2a study. We are currently evaluating the potential for further development;
- ***Custirsen/TV-1011 (OGX-011)***, an antisense drug. Teva and Oncogenex have agreed to return the rights for this asset to Oncogenex; and
- Our once-a-day fixed combination of a prostaglandin agonist and a beta blocker, for the treatment of glaucoma, has been terminated.

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, as well as the broadest generic product line in the United States;
- 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 active ingredients, as well as vertical integration efficiencies; 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 North America, Europe, Latin America, Asia and Israel. These plants manufacture solid dosage forms, sterile injectables, liquids, semi-solids, inhalers and medical devices. In 2014, Teva produced approximately 69 billion tablets and capsules and over 650 million sterile units. 20 of our plants are FDA approved, and 31 of our plants are EMA approved.

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

We have established a global Operational Excellence program to optimize our manufacturing efficiency, and in order to maintain our goal of supplying high quality, cost-competitive products on a timely basis to our customers globally. As part of our efficiency improvement effort, we sold a number of manufacturing sites and facilities this year, including our two U.S. OTC manufacturing sites in Greensboro and in Phoenix and closed our Settimo (Italy) API facility. 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 have established a 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 2014, 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, 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)	1,775	Europe and other non-U.S. markets
Debrecen, Hungary (including one other site)	1,612	Europe and other non-U.S. markets
Zagreb, Croatia (including one other site)	1,370	North America, Europe and other markets
Ulm, Germany	1,340	Europe and other non-U.S. markets
Kfar Saba, Israel	1,327	North America, Europe and other markets
Opava, Czech Republic	1,266	North America, Europe and other markets
Takayama, Japan	1,132	Asia
Neot Hovav, Israel	1,010	North America, Europe and other markets
Jerusalem, Israel	955	North America and Europe
Canada (3 sites)	909	North America, Europe and other markets
Godollo, Hungary	711	North America, Europe and other markets
Krakow, Poland	550	North America and Europe
Forest, VA, U.S.	475	North America, Europe and other markets
Haarlem, Netherlands	448	North America, Europe and other markets
Waterford, Ireland	405	North America, Europe and other markets
Runcorn, U.K.	378	North America, Europe and other markets
Cincinnati, OH, U.S.	320	North America
Irvine, CA, U.S.	305	North America
Hangzhou, China	227	North America, Europe and other markets

(1) Figures refer to operations employees as of December 31, 2014 (pharmaceutical manufacturing, API manufacturing and API R&D).

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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.

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 2014, inspections of our API facilities worldwide found our manufacturing practices to be in compliance.

Environment

Teva is committed to business practices that promote socially and environmentally responsible economic growth. In 2014, we continued to restructure and strengthen our environment, health and safety (EHS) efforts. We are developing and implementing a global EHS management system to align, streamline and enhance our EHS performance, while integrating our program into the business. The Corporate EHS Committee consisting of global senior executives meets on a routine basis and provides oversight of all material EHS matters in Teva.

We have a global environment and sustainability plan which is built on three pillars:

- **Zero incidents:** we strive for zero releases to the environment;
- **100% compliance:** we are putting systems in place that are aligned with internationally recognized standards to assure full compliance; and
- **Reduce impact:** we are working to optimize our operations, to streamline processes and to reduce our environmental footprint through efficient use of resources.

In order to assure compliance in an ever-changing business and regulatory environment, we continuously update and advance our environmental control systems. We believe that we are in substantial compliance with all applicable environment, health and safety requirements.

Quality

Teva is committed to not just complying with quality requirements but to develop and leverage quality as a competitive advantage in the future. Throughout 2014, we successfully completed numerous inspections of our facilities by regulatory agencies without any critical observations. We were in continuous dialogue with authorities about drug shortages and participated in several industry-wide task forces. Internally, we promoted a quality mindset across all of Teva s business functions. We strengthened our quality organization and improved its alignment with other functions. In the coming years, our quality organization will focus on further elevating and enhancing the consistency of our quality processes, integrating quality systems, and fostering our engagement with regulatory authorities and industry groups.

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Organizational Structure

In July 2014, we announced our new commercial structure, which 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, Teva Global R&D and Teva Global Quality, and by global support functions including Finance, Legal, Information Technology, the Corporate Development, Strategy and Innovation Group, Human Resources and the Corporate Marketing Excellence and Communications Group.

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, as well as over 40 finished dosage pharmaceutical manufacturing sites, in 25 countries, 20 API sites and more than 20 pharmaceutical R&D centers. The following sets forth by geography, as of December 31, 2014, our principal operating subsidiaries in terms of aggregate total revenues:

Name of Subsidiary*	Country
Teva Pharmaceuticals USA, Inc.	United States
Teva Santé SAS	France
Teva UK Limited	United Kingdom
ratiopharm GmbH	Germany
Teva Pharmaceutical Works Private Limited Company	Hungary
Teva Gmbh	Germany
Teva Italia S.r.l.	Italy
Teva Pharma S.L.	Spain
Teva Israel	Israel
Teva Canada Limited	Canada
Teva Limited Liability Company	Russia
Teva Seiyaku	Japan

* All listed subsidiaries are 100% held by Teva, except for 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, 2014:

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)	591	Pharmaceutical manufacturing, research laboratories and offices
Shoham Logistics Center	538	Distribution center
Netanya (3 sites)	503	API manufacturing, pharmaceutical warehousing, laboratories, distribution center and offices
Petach Tikva	371	Corporate headquarters
Ashdod	153	Manufacturing of hospital supplies
Assia, Petach Tikva	118	R&D laboratories
United States		
North Wales area, PA (4 sites)	850	Teva USA headquarters, warehousing and distribution center
Forest, VA	450	Manufacturing, packaging and offices
Cincinnati, OH	305	Pharmaceutical manufacturing, R&D laboratories and packaging
Irvine, CA (8 sites)	290	Pharmaceutical manufacturing and R&D laboratories
Miami, FL (3 sites)	240	Manufacturing, R&D laboratories, warehousing and offices
Kutztown, PA	211	Warehousing
Sellersville, PA	206	Pharmaceutical manufacturing, packaging and R&D laboratories
Frazer, PA	194	Offices
Salt Lake City, UT	188	Offices, manufacturing and R&D laboratories
Pomona, NY	181	Pharmaceutical manufacturing and R&D laboratories
Guayama, Puerto Rico	170	API manufacturing
West Chester, PA	165	Laboratories
Overland Park, KS	154	Offices
Mexico, MO	144	API manufacturing
Montvale, NJ	142	Offices
Canada		
Toronto, Ontario	335	Offices, pharmaceutical packaging, warehousing, distribution center and laboratories
Stouffville, Ontario	180	Pharmaceutical manufacturing and R&D laboratories
Markham, Ontario	122	Pharmaceutical manufacturing and warehousing
Europe		
Debrecen, Hungary (3 sites)	2,549	Pharmaceutical manufacturing, API manufacturing, R&D laboratories and warehousing

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Facility Location	Square Feet (in thousands)	Main Function
Ulm, Germany (2 sites)	1,740	Pharmaceutical manufacturing, warehousing and offices
Opava, Czech Republic	1,466	Pharmaceutical and API manufacturing, warehousing and distribution center
Krakow, Poland	939	Pharmaceutical manufacturing and warehousing
Zagreb, Croatia (5 sites)	869	Pharmaceutical manufacturing, packaging and warehousing, API manufacturing and R&D laboratories
Savski Marof, Croatia	577	API manufacturing
Weiler, Germany	425	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
Kutno, Poland	290	Pharmaceutical manufacturing, warehousing and packaging
Runcorn, England (2 sites)	275	Pharmaceutical manufacturing, warehousing, laboratories and offices
Glasshoughton, England	247	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
Malanpur, India	302	API manufacturing
Goa, India	285	Pharmaceutical manufacturing and R&D laboratories
Ahmedabad, India	183	OTC manufacturing, packaging, warehousing and laboratories
Kasukabe, Japan	169	Pharmaceutical manufacturing
Koka, Japan	151	Pharmaceutical manufacturing
Nagoya, Japan (2 sites)	141	Offices
Latin America		
Santiago, Chile (2 sites)	368	Pharmaceutical manufacturing, warehousing and R&D laboratories
Lima, Peru (3 sites)	245	Pharmaceutical manufacturing, warehousing and R&D laboratories
Mexico City, Mexico	240	Pharmaceutical manufacturing, warehousing and R&D laboratories
Munro, Argentina	179	Pharmaceutical manufacturing, warehousing, R&D laboratories and packaging
Ramos Arizpe, Mexico	109	Pharmaceutical manufacturing

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We lease certain of our facilities. In Israel, our principal executive offices and corporate headquarters in Petach Tikva are leased until December 2018. 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.

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

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specific orphan indication. The term orphan drug refers, generally, to a drug that treats a rare disease affecting fewer than 200,000 Americans. Market exclusivity provisions are distinct from patent protections and apply equally to patented and non-patented drug products. Another provision of the Hatch-Waxman Act extends certain patents for up to five years as compensation for the reduction of effective life of the patent which resulted from time spent in clinical trials and time spent by the FDA reviewing a drug application.

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

The Best Pharmaceuticals for Children Act, signed into law in 2002, continues the so-called pediatric exclusivity program established by the FDA Modernization Act of 1997. This pediatric exclusivity program provides a six-month period of extended exclusivity, applicable to certain listed patents and to other regulatory exclusivities for all formulations of an active ingredient, if the sponsor performs and submits pediatric studies 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. Implementation of the program began on October 1, 2012. 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. As part of this legislation, Congress included a provision that extended the period of time that a generic applicant has to receive tentative approval of its ANDA to preserve eligibility for 180-day exclusivity and avoid forfeiture under the Medicare Modernization Act. Applications that were submitted during the 30-month period preceding the signing of the bill (January 9, 2010 to July 9, 2012) are entitled to a 40-month period to receive tentative approval before triggering a forfeiture.

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.

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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.

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 health care 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

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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.

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.

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, or a mutual recognition procedure which requires submission of applications in other member states following approval by a so-called reference member state, or a decentralized procedure that entails simultaneous submission of applications to chosen member states.

During 2014, we continued to register products in the EU, using both the mutual recognition procedure and the decentralized procedure. We continue to use 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 difficulties affecting the whole of the European market.

Some elements of the European Falsified Medicines Directive were enacted into national laws during 2013. The provisions of the Directive are intended to reduce the risk of counterfeit medicines entering the supply chain and also to ensure the quality of API manufactured outside of the EU. Teva worked diligently at the European and country levels to ensure there was no disruption to the supply chain and safeguarded supplies of medicines to the patients who depend on them.

The requirements deriving from European pharmacovigilance legislation are constantly expanding due to an increasing number of guidances on Good Vigilance Practices and increased communication on inspectors expectations. While these new requirements are in the interest of patient safety and transparency, they are an increasing administrative burden, which drives our costs and headcount to be higher. In the fourth quarter of 2014, pharmacovigilance fee legislation became effective, which includes (i) a per license fee that is intended for the maintenance of the European Pharmacovigilance System; and (ii) a per activity fee, for the assessment of pharmacovigilance safety evaluation reports, study protocols for post authorization safety studies and referrals.

The procurement model in parts of Europe for the supply of important secondary care products such as oncology injectable medicines creates a challenge for governments and the pharmaceutical industry. We do everything we can to supply medicines for life-threatening conditions, while at the same time the market creates few incentives for us to do so. Until the procurement model recognizes that stability and sustainability, and the need to allow manufacturers to earn a return on their investment, are important components in purchasing

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decisions, shortages will be almost impossible to avoid. In 2014, we declined to participate in certain tenders and ended our supply in others since the procurement model for this segment was not sustainable. If the situation remains unchanged, we may withdraw certain products from the market because they are commercially nonviable. We continue to work with governments and our customers on ensuring that the patient s needs are protected, but we believe that governments can do more to ensure security of supply by creating adequate incentives for manufacturers to maintain manufacturing capacity.

European Union

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

During 2014, we continued to register products in the EU, 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 the centralized procedure to register our generic equivalent version of reference products that originally used this procedure.

In 2005, a legal pathway was established to allow approval of Similar Biological Medicinal Products (biosimilars) using abbreviated marketing applications. Appropriate tests for demonstration of safety and efficacy include preclinical or clinical testing or both. The reference product for this testing is the brand-name drug, and the scientific principles and regulatory requirements for comparability are followed. Guidelines have been issued providing a more detailed interpretation of the data requirements for specific products, and further guidance is being developed by the respective authorities in conjunction with the pharmaceutical industry.

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 six, eight or ten years from the date of the first market authorization of the original product in the EU. The new legislation, applicable to all members of the EU, changes and harmonizes the exclusivity period for new products where the application for marketing approval was submitted after October 2005 for products filed via the national pathway or November 2005 for products filed via the centralized procedure. The period before marketing approval for a generic product can be pursued (known as data exclusivity) is eight years (from either six or ten years before) following approval of the reference 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 for novel indications. Given that reference products submitted after October or November 2005 will take at least one year to be assessed and approved, the 2005 exclusivity provisions of 8+2+1 years will affect only generic submissions for marketing approval in late 2014 onwards.

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.

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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 market 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

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.

Russia s pricing regulations, which took effect in 2010, impose price restrictions and mark-up regulation 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. Prices are registered in Russian rubles. Local manufacturers are entitled to annual price reviews; however there is currently no procedure for adjusting the prices of foreign manufacturers to inflation or other cost increases.

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.

Various proposals for incentives to support local manufacturing are currently being considered by the Russian government. In particular, it is expected that starting from 2015, foreign-made products may be deemed ineligible under the Russian procurement system if at least two locally manufactured analogous products are available. Amendments to the healthcare legislation, including with respect to obtaining marketing authorizations and compliance rules on interaction with healthcare professionals, are also expected in 2015.

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, beginning in 2008 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 an NOC 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.

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 pharmaceutical products. We operate in pharmaceutical markets worldwide, with major operations in the United States, Europe and other markets. As the world s leading generic medicines company with a strong specialty medicines portfolio, 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, OTC joint venture with P&G, global reach, API production capability, integrated 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® and Nuvigil® and of respiratory medicines such as ProAir® HFA and QVAR®. Our specialty medicines segment includes other therapeutic areas, such as oncology, women s health and selected other areas.

In addition to these two segments, we have other activities, primarily PGT Healthcare, our OTC 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 integrated R&D and API capabilities to provide patients with comprehensive, 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 are solidifying the core foundations of our generics and specialty businesses to create additional value from our existing operations. We seek to drive organic growth in our generics business by emphasizing markets where we have or are pursuing leadership positions, and by shifting our generic pipeline and portfolio to include a larger proportion of complex products, with high barriers to entry.

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Focusing on key growth markets. While we currently operate in numerous markets throughout the world, in 2015 we intend to concentrate our efforts on a smaller number of large 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.

Maintaining Copaxone® and other key specialty products. We have enhanced our MS franchise through the introduction of our three-times-a-week Copaxone® 40 mg/mL product in the United States, and expect to launch Copaxone® 40 mg/mL in certain European and other countries in 2015. 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 plan to focus on our core therapeutic areas of CNS (including MS, neurodegenerative diseases and pain) and respiratory (including asthma and chronic obstructive pulmonary disease), establishing leadership positions in such areas. In so doing, we will leverage our focused R&D efforts, new product submissions and strong execution of product launches. In addition, in women s health and oncology, where we have a significant commercial presence, we strive to maintain the existing franchises and may consider business development opportunities to maximize sustainable profitability.

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 commercially-oriented activities.

Executing on our cost reduction program. We are focused on the continued execution of our sustainable efficiency program, which includes improvements in the operational efficiency of our production plants, in our global procurement activities, and others.

Highlights

Significant highlights of 2014 included:

Our revenues amounted to $20.3 billion, flat compared to 2013, as the decline in sales of OTC as well as generic medicines was offset by higher revenues of our specialty medicines. Excluding the impact of the sale of our U.S. OTC plants and of foreign exchange fluctuations, revenues grew 2%.

Our generic medicines segment generated revenues of $9.8 billion and profit of $2.1 billion, down 1% and up 29%, respectively. The decline in revenues was due to lower sales in the European and ROW markets, largely offset by higher sales in the United States. The increase in profit resulted from lower S&M expenses and higher gross profit.

Our specialty medicines segment generated revenues of $8.6 billion and profit of $4.6 billion, up 2% and 1%, respectively. Specialty revenues were up mainly due to higher sales of Nuvigil®, Treanda® and Azilect®, which were partially offset by the decline in Copaxone® and QVAR® sales. Profit was impacted by higher S&M expenses in support of product launches.

According to December 2014 IMS data, Copaxone® 40 mg/mL accounted for over 60% of total Copaxone® prescriptions in the United States. We expect to begin launching Copaxone® 40 mg/mL in certain European and other countries during 2015.

G&A expenses amounted to $1.2 billion, down 2% compared to 2013, and net financial expenses amounted to $313 million, down 22% compared to 2013.

Impairments, restructuring and others amounted to $650 million for the year, compared to $788 million in 2013. Legal settlements and loss contingencies for the year amounted to a gain of $111 million, compared to an expense of $1.5 billion in 2013, which was mainly due to the pantoprazole settlement.

Operating income amounted to $4.0 billion, an increase of 140% compared to 2013, mainly due to the change in legal settlements and loss contingencies.

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

Cash flow from operating activities amounted to $5.1 billion, an increase of $1.9 billion compared to 2013.
For information regarding certain transactions, see note 2 of our consolidated financial statements.

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	
	2014	2013	2012	2014-2013	2013-2012
	%	%	%	%	%
Net revenues	100.0	100.0	100.0	**	**
Gross profit	54.5	52.7	52.4	3	1
Research and development expenses	7.3	7.0	6.7	4	5
Selling and marketing expenses	19.0	20.1	19.1	(5)	5
General and administrative expenses	6.0	6.1	6.1	(2)	**
Impairments, restructuring and others	3.2	3.9	6.2	(18)	(37)
Legal settlements and loss contingencies	(0.5)	7.5	3.5	n/a	112
Operating income	19.5	8.1	10.8	140	(25)
Financial expenses net	1.6	2.0	1.9	(22)	3
Income before income taxes	17.9	6.1	8.9	191	(31)
Income taxes	2.9	(0.2)	(0.7)	n/a	(69)
Share in losses of associated companies net	*	0.2	0.2	(88)	(13)
Net loss attributable to non-controlling interests	(0.1)	(0.1)	(0.3)	(19)	(70)
Net income attributable to Teva	15.1	6.2	9.7	141	(35)

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

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,					
	2014		2013		2012	
	U.S.$ in millions / % of Segment Revenues					
Revenues	$ 9,814	100.0%	$ 9,902	100.0%	$ 10,385	100.0%
Gross profit	4,247	43.3%	4,079	41.2%	4,518	43.5%
R&D expenses	517	5.3%	492	5.0%	485	4.7%
S&M expenses	1,582	16.1%	1,919	19.4%	1,971	19.0%
Segment profit*	$ 2,148	21.9%	$ 1,668	16.8%	$ 2,062	19.9%

* 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. See note 21 of our consolidated financial statements and Operating Income below for additional information.

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

Revenues

Our generic medicines segment includes sales of generic medicines as well as API sales to third parties. Revenues from our generic medicines in 2014 amounted to $9.8 billion, a decline of $88 million, or 1%, compared to 2013. In local currency terms, sales increased 1%.

Revenues of generic medicines in the United States, our largest generic market, amounted to $4.4 billion, an increase of $246 million, or 6%, compared to 2013, representing 45% of total generics revenues in 2014. Revenues of generic medicines in Europe amounted to $3.1 billion, a decrease of $214 million, or 6%, compared to 2013. In local currency terms, European sales decreased 7%. Revenues of generic medicines in Europe represented 32% of total generics revenues in 2014. In our ROW markets, revenues from generic medicines in 2013 amounted to $2.2 billion, a decrease of 5% compared to 2013. In local currency terms, ROW sales increased 4%. Revenues from generic medicines in ROW markets represented 23% of total generics revenues in 2014.

API sales to third parties in 2014 amounted to $724 million, flat compared to 2013 in both U.S. dollar and local currency terms, mainly due to a decrease in sales in Europe and in the United States, partially offset by an increase in Japan and in other ROW markets.

Comparison of 2013 to 2012. In 2013, revenues from generic medicines amounted to $9.9 billion, a decrease of 5% compared to $10.4 billion in 2012. In local currency terms, revenues decreased 3%.

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

	Year Ended December 31,			Percentage Change	
	2014	2013	2012	2014-2013	2013-2012
	U.S. $ in millions				
United States	$ 4,418	$ 4,172	$ 4,381	6%	(5%)
Europe*	3,148	3,362	3,482	(6%)	(3%)
Rest of the World	2,248	2,368	2,522	(5%)	(6%)
Total Generic Medicines	$ 9,814	$ 9,902	$ 10,385	(1%)	(5%)

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

United States Generic Medicines Revenues

In 2014, we led the U.S. generic market in total prescriptions and new prescriptions, with total prescriptions of approximately 500 million, representing 14.2% of total U.S. generic prescriptions. We intend 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.

Revenues from generic medicines in the United States in 2014 amounted to $4.4 billion, up 6% compared to $4.2 billion in 2013. The increase resulted mainly from the 2014 exclusive launch of capecitabine (the generic equivalent of Xeloda®), the launch of omega-3-acid ethyl esters (the generic equivalent of Lovaza®) for which we were first to market, and the launch of raloxifene (the generic equivalent of Evista®), as well as products that were sold in 2014 that were not sold in 2013. These increases were partially offset by lower sales of the generic versions of Adderall IR® (amphetamine salts IR), Pulmicort® (budesonide inhalation) and Niaspan® (niacin ER).

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Among the most significant generic products we sold in the United States in 2014 were generic versions of Pulmicort® (budesonide inhalation), Xeloda® (capecitabine), Lovaza® (omega-3-acid ethyl esters), Niaspan® (niacin ER), Adderall XR® (mixed amphetamine salts ER), Evista® (raloxifene), Pravachol® (pravastatin), Tobi® (tobramycin) and Adderall® (mixed amphetamine salts).

Comparison of 2013 to 2012. Total generic sales in the United States in 2013 amounted to $4.2 billion, down from $4.4 billion in 2012. This decrease was mainly due to a decrease in sales of products for which we had exclusive rights in 2012 and the cessation of royalties of atorvastatin under our agreement with Ranbaxy.

Products. In 2014, 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)*
Metoclopramide for injection, USP 5 mg/mL, 10 mg **	Reglan®	Jan-2014	$ 12
Tolterodine tartrate ER capsules 2 & 4 mg	Detrol®	Jan-2014	$ 549
Fludarabine phosphate for injection 50mg/vial**			