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

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F

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

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

OR

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

OR

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

Commission File number: 001-16174

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant s name into English)

ISRAEL

(Jurisdiction of incorporation or organization)

5 Basel Street

P.O. Box 3190

Petach Tikva 4951033, Israel

(Address of principal executive offices)

Eyal Desheh

Group Executive Vice President, Chief Financial Officer

Teva Pharmaceutical Industries Limited

5 Basel Street

P.O. Box 3190

Petach Tikva 4951033, Israel

Tel: 972-3-914-8171

Fax: 972-3-914-8678

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

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

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

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

None

(Title of Class)

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

None

(Title of Class)

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

907,663,041 Ordinary Shares

781,355,149 American Depositary Shares

3,375,000 Mandatory Convertible Preferred Shares

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

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

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨

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

þ US GAAP

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

¨ Other

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

¨ Item 17

¨ Item 18

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

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INTRODUCTION AND USE OF CERTAIN TERMS

Unless otherwise indicated, all references to the Company, we, our and Teva refer to Teva Pharmaceutical Industries Limited and its subsidiaries, and references to revenues refer to net revenues. References to U.S. dollars, U.S.$ and $ are to the lawful currency of the United States of America, and references to NIS are to new Israeli shekels. References to MS are to multiple sclerosis. Market data, including both sales and share data, is based on information provided by IMS Health Inc., a provider of market research to the pharmaceutical industry (IMS), unless otherwise stated. References to ROW are to our Rest of the World markets. References to P&G are to The Procter & Gamble Company and references to PGT are to PGT Healthcare, the joint venture we formed with P&G. References to R&D are to Research and Development. References to S&M are to Selling and Marketing. References to G&A are to General and Administrative.

FORWARD-LOOKING STATEMENTS

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

- our business strategy;
- the anticipated results of acquisitions, including our pending Actavis Generics and Rimsa acquisitions;
- the development and launch of our products, including product approvals and results of clinical trials;
- projected markets and market size;
- anticipated results of litigation and regulatory proceedings;
- our projected revenues, market share, expenses, net income margins and capital expenditures; and
- our liquidity.

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

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

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

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PART I

ITEM 1: IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not Applicable.

ITEM 2: OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable.

ITEM 3: KEY INFORMATION

SELECTED FINANCIAL DATA

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

The following selected operating data for each of the years in the three-year period ended December 31, 2015 and selected balance sheet data at December 31, 2015 and 2014 are derived from our audited consolidated financial statements set forth elsewhere in this report, which have been prepared in accordance with U.S. GAAP. The selected operating data for each of the years in the two-year period ended December 31, 2012 and selected balance sheet data at December 31, 2013, 2012 and 2011 are derived from our audited financial statements not appearing in this report, which have also been prepared in accordance with U.S. GAAP.

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

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

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Operating Data

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

Balance Sheet Data

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

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

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Dividends

We have paid dividends on a regular quarterly basis since 1986. Our dividend policy is regularly reviewed by our board of directors based upon conditions then existing, including our earnings, financial condition, capital requirements and other factors. Our ability to pay cash dividends may be restricted by instruments governing our debt obligations. Until April 2015, dividends were declared and paid in NIS, and then converted into U.S. dollars and paid by the depositary of our American Depositary Shares (ADSs) for the benefit of owners of ADSs. Commencing in April 2015, dividends are declared and paid in U.S. dollars.

Dividends on our mandatory convertible preferred shares are payable on a cumulative basis when, as and if declared by our board of directors at an annual rate of 7% on the liquidation preference of $1,000 per mandatory convertible preferred share. Declared dividends will be paid in cash on March 15, June 15, September 15 and December 15 of each year commencing March 15, 2016, to and including December 15, 2018. So long as any mandatory convertible preferred shares remain outstanding, no dividends may declared or paid on our ordinary shares or ADSs, unless all accumulated and unpaid dividends for all preceding dividend periods have been declared and paid upon, or a sufficient sum of cash has been set apart for the payment of such dividends upon, all outstanding mandatory convertible preferred shares.

Dividends paid by an Israeli company to non-Israeli residents are generally subject to withholding of Israeli income tax at a rate of up to 25%. Such tax rates apply unless a lower rate is provided in a treaty between Israel and the shareholder s country of residence. In our case, the applicable withholding tax rate will depend on the particular Israeli production facilities that have generated the earnings that are the source of the specific dividend and, accordingly, the applicable rate may change from time to time. A 15% tax will be withheld on the dividend declared and distributed for the fourth quarter of 2015.

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

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

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RISK FACTORS

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

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

Our financial results depend upon our ability to develop and commercialize additional generic and specialty pharmaceutical products, particularly after the expiration of our patents covering the 20mg/mL version of our leading specialty medicine, Copaxone®, and patent challenges and expirations facing the 40mg/mL version of Copaxone® and certain of our other specialty medicines. Commercialization requires that we successfully develop, test and manufacture both generic and specialty products. All of our products must receive regulatory approval and meet (and continue to comply with) regulatory and safety standards; if health or safety concerns arise with respect to a product, we may be forced to withdraw it from the market.

The development and commercialization process, particularly with respect to specialty medicines as well as the complex generic medicines that we are increasingly focusing on, is both time-consuming and costly and involves a high degree of business risk. Our products currently under development, if and when fully developed and tested, may not perform as we expect. Necessary regulatory approvals may not be obtained in a timely manner, if at all, and we may not be able to produce and market such products successfully and profitably. Delays in any part of the process or our inability to obtain regulatory approval of our products could adversely affect our operating results by restricting or delaying our introduction of new products.

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

Any substantial decrease in the revenues derived from our specialty medicines would have an adverse effect on our results of operations, several of which currently face, or will soon face, intense competition. Our multiple sclerosis franchise includes our Copaxone® products and laquinimod (a developmental compound for the treatment of MS). The profitability of our multiple sclerosis franchise reflects Copaxone® revenues less cost of goods sold and S&M and R&D expenses related to our MS franchise. It does not include G&A expenses, amortization and non-recurring items. Our MS franchise profitability was $3.1 billion, $3.2 billion, and $3.3 billion in 2015, 2014 and 2013, respectively. Profitability of our multiple sclerosis franchise as a percentage of Copaxone® revenues was 77%, 75% and 76% in 2015, 2014 and 2013, respectively.

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

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

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

We may fail to consummate the acquisition of Allergan plc s worldwide generic pharmaceuticals business (Actavis Generics). Even if we successfully consummate the acquisition, we may fail to realize all of the anticipated benefits of the Actavis Generics acquisition or those benefits may take longer to realize than expected. We may also encounter significant difficulties in integrating Actavis Generics.

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

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

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

- the diversion of management s attention to integration matters;
- difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects from the combination;
- difficulties in the integration of operations and systems;
- conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the two companies;
- difficulties in the assimilation of employees;
- difficulties in managing the expanded operations of a significantly larger and more complex company;
- challenges in keeping existing customers and obtaining new customers;

challenges in attracting and retaining key personnel; and

coordinating a geographically dispersed organization.

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

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

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

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

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

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

- reducing the benefits we expect to receive from the Actavis Generics acquisition;
- making it more difficult for us to satisfy our obligations;
- limiting our ability to borrow additional funds and increasing the cost of any such borrowing;
- increasing our vulnerability to, and reducing our flexibility to respond to, general adverse economic and industry conditions;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- placing us at a competitive disadvantage as compared to our competitors, to the extent that they are not as highly leveraged; and
- restricting us from pursuing certain business opportunities.

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Our credit ratings impact the cost and availability of future borrowings and, accordingly, our cost of capital. Our ratings at any time will reflect each rating organization s then opinion of our financial strength, operating performance and ability to meet our debt obligations. Following the announcement of the Actavis Generics acquisition, Standard and Poor s Financial Services LLC and Moody s Investor Service, Inc. downgraded our ratings to BBB+ and Baa1, respectively, and expect to further downgrade our ratings in connection with the consummation of the acquisition to BBB and Baa2, respectively. Any reduction in our credit ratings may limit our ability to borrow at interest rates consistent with the interest rates that have been available to us prior to the acquisition. If our credit ratings are downgraded or put on watch for a potential downgrade, we may not be able to sell additional debt securities or borrow money in the amounts, at the times or interest rates or upon the more favorable terms and conditions that might be available if our current credit ratings are maintained.

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

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

We may be subject to material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters.

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

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

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

We cannot predict at this time the impact on the Company as a result of these matters and accordingly cannot assure you that we will not be materially and adversely affected. The DOJ, SEC and other agencies and authorities have a broad range of civil and criminal penalties they may seek to impose (on the Company and/or individuals) for violations of the FCPA and other similar laws. We may be required to pay material fines and/or penalties and/or disgorge any profits earned from improper conduct. Our operations in the affected countries may be negatively impacted, and we may be subject to injunctions or limitations on future conduct, be required to modify our business practices and compliance programs and/or have a compliance monitor imposed on us, or suffer other criminal or civil penalties or adverse impacts, including lawsuits by private litigants or investigations and fines imposed by local authorities. In addition, there can be no assurance that the remedial measures we have taken and will take in the future will be effective or that there will not be a finding of a material weakness in our internal controls. Any one or more of the foregoing could have a material adverse effect on our reputation and our business, financial condition or results of operations.

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

We must invest significant resources to develop specialty medicines (including our strategic focus on developing new therapeutic entities, as well as the development of complex generics), both through our own efforts and through collaborations and in-licensing or acquisition of products from or with third parties. In particular, in light of the expiration of our patents covering the 20mg/mL version of our leading specialty medicine, Copaxone®, and patent challenges and expirations facing certain of our other specialty medicines, we have increased our investments in the acquisition and development of products to build our specialty pipeline, including through our recent acquisitions and in-licensing of Auspex Pharmaceuticals, Inc., Eagle Pharmaceuticals, Inc. and Labrys Biologics, Inc.

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

During each stage, we may encounter obstacles that delay the development process and increase expenses, leading to significant risks that we will not achieve our goals and may be forced to abandon a potential product in which we have invested substantial amounts of time and money. These obstacles may include: preclinical failures; difficulty enrolling patients in clinical trials; delays in completing formulation and other work needed to support an application for approval; adverse reactions or other safety concerns arising during clinical testing; insufficient clinical trial data to support the safety or efficacy of the product candidate; and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured.

Because of the amounts required to be invested in augmenting our pipeline of specialty and other products, we are also reliant on partnerships and joint ventures with third parties, and consequently face the risk that some of these third parties may fail to perform their obligations, or fail to reach the levels of success that we are relying on to meet our revenue and profit goals. There is a trend in the specialty pharmaceutical industry of seeking to outsource drug development by acquiring companies with promising drug candidates, and we face substantial competition from historically innovative companies for such acquisition targets.

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

As a key part of our strategy, we continue to evaluate or pursue potential acquisitions, collaborations and licenses, among other transactions. Our reliance on acquisitions and other transactions as sources of new specialty and other products, or a means of growth, involves risks that could adversely affect our future revenues and operating results. For example:

- We may fail to identify transactions that would enable us to execute our business strategy.
- Competition in the pharmaceutical industry for target companies and development programs has intensified and has resulted in decreased availability of, or increased prices for, suitable transactions.
- We may not be able to obtain necessary regulatory approvals, including those of competition authorities, and as a result, or for other reasons, we may fail to consummate an announced acquisition.
- The negotiation of additional transactions may divert management s attention from our existing business operations, resulting in the loss of key customers and/or personnel and exposing us to unanticipated liabilities.
- We may fail to integrate acquisitions successfully in accordance with our business strategy or achieve expected synergies and other results.
- We may not be able to retain experienced management and skilled employees from the businesses we acquire and, if we cannot retain such personnel, we may not be able to attract new skilled employees and experienced management to replace them.
- We may purchase a company that has excessive known or unknown contingent liabilities, including, among others, patent infringement or product liability claims.

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

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

In recent years, there has been increasing regulatory scrutiny of pharmaceutical manufacturers, resulting in product recalls, plant shutdowns and other required remedial actions. We have been subject to increasing scrutiny of our manufacturing operations, and in previous years several of our facilities have been the subject of significant regulatory actions requiring substantial expenditures of resources to ensure compliance with more stringently applied production and quality control regulations. These regulatory actions also adversely affected our ability to supply various products worldwide and to obtain new product approvals at such facilities. If any regulatory body were to require one or more of our

significant manufacturing facilities to cease or limit

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production, our business could be adversely affected. In addition, because regulatory approval to manufacture a drug is site-specific, the delay and cost of remedial actions, or obtaining approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations.

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

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

We have been involved in numerous litigations involving challenges to the validity or enforceability of listed patents (including our own), and therefore settling patent litigations has been and is likely to continue to be an important part of our business. Parties to such settlement agreements in the U.S., including us, are required by law to file them with the Federal Trade Commission (FTC) and the Antitrust Division of the DOJ for review. The FTC has publicly stated that, in its view, some of the brand-generic settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies, including us, that have entered into such agreements. Accordingly, we may receive formal or informal requests from the FTC for information about a particular settlement agreement, and there is a risk that the FTC, or others, such as customers, may commence an action against us alleging violations of the antitrust laws.

Such settlement agreements may further expose us to claims by purchasers of the products for unlawfully inhibiting competition. We are currently defendants in private antitrust actions involving numerous settlement agreements.

Similarly, the European Commission (EU Commission) has placed our European operations, as well as those of several brand and generic companies, under intense scrutiny in connection with its inquiry into possible anticompetitive conditions in the European pharmaceutical sector. The EU Commission has initiated proceedings against us in connection with one settlement agreement, and is investigating another agreement. Although we have argued that those agreements did not restrict competition, the EU Commission may rule against us, possibly imposing fines. It is also possible that the EU Commission would open investigations relating to subsequent agreements we have entered into. More generally, there is a risk that the increased scrutiny of the European pharmaceutical sector may lead to changes in the regulation of our business that would have an adverse impact on our results of operations in Europe. See Competition Matters in note 13 to our consolidated financial statements.

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

In 2015, approximately 43% of our revenues came from sales outside the United States. As a result, we are subject to significant foreign currency risks, including repatriation restrictions in certain countries, and may face heightened risks as we enter new markets. An increasing proportion of our sales, particularly in Latin America (including Venezuela), Central and Eastern European countries and Asia, are recorded in local currencies, which exposes us to the direct risk of devaluations, hyperinflation or exchange rate fluctuations. In 2015, foreign exchange fluctuations negatively affected our revenues by approximately $1.3 billion and our operating income by $95 million. We may also be exposed to credit risks in some of these markets. The imposition of price controls or restrictions on the conversion of foreign currencies could also have a material adverse effect on our financial results.

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For example, our net monetary assets in Venezuela, which suffers from hyperinflation, totaled $487 million at December 31, 2015. As a result, if there is a devaluation of the Venezuelan currency or if our use of the preferential CENCOEX rate in our financial statements can no longer be supported, we would incur an impairment charge and our financial results, including our operating results and cash flow, would be adversely affected. See Operating and Financial Review and Prospects Impact of Currency Fluctuations on Results of Operations.

In particular, although the majority of our net sales and operating costs is recorded in, or linked to, the U.S. dollar, our reporting currency, in 2015 we recorded sales and expenses in various other currencies. Approximately 56% of our operating costs in 2015 were incurred in currencies other than the U.S. dollar, particularly in euros, Israeli shekels, Hungarian forints, Canadian dollars, Japanese yen and the British pound. As a result, fluctuations in exchange rates between the currencies in which such costs are incurred and the U.S. dollar may have a material adverse effect on our results of operations, the value of balance sheet items denominated in foreign currencies and our financial condition.

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

The success of our specialty medicines depends on the effectiveness of our patents, confidentiality agreements and other measures to protect our intellectual property rights.

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

We are currently engaged in lawsuits challenging the validity and/or enforceability of the U.S. patents covering Copaxone® 40 mg/mL, Treanda® and Amrix®. For example, Treanda® faces numerous patent challenges, and if we are unable to enforce our patents, which expire between 2026 and 2031, generic competition could commence as early as May 2016. While we intend to defend the validity of these patents vigorously, and will seek to prevent their infringement, such efforts are expensive and time-consuming. Due to the nature of litigation, there can be no assurance that such efforts will be successful. Our ability to enforce our patents also depends on the laws of individual countries and each country s practices regarding the enforcement of intellectual property rights. The loss of patent protection or regulatory exclusivity on these or other specialty medicines could materially impact our business, results of operations, financial conditions or prospects.

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

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

The continuing increase in expenditures for healthcare has been the subject of considerable government attention almost everywhere we conduct business, particularly as public resources have been stretched by financial and economic crises in the United States, Western Europe and elsewhere. Both private health insurance funds and government health authorities continue to seek ways to reduce or contain healthcare costs, including by reducing or eliminating coverage for certain products and lowering reimbursement levels. In most of the countries and regions where we operate, including the United States, Western Europe, Israel, Russia, certain countries in Central and Eastern Europe and several countries in Latin America, pharmaceutical prices are subject to new government policies designed to reduce healthcare costs. These changes frequently adversely affect pricing and profitability and may cause delays in market entry. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products.

Significant developments that may adversely affect pricing in the United States include (i) the enactment of federal healthcare reform laws and regulations, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the Patient Protection and Affordable Care Act of 2010, and (ii) trends in the practices of managed care groups and institutional and governmental purchasers, including the impact of consolidation of our customers. Changes to the healthcare system enacted as part of healthcare reform in the United States, as well as the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, may result in increased pricing pressure by influencing, for instance, the reimbursement policies of third-party payors. Healthcare reform legislation has increased the number of patients who have insurance coverage for our products, but provisions such as the assessment of a branded pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs may have an adverse effect on us. It is uncertain how current and future reforms in these areas will influence the future of our business operations and financial condition.

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

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

Our generic drugs face intense competition. Prices of generic drugs typically decline, often dramatically, especially as additional generic pharmaceutical companies (including low-cost generic producers based in China and India) receive approvals and enter the market for a given product and competition intensifies. Consequently, our ability to sustain our sales and profitability on any given product over time is affected by the number of new companies selling such product and the timing of their approvals.

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

Furthermore, brand pharmaceutical companies continue to defend their products vigorously. For example, brand companies often sell or license their own generic versions of their products, either directly or through other

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

Governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products, may result in substantial penalties.

We operate around the world in complex legal and regulatory environments, and any failure to comply with applicable laws, rules and regulations may result in civil and/or criminal legal proceedings. As those rules and regulations change or as interpretations of those rules and regulations evolve, our prior conduct or that of companies we have acquired may be called into question. In the United States, we are currently responding to federal investigations into our marketing practices with regard to several of our specialty pharmaceutical products, which could result in civil litigation brought on behalf of the federal government. Responding to such investigations is costly and involves a significant diversion of management s attention. Such proceedings are unpredictable and may develop over lengthy periods of time. Future settlements may involve large cash penalties. In addition, government authorities have significant leverage to persuade pharmaceutical companies to enter into corporate integrity agreements, which can be expensive and disruptive to operations. See Government Investigations and Litigation Relating to Pricing and Marketing in note 13 to our consolidated financial statements.

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

We are a global pharmaceutical company with worldwide operations. Although over 80% of our sales are in the United States and Europe, we expect to derive an increasing portion of our sales and future growth from other regions such as Latin America, Central and Eastern Europe and Asia, which may be more susceptible to political and economic instability.

Significant portions of our operations are conducted outside the markets in which our products are sold, and accordingly we often import a substantial number of products into such markets. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship products from any of our sites as a result of a closing of the borders of the countries in which we sell our products, or in which our operations are located, due to economic, legislative, political and military conditions, including hostilities and acts of terror, in such countries.

Our executive offices and a substantial percentage of our manufacturing capabilities are located in Israel. Our Israeli operations are dependent upon materials imported from outside Israel. We also export significant amounts of products from Israel. Accordingly, our operations could be materially and adversely affected by acts of terrorism or if major hostilities were to occur in the Middle East or trade between Israel and its present trading partners were curtailed, including as a result of acts of terrorism in the U.S. or elsewhere.

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

Our products are either manufactured at our own facilities or obtained through supply agreements with third parties. Many of our products are the result of complex manufacturing processes, and some require highly specialized raw materials. For some of our key raw materials, we have only a single, external source of supply, and alternate sources of supply may not be readily available. For example, we purchase raw materials for most of our oral contraceptive products, which make up a substantial portion of our women s health business, exclusively or primarily from the same external source. If our supply of certain raw materials or finished products is

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interrupted from time to time, or proves insufficient to meet demand, our results of operations could be adversely impacted. Moreover, as we streamline our production capacity, particularly following the Actavis Generics acquisition, we may become more dependent on certain plants and operations for our supply.

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

In addition, w