TEVA PHARMACEUTICAL INDUSTRIES LTD Form 20-F February 22, 2010 Table of Contents

# 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, 2009

OR

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

For the transition period from to

Commission File number: 0-16174

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:

# 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 49131, Israel

(Address of principal executive offices)

**Eyal Desheh** 

**Chief Financial Officer** 

**Teva Pharmaceutical Industries Limited** 

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

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

Title of each class

American Depositary Shares, each representing one Ordinary Share
Securities registered or to be registered pursuant to Section 12(g) of the Act.

Name of each exchange on which registered The Nasdaq Stock Market LLC

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.

923,400,051 Ordinary Shares

719,745,494 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 la 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					
 If	Other 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					
 If	Item 18 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. 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 ne Israeli shekels. Market share data is based on information provided by IMS Health Inc., a leading provider of market research to the pharmaceutical industry ( IMS ), unless otherwise stated.

#### 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;

projected markets and market size;

our projected revenues, market share, expenses, net income margins and capital expenditures; and

our liquidity.

ward-looking statements contained herein involve a number of known and unknown risks and uncertainties that could cause our performance or achievements to differ significantly from the results, performance or achievements to differ significantly from the results, performance or achievements to differ significantly from the results, performance or achievements to differ significantly from the results.

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: NOT APPLICABLE

ITEM 2: 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 United States (including NASDAQ), 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 financial data for each of the years in the three-year period ended December 31, 2009 and at December 31, 2009 and 2008 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 financial data for each of the years in the two-year period ended December 31, 2006 and at December 31, 2007, 2006 and 2005 are derived from 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 the 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 most of our other subsidiaries (principally operating in Western Europe, Central and Eastern Europe, Latin America and Canada) is the respective local currency.

## **Operating Data**

	For the year ended December 31,		mber 31,		
	2009	2008	2007	2006	2005
			lions (except pe		
Net sales	13,899	11,085	9,408	8,408	5,250
Cost of sales	6,532	5,117	4,531	4,149	2,770
Gross profit	7,367	5,968	4,877	4,259	2,480
Research and development net	802	786	581	495	369
Selling and marketing expenses	2,676	1,842	1,264	1,024	533
General and administrative expenses	823	669	637	548	266
Acquisition of research and development in process	23	1,402		1,295	
Legal settlements, impairment, restructuring and acquisition costs	638	124		96	
Operating income	2,405	1,145	2,395	801	1,312
Financial expenses net	202	345*	91*	137*	4
Income before income taxes	2,203	800	2,304	664	1,308
Provision for income taxes	166	184*	386*	145*	236
	2,037	616	1,918	519	1,072
Share in losses (profits) of associated companies net	33	1	3	3	(2)
Net income	2,004	615	1,915	516	1,074
Attributable to non-controlling interests	4	6**	1**	2**	2**
Net income attributable to Teva	2,000	609	1,914	514	1,072
Earnings per share Basic (\$)	2.29	0.78	2.49	0.68	1.73
Diluted (\$)	2.23	0.75	2.36	0.65	1.59
Weighted average number of shares (in millions) Basic	872	780	768	756	618
Diluted	896	820	830	805	681

<sup>\*</sup> After giving retroactive effect to the adoption of an accounting pronouncement which requires issuers to account separately for the liability and equity components of convertible debt instruments that may be settled in cash (including partial cash settlement).

## **Balance Sheet Data**

		As	at December	31,	
	2009	2008	2007	2006	2005
		(U.S.	dollars in mi	llions)	
Working capital (current assets net of current liabilities)	4,539	2,945	4,492*	3,569	3,245
Total assets	33,810	32,920*	23,423*	20,467*	10,387
Short-term credit, including current maturities:					
Short-term debt	1,301	2,906	1,837*	742	375

<sup>\*\*</sup> Non-controlling interests reclassification.

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Long-term debt, net of current maturities:					
Convertible senior debentures	817	1,821*	1,345*	2,312*	1,314
Senior notes and loans	3,494	3,654	1,914	2,127	459
Total long-term debt	4,311	5,475	3,259	4,439	1,773
Non-controlling interests	37	60	36	35	8
Total equity	19,259	16,438*	13,864*	11,319*	6,042

<sup>\*</sup> After giving retroactive effect to the adoption of an accounting pronouncement which requires issuers to account separately for the liability and equity components of convertible debt instruments that may be settled in cash (including partial cash settlement).

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## **Dividends**

We have paid dividends on a regular quarterly basis since 1986. Future dividend policy will be 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.

Dividends paid by an Israeli company to shareholders residing outside Israel are generally subject to withholding of Israeli income tax at a rate of up to 20%. 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. The rate of tax to be withheld on the dividend declared for the fourth quarter of 2009 is 20%.

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).

	2009	2008	2007	2006	2005
		In ce	nts per s	share	
1st interim	14.5	13.1	9.9	7.6	6.9
2nd interim	15.1	12.9	9.2	7.7	6.6
3rd interim	15.9	11.8	10.0	7.9	6.4
4th interim	18.7	14.7	12.4	9.4	7.2

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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 or 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, to a significant degree, upon our ability to commercialize additional generic and innovative pharmaceutical products as well as active pharmaceutical ingredients. We must successfully develop, test and manufacture generic products as well as prove that our generic products are the bioequivalent of their brand counterparts. All of our products must meet and continue to comply with regulatory and safety standards and receive regulatory approvals; 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 innovative products, 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 ability to introduce and benefit from new products also depends upon our success in challenging patent rights held by brand companies or developing non-infringing products. Our overall profitability depends on, among other things, our ability to introduce new products in a timely manner, to continue to manufacture products cost-efficiently and to manage the life cycle of our global generic portfolio.

Our revenues and profits from generic pharmaceutical products typically decline as a result of competition from both other generic makers and brand pharmaceutical companies.

Net selling prices of generic drugs typically decline, often dramatically, especially as additional generic pharmaceutical companies, both domestic and foreign, receive approvals and enter the market for a given product and competition intensifies. Our ability to sustain our sales and profitability on any product over time is affected by the number of new companies selling such product and the timing of their approvals.

In addition, our generic pharmaceutical products face intense competition from brand pharmaceutical companies, which continue to take aggressive steps to thwart competition from generic companies. In particular, brand companies 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 also seek to delay introductions of generic equivalents, and to decrease the impact of generic competition, by:

obtaining new patents on drugs whose original patent protection is about to expire;

obtaining patents that are more complex and costly to challenge;

filing patent infringement suits that automatically delay the approval of generic versions by the U.S. Food and Drug Administration (FDA);

filing citizens petitions with the FDA contesting generic approvals on alleged health and safety grounds;

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questioning the quality and bioequivalence of generic pharmaceuticals;

developing controlled-release or other slightly modified versions, which often reduce demand for the generic version of the existing product for which we are seeking approval;

changing product claims and product labeling;

developing and marketing over-the-counter versions of brand products that are about to face generic competition; and

making arrangements with managed care companies and insurers to reduce economic incentives to purchase generic versions. These strategies may increase the costs and risks associated with our efforts to introduce generic products and may delay or prevent such introduction altogether.

Our revenues and profits are closely tied to our ability to obtain U.S. market exclusivity for generic versions of significant products.

To the extent that we succeed in being the first to market a generic version of a significant product, and particularly if we obtain the 180-day period of exclusivity in the U.S. market 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. For example, our 2009 operating results included contributions from products launched with U.S. market exclusivity, or with otherwise limited competition, such as mixed amphetamine salts, Tri-Lo Sprintec , oxaliplatin, budesonide and minocycline. Our ability to achieve sales growth and profitability is dependent on our success in challenging patents, developing non-infringing products or developing products with increased complexity to provide launch opportunities with U.S. market exclusivity or limited competition. In addition, the number of significant new generic products for which Hatch-Waxman exclusivity is available, and the size of those product opportunities, vary significantly from year to year, or even from quarter to quarter, and is expected to decrease over the next several years in comparison to those available in the past. Failure to continue to develop such opportunities could have a material adverse effect on our sales and profitability.

The 180-day market exclusivity period is only triggered by commercial marketing of the product or, in certain cases, a final court decision that is no longer subject to appeal holding the applicable patents to be invalid, unenforceable or not infringed. However, the Medicare Act also contains forfeiture provisions which would deprive the first Paragraph IV filer of exclusivity if certain conditions are met, some of which may be outside our control. Accordingly, we may face the risk of forfeiture and therefore may not be able to exploit a given exclusivity period for specific products.

We have sold and may elect to sell in the future generic products prior to the final resolution of outstanding patent litigation, and, as a result, we could be subject to liability for damages.

At times, we or our partners seek approval to market generic products before the expiration of patents relating to the brand versions of those products, based upon our belief that such patents are invalid or otherwise unenforceable, or would not be infringed by our products. As a result, we are involved in patent litigation, the outcome of which, in certain cases, could materially adversely affect our business. Based upon a complex analysis of a variety of legal and commercial factors, we may elect to sell a generic product even though litigation is still pending whether before any court decision is rendered or while an appeal of a lower court decision is pending. For example, we launched, and continue to sell, generic versions of Neurontin® (gabapentin), Lotrel® (amlodipine benazepril), Protonix® (pantoprazole) and Eloxatin® (oxaliplatin), despite the fact that litigation with the companies that sell the brand versions of these products is still pending.

If we sell certain products prior to a final court decision, 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

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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 event of a finding of willful infringement, the damages 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.

Any manufacturing or quality control problems may damage our reputation for high quality production and negatively impact our financial results.

Recently there has been increasing regulatory scrutiny of pharmaceutical manufacturers. We must register our facilities, whether located in the U.S. or elsewhere, with the FDA and similar regulators 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. Compliance with production and quality control regulations requires substantial expenditure of resources. If any regulatory body were to require one of our 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 obtaining approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations.

Sales of our innovative products, especially Copaxone<sup>®</sup>, could be adversely affected by competition.

Our innovative products face or may face intense competition from competitors products, which may adversely affect our sales and profitability. Copaxone® is our leading innovative product, from which we derive approximately 18% of our net sales and which contributes disproportionately to our profits. To date, we and our marketing partners have been successful in our efforts to establish Copaxone® as the leading therapy for multiple sclerosis and have increased our global market share among the currently available major therapies for multiple sclerosis. However, Copaxone® faces intense competition from existing products, such as Avonex®, Betaseron®, Rebif®, Extavia® and Tysabri®. We may not be able to introduce price increases at the same rate as in recent years or to offset any decrease in the rate of growth of sales. We may also face competition from additional products in development, including orally administered formulations of Gilenia®, which has recently been granted priority review status by the FDA, cladribine which is the subject of a submitted NDA and fingolimod, which have completed their Phase III trials. In addition, if our patents on Copaxone® are successfully challenged, we may also face generic competition prior to 2014, when the U.S. orange book patents covering Copaxone® would otherwise expire. In July 2008, Sandoz Inc., the U.S. generic drug division of Novartis AG, in conjunction with Momenta Pharmaceuticals, Inc., filed an Abbreviated New Drug Application (ANDA) with the FDA for a generic version of Copaxone® seeking approval prior to the expiration of our patents. In August 2008, we filed a complaint against Sandoz/Momenta, which triggered a stay of any FDA approval of the ANDA until the earlier of January 2011 or a district court decision (if any) in favor of the ANDA filer. On October 16, 2009, Mylan Laboratories also filed an ANDA for a generic version of Copaxone®. Any substantial decrease in the profits derived from our innovative products would have an adverse effect on our results o

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 2009 accounted for 16% 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.

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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.

We may not be able to consummate and integrate future acquisitions.

We have grown, in part, through a number of significant acquisitions, including our acquisition of Barr Pharmaceuticals, Inc. in December 2008, Ivax Corporation in January 2006 and Sicor Inc. in January 2004. We continue to be engaged in various stages of evaluating or pursuing potential acquisitions and may in the future acquire other pharmaceutical businesses and seek to integrate them into our own operations. As part of our strategy, we also seek to enter into joint ventures with third parties. We cannot assure you that we will be successful in entering into these joint ventures or that they will achieve the expected results.

Acquisitions involve known and unknown risks that could adversely affect our future revenues and operating results. For example:

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

We compete with others to acquire companies, including brand companies that seek to expand or enter into the generic market. We believe that this competition has intensified and may result in decreased availability of, or increased prices for, suitable acquisition candidates.

We may not be able to obtain the necessary regulatory approvals, including those of competition authorities, in countries where we are seeking to consummate acquisitions.

We may ultimately fail to consummate an acquisition even if we announce that we plan to acquire a company.

Potential acquisitions may divert management s attention away from our primary product offerings, 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.

We may not be able to retain the skilled employees and experienced management that may be necessary to operate 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 contingent liabilities that include, among others, known or unknown patent infringement or product liability claims.

For various commercial and economic considerations, we may not be able to consummate acquisitions that we have identified as being critical to our strategy.

The manufacture of our products is highly complex, and an interruption in our supply chain or problems with our 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.

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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.

Our specialty pharmaceuticals businesses face intense competition from companies that have greater resources and capabilities.

As our business evolves beyond pure generic pharmaceuticals, we face intense and different competition in our respiratory and women shealth specialty businesses, which contributed a substantial portion of our revenues and profits in 2009. Our competitors in these product categories typically have substantially greater experience in the marketing and sale of brand, 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 need to emphasize to physicians, patients and third-party payors the benefits of our products relative to competing products that are often more familiar or otherwise more well-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.

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 the lawsuits that we have recently settled or announced.

The laws and regulations regarding reporting and payment obligations with respect to 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 by the government, and it is possible that such reviews could result in material changes. A number of state attorneys general, as well as state and federal government agencies, 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 civil and/or criminal sanctions, including treble damages, civil monetary penalties and possible exclusion from Medicare, Medicaid and other programs. In addition, we are notified from time to time of government investigations regarding drug reimbursement or pricing issues.

Recently, we announced settlements of the cases brought by the states of Alabama and Massachusetts and an agreement in principle to settle litigation brought by Ven-A-Care, Inc. on behalf of the states of California, Florida, Texas and the federal government. Although we have recorded reserves related to the remaining lawsuits based on our estimates of probable future costs, there is no guarantee that such lawsuits will not result in substantial further costs.

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

Over 40% of our revenues comes from sales outside of the United States. As a result, we are subject to significant foreign currency risk, including repatriation restrictions in certain countries. An increasing amount of our sales, particularly in Latin America and Central and Eastern European countries, is recorded in local currencies, which exposes us to the direct risk of devaluations, hyperinflation or exchange rate fluctuations. 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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In particular, although the majority of our net sales and operating costs is recorded in, or linked to, the U.S. dollar, which is our functional currency, in 2009 we recorded sales and expenses in over 30 other currencies. Approximately 60% of our operating costs in 2009 was incurred in currencies other than the U.S. dollar, particularly in euros, NIS, Hungarian forints, Canadian dollars and pounds sterling. 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 to manage our net exposure to currency exchange rate fluctuations in the major foreign currencies in which we operate. However, there can be no assurance that we will be able to limit all of our exposure to exchange rate fluctuations that could affect our financial results.

Reforms in healthcare regulation and the uncertainty associated with pharmaceutical pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for our products.

Increasing expenditures for healthcare have been the subject of considerable public attention almost everywhere we conduct business. Both private and governmental entities are seeking ways to reduce or contain healthcare costs. In many countries where we operate, pharmaceutical prices are subject to regulation. In the U.S., numerous proposals that would effect changes in the healthcare system have been introduced in Congress (as well as in some state legislatures), including expanded Medicare coverage for drugs, which became effective in January 2006. Similar measures are being taken or introduced throughout Western Europe, Israel, Russia, certain countries in Central and Eastern Europe and several countries in Latin America. These changes may cause delays in market entry or adversely affect pricing and profitability. We cannot predict which measures may be adopted or their impact on the marketing, pricing and demand for our products.

In the United States, the Deficit Reduction Act of 2005 mandated a new regulation, which became effective in part on October 1, 2007, establishing the method by which pharmaceutical manufacturers, including us, must calculate average manufacturer price, or AMP. The Act strongly encouraged state Medicaid programs to utilize AMP in the future as the benchmark for prescription drug reimbursement in place of the previous, widely used benchmark of average wholesale price. One potentially significant requirement is that AMP be disclosed to the public. AMP was historically kept confidential by the government and participants in the Medicaid program. Disclosing AMP to competitors, customers, and the public at large could negatively affect our leverage in commercial price negotiations.

The Act also changed the method used to determine the federal upper limit on payment for generic drugs. Payments to pharmacies for Medicaid-covered outpatient prescription drugs are set by the states. Federal reimbursements to states for the federal share of those payments are subject to this federal ceiling, which, effective January 1, 2007, was 250% of the average manufacturer price for generic drugs. This price limit may have the effect of reducing the reimbursement rates for certain medications that we currently sell. We are reviewing the potential impact of the Act on our business and profitability and have not yet been able to draw conclusions, because the implementation of certain provisions of the final regulations promulgated under the Act has been stayed by litigation. We do not know how long the court-ordered stay will remain in effect or what the final outcome will be.

A number of markets in which we operate have implemented tender systems for generic pharmaceuticals in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. The measure is impacting marketing practices and reimbursement of drugs and may further increase pressure on competition and 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 affect on our business, financial position and results of operations.

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We have significant and increasing 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 North America and Western Europe, we expect to derive an increasing portion of our sales and future growth from other regions such as Latin America and Central and Eastern Europe, which may be more susceptible to political or 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 United States or elsewhere.

Our agreements with brand pharmaceutical companies, which are important to our business, are facing increased government scrutiny in both the U.S. and Europe.

We are involved in numerous patent litigations in which we challenge the validity or enforceability of innovator companies listed patents and/or their applicability to our products, 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 Department of Justice (DOJ) for review. The FTC has publicly stated that, in its view, some of these settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies 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 violation of the antitrust laws. In addition, some members of Congress are trying to pass legislation that would limit the types of settlement agreements generic manufacturers can enter into with brand companies.

Similarly, the EU Commission has recently 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. Beginning in January 2008 and as recently as December 2009, for example, the EU Commission has conducted high-profile, unannounced raids on our European offices and those of many of our brand and generic competitors. In its July 2009 report, the EU Commission found that between 2000 and 2007, generic medicines did not reach the market on average until seven months after expiration of the relevant patent, and it has asserted that the delays were due to settlement agreements with generic companies that delayed entry of generic competition. The EU Commission is currently reviewing over 200 such settlement agreements for evidence of anticompetitive practices, including several agreements to which we are a party. Although no legal or regulatory action has been taken against us in Europe as result of the inquiry, there is a risk that the increased scrutiny of the European pharmaceutical sector may lead to changes in regulation of our business that would have an adverse impact on our results of operations in Europe.

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

The success of our innovative products depends, in part, 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 innovative products, 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. 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. In addition, such patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products, especially Copaxone®, our leading innovative product, which, as described above, is being challenged by certain competitors.

We also rely on trade secrets, unpatented proprietary know-how, trademarks, data 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.

#### Research and development efforts invested in our innovative pipeline may not achieve expected results.

We invest increasingly greater resources to develop our innovative pipeline, both through our own efforts and through collaborations with third parties, which results in higher risks. The time from discovery to a possible commercial launch of an innovative product is substantial and involves multiple stages during which the product may be abandoned as a result of such factors as serious developmental problems, the inability to achieve our clinical goals, the inability to obtain necessary regulatory approvals in a timely manner, if at all, and the inability to produce and market such innovative products successfully and profitably. In addition, we face the risk that some of the third parties we collaborate with may fail to perform their obligations. Accordingly, our investment in research and development of innovative products can involve significant costs with no assurances of future revenues or profits.

## We are subject to government regulation that increases our costs and could prevent us from marketing or selling our products.

The pharmaceutical industry is subject to regulation by various governmental authorities. For instance, we must comply with requirements of the FDA and other national healthcare regulators with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with these requirements may 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. Under certain circumstances, the regulators may also have the authority to revoke previously granted drug approvals. Although we have internal regulatory compliance programs and policies and have had a favorable compliance history, there is no guarantee that these programs, as currently designed, will meet regulatory agency standards in the future. Additionally, despite our efforts at compliance, there is no guarantee that we may not be deemed to be out of compliance in some respect in the future. If we were deemed to be significantly noncompliant, our business, financial position and results of operations could be materially affected.

Data exclusivity provisions exist in many countries where we operate, although their application is not uniform. In general, these provisions prevent the approval by, and/or submission of generic drug applications to, the health authorities for a fixed period of time following the first approval of a novel brand-name product in that

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country or other recognized countries. As these exclusivity provisions operate independently of patent exclusivity, they may prevent the approval and/or submission of generic drug applications for some products even after patent protection has expired.

We are subject to legislation in Israel relating to patents and data exclusivity, among other things. Modifications of such legislation or court decisions regarding this legislation may adversely affect us and may impact our ability to export Israeli-manufactured products in a timely fashion. Additionally, the existence of third-party patents in Israel, with the attendant risk of litigation, may cause us to move production outside of Israel or otherwise adversely affect our ability to export certain products from Israel. Exports from Europe may similarly be affected by legislation relating to patents and data exclusivity and also by the risk of patent litigation.

Regulations to permit the sale of biotechnology-based products as bioequivalent or biosimilar drugs, primarily in the U.S., may be delayed, or may otherwise jeopardize our investment in such products.

We have made, and expect to continue to make, substantial investments in our ability to develop and produce biotechnology-based products, which require significantly greater early-stage financial commitments than small-molecule generic product development. Although some of these products may be sold as innovative products, one of our key strategic goals in making these investments is to position Teva at the forefront of the development of bioequivalent or biosimilar generic versions of currently marketed biotechnology products. To date, in many markets, most notably the U.S., there does not yet exist a legislative or regulatory pathway for the registration and approval of such biogeneric products. Significant delays in the development of such pathways, or significant impediments that may be built into such pathways, could diminish the value of the investments that we have made, and will continue to make, in our biotechnology capabilities. For example, in the proposed healthcare reform legislation pending in the U.S. Congress, biosimilar products may not be approved for twelve years following approval of the branded biotechnology product. As a result, generic competition may be delayed significantly, adversely affecting our ability to develop a successful biosimilars business.

The increased amount of intangible assets and goodwill recorded on our balance sheet will likely lead to significant impairment charges in the future.

We regularly review our long-lived assets, including identifiable intangible assets and goodwill, for impairment. Goodwill, trade names and acquired product and marketing rights are subject to impairment review at least annually. Other long-lived assets are reviewed when there is an indication that an impairment may have occurred. The amount of goodwill and other intangible assets on our consolidated balance sheet has increased significantly in recent years to \$16.7 billion, primarily as a result of our recent acquisitions, and will increase further following future acquisitions as a result of changes in U.S. accounting rules regarding the treatment of in-process research and development. Impairment testing under U.S. GAAP will likely 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. Any significant impairment charges could have a material adverse effect on our results of operations.

If our intercompany arrangements are challenged and determined to be inappropriate, our tax liabilities could increase.

We have potential tax exposures resulting from the varying application of statutes, regulations and interpretations, including exposures with respect to manufacturing, research and development, marketing, sales and distribution functions. Although our arrangements are based on accepted tax standards, tax authorities in various jurisdictions may disagree with and subsequently challenge the amount of profits taxed in such jurisdictions, which may increase our tax liabilities and could have a material adverse effect on the results of our operations.

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We may be susceptible to 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 we continue to expand our portfolio of available products, we have experienced an increase in the number of product liability claims against us, and we expect that trend to continue. Moreover, we sell, and will continue to sell, certain pharmaceutical products for which product liability insurance coverage is not available to us, and, accordingly, we may be subject to claims that are not covered by insurance. In addition, products for which we currently have coverage may be excluded from coverage in the future. Certain claims may be subject to our self-insured retention, exceed our policy limits or relate to damages that are not covered by our policy. Because of the nature of these claims, we are generally not permitted under U.S. GAAP to establish reserves in our accounts for such contingencies. In addition, product liability coverage for pharmaceutical companies is becoming more expensive and increasingly difficult to obtain and, as a result, we may not be able to obtain the type and amount of coverage we desire or to maintain our current coverage.

Termination or expiration of governmental programs or tax benefits could adversely affect our overall effective tax rate.

Our tax expenses and the resulting effective tax rate reflected in our 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 the mix of countries where we generate profit. We have benefited or currently benefit from a variety of 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,

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. *Current economic conditions may adversely affect our industry, business and results of operations.* 

Although economic conditions in many countries have stabilized somewhat following the widespread contraction in late 2008 and 2009, government revenues have decreased substantially compared to recent years. As a result, national healthcare budgets will continue to face cost pressures, which may result in reduced spending on healthcare and drive us and our competitors to decrease prices. Moreover, decreases in personal incomes may cause patients to reduce their expenditures on medications. While generic drugs present an alternative to higher-priced branded products, our sales could nevertheless be negatively impacted if patients forego obtaining healthcare and purchasing pharmaceutical products.

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

Given the 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 the quality of our management and workforce. 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, our increasing 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.

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 that develops, produces and markets generic drugs covering all major treatment categories. We are the leading generic drug company in the world, as well as in the United States, in terms of both total and new prescriptions. We also have a significant and growing branded pharmaceutical portfolio, including Copaxone® for multiple sclerosis and Azilect® for Parkinson s disease, respiratory products and women s health products. Our active pharmaceutical ingredient (API) manufacturing capabilities provide significant vertical integration to our own pharmaceutical production.

Our global presence covers North America, Europe, Latin America, Asia and Israel. We currently have direct operations in more than 60 countries, including 38 finished dosage pharmaceutical manufacturing sites in 17 countries, 15 generic R&D centers operating mostly within certain manufacturing sites and 21 API manufacturing sites around the world. In 2009, we generated approximately 60% of our sales in North America (which for the purpose of this report includes the United States and Canada only), approximately 25% in Europe (which for the purpose of this report includes all European Union (EU) member states and other Western European countries) and approximately 15% in other regions (primarily Latin America, including Mexico, Israel and Central and Eastern European countries that are not members of the EU). For a breakdown of our sales by product lines and by geographic market for the past three years, see Item 5: Operating and Financial Review and Prospects Results of Operations Sales General.

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 49131 Israel, telephone number 972-3-926-7267. Our website is www.tevapharm.com.

## Strategy

In January 2010, we announced our revised strategic goals of generating by 2015 revenues of \$31 billion and non-GAAP net income of \$6.8 billion. The core elements of our strategy to reach those goals include:

Increasing Our Market Share: Growing our market share in key markets, including the world s largest market for generic pharmaceuticals, the U.S., and securing or enhancing our market positions in Europe and in key international markets in Latin America, Central and Eastern Europe and Asia. We believe that such growth will result from the growing demand for generic pharmaceuticals, as governments and other payors strive to expand access to affordable high-quality medicine and control healthcare costs, from new product opportunities, as brand products with current sales of approximately \$150 billion will lose patent protection by 2015, and from our competitive advantages and leadership position in the market. We expect that a significant portion of this growth will come from European and international markets that currently have low generic penetration rates;

*Investment in Our Product Portfolio:* Improving our generic R&D capabilities and production capacity, with a focus on capturing more high-value first-to-market opportunities in key markets, including Paragraph IV filings in the U.S., as well as leveraging our broad product portfolio to enhance our market position globally;

**Redefining Customer Service:** Rapidly responding to customers most significant needs by, among other things, broadening our product portfolio and executing more new product launches, optimizing a truly global supply chain, helping customers more efficiently manage their inventory and customizing shipping methods based on specific customer needs;

*Proprietary Pharmaceuticals:* Continuing to strengthen and broaden our innovative and branded product portfolio through internal R&D, licensing and other business development opportunities and

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geographic expansion of our existing product portfolio. Our focus will be two-fold: strengthening our existing franchises (including central nervous system, respiratory and women s health products), while exploring opportunities to expand into other niche therapeutic areas, such as oncology;

**Biopharmaceuticals:** Continuing to invest, either directly or in partnership with others, in the technologies, infrastructure and capabilities necessary to develop and produce affordable biopharmaceuticals, including biogenerics, leveraging our formulation and manufacturing expertise;

Vertical Integration: Extending our already significant vertical integration with our own pharmaceutical production to provide us with early access to high quality APIs and improve our profitability, in addition to further enhancing our R&D capabilities; and

**Pursuing Potential Acquisitions:** Continuing to actively seek and evaluate potential acquisitions, collaborations and other business combinations that may complement or enhance our business, either through expanding our market share in attractive geographies or acquiring niche specialty products.

Our strategy is designed to reinforce our balanced business model, by diversifying our sources of revenue, to make us less dependent on any single market or product. Although we expect generic pharmaceuticals to remain our core business generating approximately 70% of our revenues we seek to achieve greater geographical diversity, with European and other international markets comprising a greater portion of our revenues, and to have our branded portfolio incorporate a larger number of marketed products.

## **Product Offerings**

#### **Generic Products**

Generic pharmaceuticals are the chemical and therapeutic equivalents of brand-name drugs and are typically sold under their chemical names at prices substantially below those of the brand-name pharmaceuticals. Generics are required to meet similar governmental regulations as their brand-name equivalents and must receive regulatory approval prior to their sale in any given country. For example, in the U.S., generic pharmaceuticals may be manufactured and marketed only if relevant patents on their brand-name equivalents (and any additional government-mandated market exclusivity periods) have expired or have been challenged and invalidated or otherwise legally circumvented.

Sales of generic pharmaceuticals have benefited 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 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. We believe that these factors, together with an aging population and an increased focus on decreasing healthcare costs, as well as the large number of branded products losing patent protection over the coming years, should lead to continued expansion of the generic pharmaceuticals market.

Through coordinated global research and development activities, we constantly seek to expand our range of generic products. Our generic product development strategy is two-fold: to be first to introduce generic products to market and to achieve market introduction at the earliest possible date, which may involve attempting to invalidate or otherwise legally circumvent existing patents. We actively review pharmaceutical patents and seek opportunities to challenge those patents that we believe are either invalid or would not be infringed by a generic version. In furtherance of this strategy, we also seek to enter into alliances to acquire rights to products we do not have or to otherwise share development costs or litigation risks, or to resolve patent barriers to entry.

We manufacture and sell generic pharmaceutical products in a variety of dosage forms, including tablets, capsules, ointments, creams, liquids, injectables and inhalants.

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We also continue to focus on sales of generic injectable products to hospitals, clinics and other institutional channels, mostly in the U.S. and Europe, but also in Latin America and Central and Eastern Europe. Our competencies in the development and manufacturing of sterile products and our efficient global supply chain permit us to offer a wide range of oncology products, with different therapeutic mechanisms, in both parenteral and solid dosage forms.

Below is a summary of our North American, European and International generic activities:

#### North America

*United States.* Our principal U.S. subsidiary, Teva Pharmaceuticals USA, Inc., is the leading generic drug company in the U.S. We market over 400 generic products in more than 1,300 dosage strengths and packaging sizes. We also have the capability to formulate, fill, label and package finished dosage forms of injectable pharmaceutical products. We believe that the breadth of our product offerings has been and will continue to be of strategic significance as the generics industry grows and as consolidation continues among purchasers, including large drugstore chains, wholesaling organizations, buying groups and managed care providers.

In 2009, following our acquisition of Barr Pharmaceuticals Inc., we enhanced our position as the U.S. generic market leader in total prescriptions and new prescriptions, with total prescriptions increasing from approximately 475 million in 2008 to approximately 599 million in 2009 after the Barr acquisition, representing 22% of total U.S. generic prescriptions. We expect that our U.S. market leadership will continue to increase as a result of our ability to introduce new generic equivalents for brand-name products on a timely basis, emphasis on customer service, the breadth of our product line, our reputation for regulatory compliance and our cost-effective production.

Several factors continued to affect the U.S. generics industry in recent years, including consolidation at all levels, the introduction of a Medicare prescription drug program and the efforts of brand companies to fight generic competition. Industry consolidation, which has taken place among pharmacy chains, wholesalers, benefit managers and generic producers themselves, has generally resulted in fewer, but larger, players throughout the supply chain, from manufacturers to middlemen to customers.

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Products. In 2009, we launched 19 generic versions of the following branded products in the U.S. (listed by date of launch):

			tal Annual
		Launch	ded Market at Generic Launch
Generic Name	Brand Name	Date	llions (IMS)*
Phenylephrine HCl injection	n/a	Jan-09	\$ 8.5
Diltiazem HCl injection	Cardizem <sup>®</sup>	Jan-09	\$ 6.7
6% hetastarch in 0.9% sodium chloride injection	Hespan <sup>®</sup>	Jan-09	\$ 9.5
Levetiracetam tablets	Keppra <sup>®</sup>	Jan-09	\$ 1,245.6
Risperidone oral solution	Risperdal®	Jan-09	\$ 75.8
Sumatriptan succinate injection	Imitrex <sup>®</sup>	Feb-09	\$ 25.1
Sumatriptan succinate tablets	Imitrex <sup>®</sup>	Feb-09	\$ 1,037.6
Topiramate tablets	Topamax <sup>®</sup>	Mar-09	\$ 2,517.8
Mixed amphetamine salts ER capsules	Adderall XR®	Apr-09	\$ 1,487.3
Topiramate capsules sprinkle	Topamax <sup>®</sup>	Apr-09	\$ 54.9
Mycophenolate mofetil tablets	CellCept <sup>®</sup>	May-09	\$ 690.5
Mycophenolate mofetil capsules	CellCept <sup>®</sup>	May-09	\$ 371.1
Ursodiol tablets	Urso®	May-09	\$ 75.9
Tri-Lo-Sprintec <sup>®</sup> tablets	Ortho Tri-Cyclen® Lo	Jul-09	\$ 390.3
Bicalutamide tablets	Casodex®	Jul-09	\$ 315.8
Oxaliplatin injection	Eloxatin <sup>®</sup>	Aug-09	\$ 1,427.1
Divalproex sodium ER tablets	Depakote ER®	Aug-09	\$ 752.6
Fexofenadine HCl & pseudoephedrine HCl ER tablets	Allegra-D <sup>®</sup> 12 Hour	Nov-09	\$ 291.5
Lansoprazole delayed release capsules	Prevacid <sup>®</sup> Delayed Release	Nov-09	\$ 2,863.6

<sup>\*</sup> Branded annual market size as quoted by IMS is a commonly used measurement of the relative significance of a potential generic product. The figures given are for the twelve months ended in the calendar quarter closest to our launch. Generic equivalents of any given product are typically sold at prices substantially below the branded product price.

The FDA requires companies to submit abbreviated new drug applications (ANDAs) for approval to manufacture and market generic forms of brand-name drugs.

In 2009 we received, in addition to 27 final generic drug approvals, 10 tentative approvals. A tentative approval letter indicates that the FDA has substantially completed its review of an application and final approval is expected once the relevant patent expires, a court decision is reached, a 30-month regulatory stay lapses or a 180-day exclusivity period awarded to another manufacturer either expires or is forfeited. The 10 tentative approvals received were for generic equivalents of the following products:

		I	al Branded Market
Generic Name	Brand Name	\$ mill	ions (IMS)*
Alfuzosin HCl ER tablets	Uroxatral <sup>®</sup>	\$	214.1
Ibandronate sodium injection (vials)	Boniva <sup>®</sup>		No data
Moxifloxacin ophthalmic solution	Vigamox <sup>®</sup>	\$	233.7
Montelukast sodium tablets	Singulair <sup>®</sup>	\$	2720.1
Zoledronic acid injection (vials)	Zometa <sup>®</sup>	\$	732.1
Montelukast chewable tablets	Singulair <sup>®</sup>	\$	877.5
Temozolamide capsules	Temodar <sup>®</sup>	\$	369.6
Rosiglitazone/glimepiride tablets	Avandaryl®	\$	54.1
Atomoxetine HCl capsules	Strattera <sup>®</sup>	\$	520.9
Lamiyudine/zidoyudine tablets	Combivir®	\$	372.4

\* The figures given are for the twelve months ended September 30, 2009.

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We expect that our revenue stream in North America will continue to be fueled by our strong U.S. generic pipeline, which, as of February 5, 2010, had 216 product registrations awaiting FDA approval (including some products through strategic partnerships), including 43 tentative approvals. Collectively, the branded versions of these 216 products had U.S. sales in 2009 exceeding \$113 billion. Of these applications, 140 were Paragraph IV applications challenging patents of branded products. We believe we are the first to file with respect to 89 of these products, the branded versions of which had U.S. sales of more than \$55 billion in 2009. IMS reported brand sales are one of the many indicators of future potential value of a launch, but equally important is the mix and timing of competition, as well as cost effectiveness. The potential advantages of being the first filer with respect to some of these products may be subject to forfeiture.

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

*Collaborations.* As part of our strategy to bring generic versions to market as early as possible, we seek to enter into alliances with partners to acquire rights to products we do not have, to share development costs or litigation risks, and/or to resolve patent barriers to entry. Described below are certain alliances that provide significant current contributions to our generic product offering.

In 1997, we entered into a marketing and product development agreement with Biovail Corporation that provided us with exclusive U.S. marketing rights for certain of Biovail spipeline of controlled-release generic versions of successful brands. Under this agreement, which expires in 2011, we currently market generic versions of Cardizem® CD (diltiazem HCl), Adalat® CC (nifedipine) and Procardia XL® (nifedipine XL) in the U.S. We have also entered into a long-term supply agreement under which Biovail purchases active pharmaceutical ingredients from us.

In 2001, we entered into a strategic alliance agreement for twelve controlled-release generic pharmaceutical products with Impax Laboratories, Inc. The agreement grants us exclusive U.S. marketing rights and an option to acquire exclusive marketing rights in the rest of North America, Latin America, Europe and Israel. In 2002, we exercised our option with respect to certain products in Canada. Under this agreement, we currently market generic versions of Wellbutrin  $SR^{\circledast}$  (bupropion) tablets, Zyban $^{\$}$  (bupropion) tablets, Ditropan  $XL^{\$}$  (oxybutynin), and Wellbutrin  $XL^{\$}$  (bupropion XL) tablets. We hold approximately 3.8% of Impax s common stock, which was issued to us under the agreement and in repayment of loans from us under such agreement.

**Patent Litigation Settlements.** From time to time we enter into agreements settling patent litigation with brand companies. We believe that these agreements benefit both U.S. consumers, by accelerating the introduction and increasing the availability of our lower cost generic products, and us, by removing uncertainty regarding possible litigation risks. We will continue to evaluate any potential future settlements on a case-by-case basis.

Marketing and Sales. In 2009, our sales in the U.S. by channel were as follows:

	2009
Drug store chains	54%
Drug wholesalers*	33%
Managed care organizations	6%
Generic distributors	6%
Governmental facilities and others	1%

<sup>\*</sup> A major portion of the products sold to wholesalers ends up in drug store chains, and is not reflected in the data presented above.

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Our sales organization consists of the Teva Generics group and the Teva Health Systems group. The Teva Generics sales force calls on purchasing agents for chain drug stores, drug wholesalers, health maintenance organizations, mail order pharmacies, pharmacy buying groups and nursing homes. The Health Systems group handles unit dose products and finished-dosage injectable pharmaceutical products that are used primarily in institutional settings. It focuses on the injectable pharmaceutical market and key institutional accounts, including hospitals and clinics for critical care, government systems, hospital group purchasing organizations, managed care groups and other large healthcare purchasing organizations.

In the U.S., our wholesale selling efforts are supported by professional journal advertising and exhibitions at key medical and pharmaceutical conventions. From time to time, we also bid for U.S. government-tendered contracts.

Canada. Through Teva Canada Ltd. (formerly known as Novopharm Limited), our Canadian subsidiary, we manufacture and market generic prescription pharmaceuticals in Canada. We are the second largest generic pharmaceutical company in Canada, with a product portfolio that includes 217 generic products in 765 dosage forms and packaging sizes. In 2009, we launched generic equivalents of the following branded products (in order of launch date): MS Contin® (morphine sulfate) (15mg and 30mg), Inhibace Plus® (cilazapril/HCTZ), Duragesic® (fentanyl transdermal patch), Didrocal® (etidronate cal), Levaquin® (levofloxacin), Norvasc® (amlodipine), Evista® (raloxifene), Pharmorubicin® (epirubicin HCl injection), Exelon® (rivastigmine), Vasotec® (enalapril maleate), Prevacid® (lansoprazole DR), and Amerge® (naratriptan).

The Therapeutic Products Directorate of Health Canada requires companies to make an abbreviated new drug submission in order to receive approval to manufacture and market generic pharmaceuticals. In Canada, as of December 31, 2009, we had 67 product registrations awaiting approval by the Therapeutic Products Directorate of Health Canada. Collectively, the branded versions of these products had Canadian sales in 2009 of approximately U.S. \$4.2 billion.

Our sales force in Canada markets generic products to retail chains, retail buying groups and independent pharmacies reaching approximately 7,500 outlets. Canada continues to see consolidation of independent retail pharmacies and increased expansion of retail chains and buying groups: the top five retail chain customers in Canada represent approximately half the market (by dollar). The business is conducted primarily through agreements with corporate accounts or retail and hospital buying groups.

## Europe

Teva Europe is one of the leading generic pharmaceutical companies in Europe, with direct operations in 26 EU member states as well as Norway and Switzerland. Our primary strategic objective in Europe is to extend and secure a strong leadership position in each country in which we operate. Currently, we are the leading generic pharmaceutical company in the U.K., the Netherlands and Italy in terms of sales. In 2009, we reached the top three leading market positions in France, Spain, Hungary, Poland and the Czech Republic. We expect to continue to seek to register a broad portfolio of generic products, expand our customer base, capitalize on pro-generic governmental reforms and, where appropriate, pursue strategic acquisitions and alliances. We have also established pan-European relationships with many of our customers. In 2009, we were able to either maintain our leading position or increase our market share in our main markets in Europe.

In 2009, we launched 19 generic versions of the following branded products in Europe (listed in order of launch): Vancenase® (beclomethasone dipropionate), Losec®/Prilosec® (omeprazole), Ventolin® (salbutamol sulfate), Neurontin® (gabapentin), Eloxatin® (oxaliplatin), Casodex® (bicalutamide), Rhinocort® (budesonide), Effexor® (venlafaxine HCl), Protonix® (pantoprazole sodium), Temesta® (lorazepam), Dostinex® /Cabaser® (cabergoline), Camptosar® (irinotecan HCl), Neupogen® (filgrastim), Gemzar® (gemcitabine HCl), Femara® (letrozole), Plavix® (clopidogrel hydrobromide) and Hyzaar® (losartan potassium/HCTZ).

In Europe, while marketing authorizations for generic products may be obtained through a decentralized mutual recognition procedure, a centralized procedure involving the European Medicines Agency ( EMEA ) may also be used, which results in an approval valid in all EU member states. As of December 31, 2009, Teva

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had received 1,035 generic approvals in Europe relating to 164 compounds in 324 formulations, including 12 European Commission approvals valid in all EU member states. We have the broadest pipeline in Europe, with 3,143 marketing authorization applications pending approval in 30 European countries relating to 241 compounds in 485 formulations, including nine applications pending with the EMEA.

European Generic Market. In Europe, the generics market varies considerably from country to country in terms of market penetration and other characteristics. Some European countries, such as the U.K., the Netherlands, Germany, Poland and the Czech Republic, are characterized by relatively high generic penetration, ranging between 54% and 77% of total pharmaceutical sales (measured by volume) in 2009. Such relatively high penetration rates are in contrast with other major European markets, such as France, Italy and Spain, where the market share of generics ranged between 10% and 21% in 2009. However, recent efforts by governments in these countries to reduce healthcare costs by encouraging use of generic pharmaceutical products may provide a significant opportunity for growth.

In certain European countries, there is a market for both branded generic products and drugs sold under their generic chemical names, while in others there is a market for branded generics only. Some countries, such as the U.K. and the Netherlands (so-called pure generic markets), permit substitution by pharmacists, while other countries, such as Germany, Poland, and Hungary, permit pharmacists to dispense only the specific pharmaceutical product prescribed by doctors. In France, Italy, Spain and Portugal, as in certain Central and Eastern European countries, the market is a hybrid, with elements of both approaches.

European markets also vary considerably in terms of the primary decision maker for selecting the pharmaceutical product to be used. In countries such as Hungary and Poland, the physician is the primary decision maker, whereas in other European markets, such as the U.K., France and Italy, the pharmacist has greater discretion over which product is dispensed. In countries such as Germany and Spain, there is more than one primary decision maker for selecting the pharmaceutical product.

Below is a summary of our operations in selected European countries:

*Czech Republic.* We are the second largest generic pharmaceutical company in the Czech Republic, with a portfolio of 153 products in approximately 310 dosage forms and packaging sizes.

The Czech pharmaceutical market is characterized by high generic penetration of approximately 54% in terms of volume. However, as a result of government healthcare reforms initiated in 2008, the generic segment of the market declined in both value and volume. In 2009, we launched 14 new products or line extensions, including the generic versions of Cozaar® (losartan potassium), Camptosar® (irinotecan HCl), Femara® (letrozole), Meridia® (sibutramine HCl), Arimidex® (anastrozole), Actonel® (risedronate sodium), Topamax® (topiramate), CellCept® (mycophenolate mofetil), Fludex® (indapamide), Tritace® (ramipril/HCTZ), Seroquel® (quetiapin), Paxil® (paroxetin), Cozaar® (losartan/HCTZ) and Dostinex® (cabergoline).

*France.* We are the third largest generic company in France by sales, with a portfolio of approximately 230 generic products sold in approximately 550 dosage forms and packaging sizes. The French pharmaceutical market is characterized by increasing generic penetration, which in 2009 reached approximately 23% of the market in terms of volume following government reforms that sought to encourage the dispensing of generic products.

In 2009, we launched 37 new products in France, including the generic versions of Protonix® (pantoprazole sodium), Effexor® (venlafaxine HCl), Ventolin® (salbutamol sulfate), Plavix® (clopidogrel hydrobromide), Xyzal® (levocetirizine dihydrochloride), Suprax® (cefixime), Concor® (bisoprolol fumarate/HCTZ), Proscar® (finasteride), Alphagan® (brimonidine tartrate), Gemzar® (gemcitabine HCl), Camptosar® (irinotecan HCl), Lamictal® (lamotrigine), Peridex® (chlorhexidine/chlorobutanol), Nizoral® (ketoconazole) and Moxaviv® (moxonidine).

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*Germany*. In Germany, following the inclusion of Pliva s sales, we became the fifth largest generic company, with a product portfolio that includes 188 generic products sold in approximately 1,180 dosage forms and packaging sizes.

As a result of legislative changes introduced in 2007, incentivizing the use of tenders, there are two distinguishable generic markets in Germany: a large branded market and a smaller tender-based generic market with a very competitive pricing environment. Under recent legislation, state health insurers may issue tenders for the selection of a single supplier of a molecule, and may also issue tenders for selecting multiple suppliers with which the insurer enters into direct rebate agreements or portfolio contracts. Under this tender-based system, pharmacists are required to dispense products of the pharmaceutical manufacturers that were awarded tenders by the patient shealth insurer, except in cases where the physician has specifically ruled out substitution.

In 2009, we launched 11 new products in Germany, including the generic versions of Gemzar® (gemcitabine HCl), Camptosar® (irinotecan HCl), Protonix® (pantoprazole sodium), Topamax® (topiramate), Requip® (ropinirole HCl), Anexate® (flumazenil), Plavix® (clopidogrel HCl) and Atrovent® (ipratropium bromide).

*Hungary*. We are the third largest generic company and the fifth largest pharmaceutical company by sales in Hungary, with a portfolio of 232 products in 741 dosage forms and packaging sizes. In addition to the retail reimbursed business, we are the second largest supplier in the over-the-counter (OTC) market and among the three leading suppliers to hospitals. We also have a wholesale division, which is the third largest in Hungary. The Hungarian pharmaceutical market is characterized by high generic penetration of approximately 50% in terms of volume.

In 2009, we launched 22 new molecules in Hungary, including the generic versions of Hyzaar® (losartan potassium/HCTZ), Aciphex® (rabeprazole sodium), Meridia® (sibutramine HCl), nebivolol HCl, CellCept® (mycophenolate mofetil), Arimidex® (anastrozole), Lescol® (fluvastatin sodium), Femara® (letrozole), Effexor® (venlafaxine HCl), Seroquel® (quetiapine fumarate), Cosopt® (dorzolamide HCl/timolol maleate), Plavix® (clopidogrel) and Triflux® (triflusal).

Italy. We are the leading generic company by units and sales in Italy, with a portfolio of 146 products in 287 dosage forms and packaging sizes.

In 2009, the Italian generic market experienced low growth in volume and a decrease in the value of generic products sold. The generic penetration rate remained relatively low, at approximately 10% in terms of volume.

New pharmaceutical regulations came into effect in May 2009, reducing prices for generics by 12%, and setting discounts to wholesalers at 41% of the retail price for a portfolio of reimbursement products. These regulations expired on January 1, 2010, yet some manufacturers reduced prices by an additional 12% on average. Because reimbursement in Italy is based on the lowest price available in the market, we reduced our prices to remain competitive.

In 2009, we launched 17 new products, including generic versions of Effexor® (venlafaxine HCl), Zosyn® (piperacillin sodium/tazobactam sodium), Coversyl® (perindopril), Camptosar® (irinotecan HCl), Zithromax® (azithromycin), Novatec® (lisinopril/HCTZ), Protonix® (pantoprazole sodium), Monouril® (fosfomycin trometamol), Lescol® (fluvastatin sodium), Monopril HCT® (fosinopril sodium/HCTZ), Famvir® (famciclovir), Monopril® (fosinopril sodium), Eloxatin® (oxaliplatin), Imigran® (sumatriptan), Gemzar® (gemcitabin), Octostim® (desmopressin) and Mucosolvan® (ambroxol).

The Netherlands. We are the leading generic company in the Netherlands and the third largest pharmaceutical company by sales (based on reimbursement price level). Our portfolio includes approximately 270 generic products, which are sold in 823 dosage forms and packaging sizes.

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The tender-like system introduced in the Netherlands provides pharmaceutical companies an incentive to reduce prices by becoming exclusive suppliers to health insurers for a six-month to one-year period. Due to our broad portfolio, partly sold through this preference system and partly unaffected by it, we were able to extend our market share in the Netherlands.

In 2009, we launched 55 new products in the Netherlands, including the generic versions of Protonix® (pantoprazole sodium), Efexor-XR® (venlafaxine HCl), Toprol-XL® (metoprolol tartrate), Plavix® (clopidogrel bisulfate), Toprol XL® (metoprolol succinate), Imitrex® (sumatriptan succinate), Famvir® (famciclovir), Minesse® (ethinylestradiol/gestodene), Ventolin® (salbutamol sulfate), Tritace® (ramipril), Cardura® (doxazosin mesilate), Restoril® (temazepam), Xyzal® (levocetrizine), Nebilet® (nebivolol) and Valtrex® (valaciclovir).

**Poland.** Following the inclusion of Pliva, we became the third largest generic company and the sixth largest pharmaceutical company in Poland, with a portfolio that includes 180 generic products in 466 dosage forms and packaging sizes.

The pharmaceutical industry in Poland has experienced significant structural change in recent years. Many formerly state-owned companies have been privatized, and foreign firms account for a high proportion of sales. The competitive landscape, which is dominated by several very strong local and regional competitors, continues to be fragmented, with hundreds of manufacturers.

In 2009, we launched nine new products in Poland, including the generic versions of Zyprexa® (olanzapine), Singulair® (montelukast), Meridia® (sibutramine HCl), Losec® (omeprazole), Femara® (letrozole), Exelon® (rivastigmine tartrate) and Oncovin® (vincristine).

*Spain.* We are the third largest generic company by sales in Spain with a portfolio of 117 products, sold in approximately 450 dosage forms and packaging sizes. The Spanish pharmaceutical market is characterized by low generic penetration of approximately 20% in terms of volume.

In 2009, we launched more than 20 new products in Spain, including the generic versions of Plavix® (clopidogrel), Avapro® (irbesartan), Lescol® (fluvastatin slow release), Actonel® (risedronic acid), Merrem® (meropenem), and Camptosar® (irinotecan HCl).

*United Kingdom.* We are the leading generic pharmaceutical company in the U.K. in terms of sales to the National Health Service, which is the sole national insurer. We have a portfolio of 217 generic products, which are sold in 617 dosage forms and packaging sizes. We maintain the largest sales force in the generic industry, focusing on independent retail pharmacies.

The U.K. pharmaceutical market is characterized by a high generic penetration of approximately 57% in terms of volume. During 2009, the government continued its program to limit pharmacy profits from the sale of medicines through a complex reimbursement price mechanism for generic items that is reviewed quarterly. This has had the continued effect of exerting downward pressure on prices in the market. During 2009, we maintained our leadership position, with a market share of approximately 29% at the end of the year.

In order to meet the requirements of the U.K. market and to improve customer service, we have invested in a highly automated distribution center that became fully operational in the second quarter of 2009. We believe that this new distribution center provides a competitive advantage by enabling us to tailor the distribution of products to both wholesalers and pharmacy chains.

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In 2009, we launched 19 new products in the U.K., including the generic versions of Plavix® (clopidogrel hydrobromide), Protonix® (pantoprazole sodium), Topamax® (topiramate), Neupogen® (filgrastim), Solian® (amisulpride), Gemzar® (gemcitibine), Camptosar® (irinotecan HCl), Trileptal® (oxcarbazapine), Alphagen® (brimonidine), Cipramil® (citalopram oral drops) and Trusopt® (dorzolamide).

#### International

Our International Group is responsible for markets other than the U.S., Canada, and those included under Teva Europe. While each of these markets is different, in general the larger of these markets are characterized by rapid growth and relatively high sales of branded generic and OTC products.

Below is a summary of our operations in Latin America, Croatia, Israel, Japan and Russia:

#### Latin America

We market a broad portfolio containing innovative, branded generic, generic and OTC pharmaceutical products in Latin America. We distribute our products in most of the Latin American countries. In most cases, these products are manufactured in our facilities in Mexico, Chile, Argentina, and Peru.

Brazil, Mexico, Venezuela, and Argentina are the largest pharmaceutical markets in the region, with substantial local manufacturing and, due to the historical absence of effective patent protections for innovative drugs, a history of reliance on generic and branded generic products.

Total pharmaceutical retail sales in the region exceeded \$40 billion in 2009 and, according to IMS forecasts, the Latin American pharmaceutical market is expected to grow at an average annual rate of approximately 12% through 2013.

We intend to expand our operations in Latin America, taking advantage of the expected increases in spending on healthcare (and on pharmaceuticals in particular) and growing populations, leveraging our manufacturing expertise, building on our existing brands and expanding the indications served.

In *Argentina*, we manufacture and sell approximately 160 branded generic and OTC products. The Argentine pharmaceutical market is highly fragmented with no single company claiming market leadership. We are the third largest pharmaceutical company in terms of sales, with a market share of approximately 3% for 2009. Sales are made primarily to distributors and wholesalers, with the remainder directly to healthcare institutions.

In *Chile*, we are the largest pharmaceutical company in terms of sales and prescriptions for both branded generics and pure generics. We market our products to retail and institutional (hospitals and clinics) customers and export to 13 other countries within the region. Branded generics account for approximately three-quarters of our sales in dollar terms, with the remainder consisting of generics and OTC products.

In *Mexico*, our operations include two pharmaceutical manufacturing sites, which primarily supply the domestic market, but also supply other markets in Latin America. Sales are made primarily to the public sector (through government tenders and institutional sales), with the remainder primarily sales of our innovative products (Copaxone® and Azilect®).

In *Peru*, we are the fourth largest pharmaceutical company in terms of sales. The vast majority of our sales is made to pharmacy chains, distributors and wholesalers, with approximately 7% of sales being made to governmental customers. We also operate the third largest pharmacy chain in the country, which purchases 19% of its pharmaceutical products from Teva s local company.

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## Other Countries in Teva s International Group

*Croatia.* Pliva, Teva s subsidiary in Croatia, is the leading healthcare company in Croatia. It is the market leader in the prescription and OTC market segments, and is also a supplier to the hospital market segment. Pliva s share of the Croatian generic market is approximately 33%.

*Israel.* We are the leading provider of professional healthcare products and services in the Israeli market. Sales in Israel accounted for 4% of our total sales in 2009. In addition to innovative, generic and OTC pharmaceutical products, we sell and distribute a wide range of healthcare products and services, including consumer healthcare products, hospital supplies, dialysis equipment and disposables, diagnostics and home care services. Our Israeli product portfolio also includes products sold under licensing arrangements. Our distribution company, Salomon Levin and Elstein Ltd., provides logistical support for the selling and distribution activities of Teva in Israel, which include distribution of products of third parties, including several multinational pharmaceutical companies. A new logistics center currently under construction is expected to increase our technological and logistical capabilities in Israel significantly when it is completed in 2011.

Prices for our products in Israel are significantly affected by pricing regulations and governmental policies.

Japan. Japan is the second largest pharmaceutical market worldwide, estimated at approximately \$87 billion in 2009. Generic penetration is estimated at 19% of volume and 7% of value. In 2007, the Japanese government set an objective to double generic usage and reach 30% market share in terms of volume by 2012. In 2008, we established a joint venture with Kowa Company Ltd., a leading generic pharmaceutical company in Japan. The joint venture, Teva-Kowa Pharma Co., Ltd., seeks to leverage the marketing, research and development, manufacturing and distribution capabilities of each partner to become a broad-based supplier of high quality generic pharmaceutical products for the Japanese market. On December 28, 2009, Teva-Kowa Pharma acquired approximately 70% of Taisho Pharmaceutical Industries Ltd., a Japanese generics company with over 200 products and sales exceeding \$130 million for the twelve months ended September 30, 2009. As a result of the acquisition of Taisho Pharma, Teva-Kowa Pharma is the sixth-largest generic pharmaceutical company in Japan.

Russia. As one of the top ten pharmaceutical companies by value, our activities in Russia include sales of Copaxone®, sales of OTC and respiratory products, sales of generic pharmaceuticals to the retail and hospital channels, and sales of biogeneric products. We have a leading market position with Copaxone® in Russia, enjoying the largest market share among the various multiple sclerosis therapies. Russia is substantially an out-of-pocket, cash-paying market, although selected government-funded products included for reimbursement are procured using a tender process. The regulatory environment in Russia is characterized by continuing government-imposed cost containment measures for life saving products included in the reimbursement list. The government seeks to encourage generic products as a means of enabling more of the population to have access to lower cost pharmaceuticals. Russian pharmaceutical law is currently under review, with a focus on increasing access and controlling pricing of products.

## **Branded Products**

Our branded product offerings include two innovative products that we developed: Copaxone®, for the treatment of multiple sclerosis, and Azilect®, for the treatment of Parkinson s disease, respiratory products, women s health products and biopharmaceuticals and biogenerics.

## **Innovative Products**

## Copaxone®

Copaxone® (glatiramer acetate, or GA), our largest product and first major innovative drug, is the leading multiple sclerosis (MS) therapy in the U.S. and globally and is approved in 52 countries worldwide, including the U.S., Canada, Mexico, Australia, Israel, and all European countries. It is indicated for reduction of the frequency

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of relapses in patients with relapsing-remitting multiple sclerosis. Copaxone® is also indicated for the treatment of patients who have experienced clinically isolated syndrome and are determined to be at high risk of developing clinically definite MS.

Multiple sclerosis is the most common disabling neurological disease among young adults, mostly women diagnosed between the ages of 20-40, and affects over 2.5 million people worldwide. The first clinical event of almost all patients eventually diagnosed with MS is an acute episode (relapse), known as clinically isolated syndrome, of neurologic deficits leading to clinical symptoms that suggest a lesion in the central nervous system. However, not all patients with this syndrome develop MS, and of those who do, the prognosis is highly variable. In the majority of patients, the disease is of the relapsing-remitting form, which is manifested by relapses followed by recovery (remission). Recovery may be incomplete at times, resulting in a disability progression which is measured by the Expanded Disability Status Scale. Clinical evidence and MRI testing suggest that early treatment can prevent or delay accumulation of irreversible neuronal damage and the progression of multiple sclerosis.

Copaxone<sup>®</sup> is the first, and currently the only, non-interferon immunomodulator approved for the treatment of relapsing-remitting multiple sclerosis. The research to date suggests that it has a dual mechanism of action both outside and within the central nervous system that regulates inflammation at the site of brain lesions. In addition, it has been demonstrated that Copaxone<sup>®</sup> controls neurodegeneration and enhances repair. Copaxone<sup>®</sup> reduces the number of brain lesions that evolve into permanent black holes, slows brain shrinkage and increases the production of factors that enhance neuronal repair.

In April 2008, we assumed the U.S. and Canadian distribution of Copaxone® from sanofi-aventis. Under the terms of the agreements, sanofi-aventis is entitled to receive payment from us of previously agreed-upon termination consideration of 25% of the in-market sales of Copaxone® in the U.S. and Canada for an additional two-year period. Although we record higher revenues as a result of this change, we also became responsible for certain marketing and administrative expenses, which are no longer shared with sanofi-aventis. In April 2010, we will cease making the termination payments to sanofi-aventis and thereafter will record all in-market sales and profits of Copaxone® for the U.S. and Canada.

Teva has an additional agreement with sanofi-aventis for the marketing of Copaxone® in Europe and other markets. Under the terms of this agreement, Copaxone® is co-promoted with sanofi-aventis in Germany, the U.K., France, Spain, the Netherlands and Belgium, and is marketed solely by sanofi-aventis in the rest of the European markets, Australia and New Zealand. Commencing in 2009, and to a greater extent by 2012, we are gradually assuming marketing responsibilities for Copaxone® in territories covered under this additional agreement. Sanofi-aventis is entitled to pre-specified residual payments for a period of two years, following a pattern similar to that under the North America agreement described above, but with substantially lower payments.

Three confirmatory clinical studies with relapsing-remitting multiple sclerosis patients have demonstrated that daily subcutaneous injection of Copaxone® significantly reduces the relapse rate as well as the level of activity and burden as measured by magnetic resonance imaging. Furthermore, three studies (the BECOME, BEYOND and REGARD studies), conducted by our competitors, which involved over 3000 patients treated with both high-dose beta-interferon and Copaxone®, failed to demonstrate any superiority of high-dose beta-interferon products over Copaxone® in any of the primary endpoints. Moreover, the REGARD study comparing Copaxone® and Rebif® 44mcg showed that Copaxone® was superior to Rebif® 44mcg in slowing the rate of brain shrinkage.

Results from the U.S. pivotal study of Copaxone<sup>®</sup>, which was extended as an open-label trial to 15 years making it the longest continuous study ever of patients with relapsing-remitting multiple sclerosis demonstrated that the number of attacks was reduced to an average of one every five years and that more than 80 percent of patients, with an average disease duration of 22 years, were able to walk unassisted following 15 years of treatment. Additional studies conducted provide evidence that long-term benefits of Copaxone<sup>®</sup> may be, in part,

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due to remyelination. Findings demonstrate that treatment with Copaxone® may offer sustained protection from neuronal/axonal injury as reflected biologically by a significant increase in N-acetylaspartate, a specific marker of neuronal mitochondrial function, in treated versus non-treated relapsing-remitting multiple sclerosis patients.

The PreCISe study, a phase III, randomized, placebo-controlled, double-blind study in which 481 clinically isolated syndrome patients were monitored over periods of up to 36 months, showed that clinically isolated syndrome patients treated early with Copaxone® had a 45% reduction in the risk of developing clinically definite MS. Of the patients who developed clinically definite MS, the time to clinically definite MS more than doubled, from 336 days for patients given a placebo to 722 days for patients treated with Copaxone®. Copaxone® was also shown to be well tolerated in the PreCISe study. The results of this study were published in the British medical journal Lancet in October 2009.

Based on the results of the PreCISe study, in March 2009 the FDA approved an expanded indication for Copaxone® to include the treatment of patients who have experienced a first clinical episode and have magnetic resonance imaging features consistent with MS. The FDA s approval followed a similar decision by the United Kingdom s Medicines and Healthcare Products Regulatory Agency in February 2009 to expand the label for Copaxone® to include the treatment of patients with clinically isolated syndrome suggestive of MS. This approval also includes 24 European countries that take part in the EU mutual recognition procedure. Approval for an expanded label for Copaxone® was also granted by the Australian Health Authority in December 2008 and by the Israeli Ministry of Health in July 2009.

The recently completed SONG study is a Phase IIIb, randomized, open-label, crossover study, designed to examine whether a decrease in the volume of the Copaxone® dosage formulation (20 mg/0.5 mL versus 20 mg/1.0 mL) will decrease injection pain and increase tolerability for patients. The study, in which some 130 patients participated, was completed successfully, and the results are expected to be submitted to the FDA by the end of March 2010.

In December 2008, Teva launched a new, thinner, 29-gauge Copaxone® pre-filled syringe in the U.S., based on a survey of MS patients that found that the thinner needle was significantly preferred by 77% of patients over the previous 27-gauge needle. The survey also found that 66% of the participants experienced less pain while using the thinner needle and 49% had a better experience dealing with injection-site reactions. This new needle was launched in Canada in April 2009 and gradually introduced in Europe beginning in the fourth quarter of 2009, and is expected to be launched in other international markets throughout 2010.

We have Orange Book-listed patents relating to Copaxone® with terms expiring in May 2014 in the U.S. and in May 2015 in most of the rest of the world. Copaxone® is also protected by data exclusivity protections in certain European countries until August 2010. We also hold additional patents protecting various aspects of the process of preparing Copaxone® which expire between 2019 and 2024. On July 11, 2008, we learned that Sandoz Inc., the U.S. generic drug division of Novartis AG, in conjunction with Momenta Pharmaceuticals, Inc., filed an ANDA with the FDA for a generic version of Copaxone® (glatiramer acetate) containing Paragraph IV certifications to each of our patents listed in the FDA s Orange Book for the product. On August 28, 2008, we filed a complaint against Sandoz, Inc., Sandoz International GmbH, Novartis AG and Momenta Pharmaceuticals, Inc. in the United States District Court for the Southern District of New York, alleging infringement of four Orange Book patents. The patents, which expire on May 24, 2014, cover the composition of Copaxone®, pharmaceutical compositions containing it, and methods of using it. The lawsuit has triggered a stay of any FDA approval of the Sandoz ANDA until at least January 10, 2011 or a district court decision in Sandoz favor. Sandoz filed its answers to our complaint on November 3, 2008. A hearing was held on January 20, 2010 to determine, among other claim terms, the meaning of average molecular weight and molecular weight as used in the claims of Teva's Orange Book patents. We do not yet have a trial date.

On December 10, 2009, we filed a separate patent infringement suit against Sandoz and Momenta in the Southern District of New York regarding Teva s patents covering our proprietary set of molecular weight markers. The latest of these patents is set to expire in February 2020. This case has been assigned to the same judge as in the case described above.

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On September 14, 2009, Teva learned that the FDA had accepted the filing of a second ANDA for glatiramer acetate by Mylan Inc. in collaboration with Natco Pharma Ltd. The Mylan filing alleged invalidity and non-infringement of all Orange Book patents. On October 16, 2009, we filed a complaint in the United States Court for the Southern District of NY against Mylan Pharmaceuticals, Inc., Mylan Inc. and Natco Pharma Ltd. alleging infringement of all seven Orange Book patents. Mylan s response contained declaratory judgment counterclaims of non-infringement, invalidity, and unenforceability of all seven Orange Book listed patents, as well as two process patents, including a process patent that does not expire until September 2015. We do not yet have a schedule for this case. We are also involved in litigation in India against Natco Pharma Ltd. for infringement of a corresponding Indian patent.

In addition, we have filed two citizen s petitions with the FDA noting that even minor modifications in the composition of glatiramer acetate can lead to potentially significant differences in safety and efficacy. Since it is impossible to fully characterize the active components in Copaxone<sup>®</sup>, we believe that no generic version should be deemed its therapeutic equivalent without a demonstration of sameness. Additionally, we believe that any purported generic version of Copaxone<sup>®</sup> should undergo full clinical testing in humans.

#### Azilect®

Azilect® (rasagiline tablets), indicated for the treatment of Parkinson s disease both as initial monotherapy in the early stage of the disease and as an adjunct to levodopa in moderate to advanced stages of the disease, is our second innovative drug to be marketed. An estimated four million patients are affected by this chronic disease worldwide, which typically occurs at a late age, affecting approximately 1% of the population over the age of 60. Although many symptomatic therapies are available, there is still a high level of dissatisfaction with many of these treatments, both in terms of their efficacy and tolerability, and most of all in their ability to halt or slow the disease.

Azilect<sup>®</sup> is a potent, second-generation, irreversible monoamine oxidase type B (MAO-B) inhibitor with neuroprotective activities demonstrated in various in vitro and in vivo studies. Azilect<sup>®</sup> offers a unique combination of beneficial clinical effect, seen in the entire spectrum of the disease, once-daily dosing, lack of need for titration and high tolerability. This unique combination allows Azilect<sup>®</sup> to address significant unmet needs in the treatment of Parkinson s disease.

The development of Azilect® is part of a long-term strategic alliance with Lundbeck, which includes the global co-development and marketing of Azilect®, mainly in Europe, for the treatment of Parkinson s disease. Under the agreement, we jointly market the product with Lundbeck in certain key European countries. Lundbeck exclusively markets Azilect® in the remaining European countries and certain other international markets.

Azilect<sup>®</sup> was launched in its first market, Israel, in March 2005, followed by a rolling launch in various European countries, and became available in the U.S. in 2006. Currently, Azilect<sup>®</sup> is approved for marketing in 45 countries.

During the development program, Azilect® has demonstrated efficacy and safety in three major studies that included over 1,500 patients with Parkinson s disease at different stages of the disease. Two Phase III studies demonstrated Azile& s efficacy as adjunctive therapy to levodopa in moderate-advanced patients. The TEMPO Phase III study was done in early-stage patients. Azilect® demonstrated efficacy and safety as monotherapy treatment at 6 months, and suggested a possible effect on disease progression based on the 12-month results. A follow up study showed benefits of early treatment were maintained over time, for up to 6.5 years.

In June 2008, we announced the results of the Azilect® ADAGIO Phase IIIb study, one of the largest studies ever conducted for Parkinson s disease, which employed a delayed-start design to assess the effect of Azilect on slowing the clinical progression of the disease in early untreated Parkinson s patients. The study indicates that the results of early treatment with Azileet 1mg/day may be consistent with a disease modifying effect by

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slowing down the clinical progression of the disease. The study also confirmed the safety and tolerability of Azilect<sup>®</sup>. The results of the ADAGIO study were published in the New England Journal of Medicine in September 2009.

In November 2008, we announced the results of a study in which Azilect® demonstrated selective MAO-B inhibition at the approved dose of 1 mg. Non-selective MAO inhibitors may have some contra-indications with foods that contain large amounts of tyramine and certain drugs. These limitations are not associated with selective MAO inhibitors and therefore such treatments can be more broadly prescribed. Based on this study, in December 2009 the FDA approved revised prescribing information for Azilect®, reducing medication and food restrictions.

Azilect<sup>®</sup> is protected in the U.S. by several patents that will expire between 2012 and 2017. In addition, Azilect<sup>®</sup> is entitled to new chemical entity exclusivity for a period of five years from its 2006 approval date. We hold several European patents covering Azilect<sup>®</sup> that will expire between 2011 and 2014. Supplementary Protection Certificates have been granted in a number of European countries with respect to the patent expiring in 2014, thereby extending its term to 2019. Azilect<sup>®</sup> is also protected by data exclusivity protection in EU countries until 2015.

#### **Respiratory Products**

We are committed to delivering a range of respiratory products for asthma, chronic obstructive pulmonary disease (COPD) and allergic rhinitis. Our global respiratory product strategy is to extract value from both the branded and generic environments; accordingly, our portfolio includes both branded products that utilize specific proprietary devices and pure generic products.

Our principal branded respiratory products in the U.S. include ProAir (albuterol HFA), a short-acting beta-agonist for treatment of bronchial spasms linked to asthma or COPD and exercise-induced bronchospasm, and Qvar® (beclomethasone diproprionate HFA), an inhaled corticosteroid for long-term control of chronic bronchial asthma. Qvar® is manufactured by 3M. These products are marketed directly to physicians, pharmacies, hospitals, managed healthcare organizations and government agencies. In 2009, ProAir maintained its position as the leading rescue inhaler in the U.S.

In January 2008, we entered into a co-promotion agreement for the promotion of ProAir<sup>TM</sup> with UCB. During 2009, we and UCB promoted ProAir<sup>TM</sup> with approximately 230 and 350 sales representatives, respectively. At the request of UCB, we recently terminated the co-promotion agreement. UCB scales representatives will continue to promote ProAfr<sup>M</sup> through the end of February 2010 as we increase our dedicated sales force.

In Europe, our principal markets for respiratory products are the U.K., France, the Netherlands and Germany. The main products in these countries include salbutamol, beclomethasone in metered dose inhalers, Qvar® and Airomir® in metered dose inhalers and in Autohaler , as well as Qvar®, beclomethasone and salbutamol in Easi-Breathe®, the Cyclohaler® franchise and several products in Steri-Nebs .

In the short term, we believe our current portfolio of respiratory products is well positioned to capture opportunities globally. 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. At the core of our efforts to grow our respiratory franchise globally is a continued investment in high quality manufacturing capacity for press and breathe metered-dose inhalers, nasal sprays and Steri-Nebs ampoules for nebulization treatment, allowing us to play an important role in all major markets and to address all of the major areas of therapeutic need.

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Over the longer term, we expect to utilize our research and development capabilities, both internal and through alliances, to develop additional products based on our proprietary delivery systems, including Easi-Breathe®, an advanced breath-activated inhaler, Spiromax /Airmax , a multi-dose dry powder inhaler, Steri-Nebs , the blow-fill-seal based nebulizers, and Cyclohal®r, a single dose dry powder device. This strategy is intended to result in device consistency , allowing physicians to choose which device matches a patient s needs both in terms of ease of use and effectiveness of delivery of the prescribed molecule for the therapeutic need.

All of our asthma products (except for beclomethasone in the U.K. and some in-licensed products sold in our International markets) are free of chlorofluorocarbon (CFC) propellants, which are being phased out worldwide under the Montreal Protocol, a 1987 international treaty to eliminate the production and use of ozone-depleting chemicals. As of December 31, 2008, CFC propellants ceased being sold in the U.S. in 2009, our inhaler products containing the ozone-friendly propellant hydrofluoroalkane (HFA) captured approximately 54% of the HFA propellant-based product market in the U.S. We have additional non-CFC products in development.

#### Women s Health

Our women s health unit manufactures and markets proprietary pharmaceutical products in the U.S. and Canada and maintains its own proprietary sales force. Product development activities are focused on several categories, including oral contraceptives, intrauterine contraception, hormone therapy treatments for menopause/perimenopause and therapies for use in infertility and urinary incontinence. Development is also focused on products that utilize our vaginal ring platform. Two new products were launched in 2009: LoSeasonique®, an extended regimen oral contraceptive with low-dose estrogen, and Plan B® One-Step, a single tablet dose for emergency contraception. The current portfolio of actively promoted products includes:

Seasonique® (levonorgestrel/ethinyl estradiol and ethinyl estradiol), a 91-day extended regimen oral contraceptive

LoSeasonique® (levonorgestrel/ethinyl estradiol and ethinyl estradiol), a 91-day extended regimen oral contraceptive with low-dose estrogen

Plan B® One-Step OTC/Rx (levonorgestrel), an emergency oral contraceptive

ParaGard® T380 A (intrauterine copper contraceptive), an intrauterine contraceptive

Enjuvia® (synthetic conjugated estrogens, B), hormone therapy for treatment of vasomotor symptoms and vaginal atrophy Seasonique® and LoSeasonique® represent our next generation extended regimen oral contraceptive products. Both provide continuous hormonal support in the form of a low dose of estrogen in place of the usual seven placebo pills. Under the Seasonique® extended-cycle regimen, women take active tablets of 0.15 mg levonorgestrel/0.03 mg of ethinyl estradiol for 84 consecutive days, followed by seven days of low-dose estrogen alone instead of placebo (0.01 mg of ethinyl estradiol). LoSeasonique® provides the option of a lower estrogen dose in the combination tablets and contains 0.10mg levonorgestrel/0.02mg of ethinyl estradiol to be taken for 84 consecutive days followed by seven days of estrogen alone instead of placebo (0.01mg of ethinyl estradiol).

Plan B<sup>®</sup> One-Step was approved in the U.S. in July 2009 and consists of a single tablet dose of levonorgestrel for emergency contraception. It is intended to prevent pregnancy when taken within 72 hours after unprotected intercourse or contraceptive failure. Plan B<sup>®</sup> One-Step is available over-the-counter for women 17 years of age and older and by prescription for girls under 17. During August 2009, Watson Pharmaceuticals launched Next Choice<sup>®</sup>, a generic version of the our original Plan B<sup>®</sup>, the two tablet emergency contraceptive.

ParaGard® intrauterine copper contraceptive provides women with a highly effective, long-term, reversible, non-hormonal contraceptive option. It is the only intrauterine contraceptive approved for up to 10 years of continuous use and is more than 99% effective at preventing pregnancy.

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Enjuvia® is approved for the treatment of moderate-to-severe vasomotor symptoms associated with menopause and was the first oral estrogen to be approved by the FDA to treat moderate-to-severe vaginal dryness and pain with intercourse, symptoms of vulvar and vaginal atrophy associated with menopause. Enjuvia® uses a unique delivery system to provide slow release of estrogens over several hours.

#### **Biopharmaceuticals and Biogenerics**

We have identified biopharmaceuticals in particular, biogenerics as an important long-term growth opportunity. Unlike chemical (non-biological) compounds, which are produced synthetically, biopharmaceutical production involves the use of live organisms. These drugs, which are used to treat diseases like cancer, arthritis, and rare genetic disorders, make up one of the fastest-growing segments of the global pharmaceutical market and are a major contributor to increasing prescription drug costs.

During the next decade, over 85% of current biopharmaceutical sales are expected to face competition from generic versions known as biosimilars, which are biological products that approximate the structure and activity of a previously marketed biological entity (the reference product), with a target site and/or mechanism of action, if known, as described in the innovator s documentation for such reference product. In furtherance of our plans to take a leading role in the biogenerics field, we have established a dedicated research, development and manufacturing infrastructure. Our biopharmaceutical R&D facilities specialize in different technologies. Finished dosage biopharmaceutical manufacturing is carried out in our existing sterile manufacturing facilities. A joint venture with Switzerland-based Lonza Group Ltd. provides us with access to the expertise and infrastructure of the world s largest producer of biological API. In addition, through the CoGenesys acquisition in February 2008, we have proprietary albumin fusion technology which can be applied for the development of long-acting biological drugs providing us an important competitive asset in this field.

We market the following biogeneric products:

Granulocyte Colony-Stimulating Factor (GCSF). GCSF stimulates the production of white blood cells and is primarily used to reduce the risk of infections in oncology patients receiving chemotherapy. In September 2008, Teva s GCSF product, Tevagrastim, became the first biosimilar GCSF to be approved in the EU. Tevagrastim was granted the entire scope of therapeutic indications for which Amgen s Neupogen, the first GCSF product, was approved. Tevagrastim is now available in several European countries and will be launched in additional markets over time. Clinical trials have demonstrated that Tevagrastim has an efficacy and safety profile equivalent to that of Neupogen. In December 2009, Teva submitted a biologic license application (BLA) for this product with the FDA, after seeking on November 30, 2009 to have two Amgen patents that relate to the Neupogen declared invalid. On February 2, 2010, the FDA accepted for filing Teva s BLA for this product. The proposed trade name for the product is Neutroval.

Tev-Tropin® is a human growth hormone indicated for the treatment of children who have growth failure due to growth hormone deficiency. The current size of the growth hormone market in the U.S. exceeds \$1 billion. Tev-Tropin® was launched in the U.S. in 2005 pursuant to an agreement between Teva and Savient Pharmaceuticals, Inc. In September 2009, the FDA approved a needle-free injection of Tev-Tropin®.

We are also developing several additional biogeneric products, including Neugranin®, a long-acting Granulocyte Colony-Stimulating Factor (albumin-fused GCSF). Neugranin® stimulates the generation of white blood cells and is developed to reduce the risk of infection in patients undergoing chemotherapy. Neugranin® offers the advantage of one injection per chemotherapy cycle, compared to multiple daily injections of the first-generation GCSF products. Neugranin® is expected to have a profile equivalent to Amgen s long-acting GCSF product, Neulasta (Peg-GCSF).

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#### **Animal Health**

Teva Animal Health, Inc. is a manufacturer of generic animal pharmaceuticals and marketer of proprietary dermatological and nutraceutical veterinary products in the U.S. animal health market.

Teva Animal Health s headquarters, primary manufacturing, distribution, research and development, sales and marketing facilities, are located in St. Joseph, Missouri. On July 31, 2009, Teva and the FDA entered into a consent decree with respect to the operations of Teva Animal Health, after which operations were temporarily ceased pending the resolution of certain compliance issues. As a result of the consent decree, the FDA mandated that all Teva Animal Health products be recalled and all finished goods inventory be disposed of. The Animal Health facility in Fort Dodge is to be shut down. Remediation of the remaining facilities is expected to continue into 2010. There have not been any sales by Teva Animal Health since August 2009.

On January 29, 2009, we sold our Israeli animal health unit to Phibro Animal Health Corporation for total consideration of approximately \$47 million.

#### Competition

#### Generics

In the *U.S.*, we are subject to intense competition in the generic drug market from other local and foreign generic drug manufacturers, brand-name pharmaceutical companies through authorized generics, existing brand equivalents and manufacturers of therapeutically similar drugs. We believe that our primary competitive advantages are our ability to continually introduce new generic equivalents for brand-name drug products on a timely basis, quality and cost-effective production, our customer service and the breadth of our product line.

A significant proportion of our U.S. generic sales are made to a relatively small number of retail drug chains and drug wholesalers. These customers have undergone and continue to undergo significant consolidation, which has resulted in customers gaining more purchasing power. Consequently, there is heightened competition among generic drug producers for the business in this smaller and more selective customer base. On the other hand, this trend provides a competitive advantage to large suppliers that are capable of providing quality, cost efficient quantities of products.

Price competition from additional generic versions of the same product may result in significant reductions in sales and margins over time. To compete on the basis of price and remain profitable, a generic drug manufacturer must manufacture its products in a cost-efficient manner. In addition, our competitors may develop their products more rapidly or complete the regulatory approval process sooner, and therefore market their products earlier. New drugs and future developments in improved and/or advanced drug delivery technologies or other therapeutic techniques may provide therapeutic or cost advantages to competing products.

Many brand competitors try to prevent or delay approval of generic equivalents through several tactics, including legislative initiatives (e.g., pediatric exclusivity), extending patent protection, changing dosage form or dosing regimens prior to the expiration of a patent, regulatory processes, including citizens petitions, negative public relations campaigns and alliances with managed care companies and insurers to reduce prices and economic incentives to purchase generic pharmaceuticals. In addition, brand companies sometimes launch, either through an affiliate or through licensing arrangements with another company, an authorized generic concurrent with the first generic launch, so that the patent challenger no longer has the full exclusivity granted by the Hatch-Waxman Act.

In *Canada*, the competitive landscape continues to intensify with the increasing presence of foreign competitors. Five major generic drug manufacturers, three of which, including our subsidiary Teva Canada Ltd., are subsidiaries or divisions of global manufacturers, satisfy approximately 85% of the Canadian demand for generic pharmaceuticals.

The customer base for Teva Canada continues to change as the number of independent community pharmacies decreases at the expense of chain drug and banner-aligned store groups, which work closely with selected suppliers for specific products. This trend is expected to continue, resulting in increased competition for

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generic drug manufacturers at the chain and banner buying offices. These larger 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 *Latin America*, the pharmaceutical market is generally fragmented, with no single company enjoying market dominance. Local generic companies predominate, especially in Brazil, Argentina and Chile. These local companies, as well as multinational brand companies, compete with our local operations in all of the markets. Our strengths in the region include our comprehensive range of products, which cover a wide range of therapeutic categories, strong sales forces and the opportunity to leverage our global product portfolio.

In *Europe*, we compete with other generic companies (several major multinational generic drug companies and various local generic drug companies) and brand drug companies that continue to sell or license branded pharmaceutical products after patent expirations. As in the U.S., the generic market in Europe is very competitive, with the main competitive factors being price, time to market, reputation, customer service and breadth of product line.

As part of its efforts to improve the affordability of medicines for patients and address the challenges of public health systems by increasing generic penetration, in 2008 the European Commission launched an inquiry into competition in the pharmaceutical sector. According to the Commission's final report, published in July 2009, there is evidence that innovator companies have sought to delay or block market entry of generic medicines. Following the publication of the report, the Commission has sent questions to several pharmaceutical companies with European operations, including Teva. The answers provided from the questionnaires are expected to be used by the Commission to develop new legislation designed to help to increase the competition within the pharmaceutical market in the E.U. This will be aimed at providing consumers in the E.U. with affordable high quality medicine.

The *United Kingdom*, where we are the leading pharmaceutical company by volume and have twice the sales of our closest generic competitor, is one of the largest markets for generic pharmaceuticals in Europe. It is also one of the most competitive markets, due to its very low barriers to entry. Significant vertical integration exists between wholesalers and retailers, ensuring low prices as long as there are several suppliers. The number of major players in the U.K. pharmaceutical market has decreased due to consolidation.

**France** has some of the lowest pharmaceutical prices in the region largely due to aggressive pharmacist buying groups and to the French government s efforts to control healthcare costs by imposing significant price decreases.

In the *Netherlands*, there is a developed pure generics market that operates in a manner similar to that of the U.K. As in the U.K., many pharmacies are grouped into chains that are owned by major wholesalers. However, due to a new, tender like, system introduced in 2008 and the subsequent shift of bargaining power from pharmacies to insurers, there was a slow-down in the consolidation of independent retail pharmacies.

In *Spain*, the generic pharmaceutical market is largely represented by local companies. Regulations in seventeen local regions have varying policies regarding generic substitution. We have been able to develop different approaches to accommodate every region which, following the Bentley acquisition, has resulted in our becoming the third largest generic company.

In *Italy*, there is a relatively low rate of generic penetration with intense competition at the retail level. The market is increasingly categorized by independent pharmacies that have the ability to dispense products from selected companies, which has resulted in increasing competition among generic companies. There is uncertainty in the market as the direction of government policy seems unclear.

In *Hungary*, we compete with local Hungarian manufacturers and also face increasing competition from multinational brand and generic pharmaceutical companies. We are continuing to strengthen our position and presence in Hungary, while creating a more diversified product and service portfolio, including wholesaling services.

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In *Germany*, there is a high level of generic penetration and intense competition with a relatively high number of competitors of varying sizes and capabilities, including large domestic companies. Price levels for pharmaceuticals in Germany are negatively impacted by the on-going implementation of a tender system.

In *Poland*, the pharmaceutical industry has experienced significant structural change in recent years. Most of the state-owned companies have been privatized and foreign firms account for a high proportion of sales. The competitive landscape, which is dominated by several very strong local and regional competitors, continues to be challenging, with hundreds of manufacturers.

The *Czech Republic* is a branded generic market where we compete with other generic drug companies (both local and regional generic drug companies) and brand drug companies that continue to sell or license branded pharmaceutical products after patent expirations. New governmental reforms reduced the reimbursement level of low-priced products in favor of high-priced new products, resulting in a shift of demand to newer and more expensive pharmaceuticals.

In *Israel*, our products compete with those of other local manufacturers, as well as with imported products. Generic competition has increased in recent years in Israel, and this trend is expected to continue, with additional pressure on prices coming from the healthcare funds and other institutional buyers. The introduction of private labels into the retail market has increased competition in the total over-the-counter market, a trend that is expected to increase in the future.

#### **Innovative Products**

We rely on a combination of intellectual property protections and exclusivity periods provided under applicable regulations to protect our innovative products. We seek to obtain, where possible, product, process and use patents. We also rely on trade secrets, unpatented proprietary know-how and confidentiality agreements, as well as FDA data exclusivity rules, trademarks, copyright protection and other intellectual property rights. Similar laws and regulations in the European Union historically provided for periods of six to ten years of data exclusivity, some of which are still in force. Newer EU legislation provides for a uniform period of European Union data exclusivity for newly registered products for a period of eight years which, under certain circumstances, can be extended to nine years. This is followed by a two-year period of marketing exclusivity, preventing generic products from being launched, even if authorized.

Copaxone® is an immunomodulatory therapy available for the treatment of relapsing remitting multiple sclerosis. Its primary competition is three formulations of beta-interferon: Avonex®, Betaseron®, Extavia® and Rebif®. Another therapy, Tysabri®, was reintroduced in the U.S. in June 2006 with a black box label, which includes the most critical information about TysaBrisuch as indications and warnings, and with an indication for patients who have had an inadequate response to, or are unable to tolerate, alternate multiple sclerosis therapies. In July 2006, Tysabri® was launched in the EU with a restricted indication for patients who have failed beta interferons or for highly active patients. Several cases of progressive multifocal leukoencephalopathy (PML) (a fatal brain infection) have been reported in patients treated with TysaBris mono-therapy. A change in labeling was recently implemented in the U.S. suggesting that the risk of PML increases with the number of Tysabri® infusions, and on January 21, 2010 the EMEA issued its conclusions regarding Tysabri®-associated PML, recommending adoption of measures, including label changes, aimed at reducing the risk of PML.

We may also face competition from additional products in development, including orally administered formulations of cladribine, fingolimod and Gilenia<sup>®</sup>. An NDA was filed during 2009 with respect to cladribine and is currently being reviewed by the FDA and the EMEA. The approval and launch of oral cladribine may be delayed following the issuance in November 2009 of a refuse to file letter by the FDA due to an incomplete NDA submission. An NDA was filed during 2009 with respect to fingolimod and is currently being reviewed by the FDA and the EMEA. Gilenia<sup>®</sup> has recently been granted priority review status by the FDA.

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In July 2008, Sandoz Inc., the U.S. generic drug division of Novartis AG, in conjunction with Momenta Pharmaceuticals, Inc., filed an ANDA with the FDA for a generic version of Copaxone<sup>®</sup> seeking approval prior to the expiration of our patents and a second ANDA filed by Mylan Inc. and Natco Pharma Ltd. was accepted for review by the FDA in September 2009.

Azilect® s competitors include the newer non-ergot dopamine agonists class, Mirapex®/Sifrol® (pramipexole) and Requip® (ropinirole), which are the leading products in this class, indicated for all stages of Parkinson s disease. Generic versions of those products were introduced in certain markets in 2008. Slow-release formulations of Requip® and Mirapex® once-daily were launched in the U.S. and certain European countries during 2008 and 2009 (the latter in EU only). It was recently reported that the dopamine agonist Mirapex® failed to demonstrate a disease-modifying effect in a clinical trial with a design similar to the ADAGIO trial. An additional competitor in this class is Neupro®, a dopamine agonist with a once-daily patch delivery system. Neupro® has experienced quality problems and was recalled from the market in the U.S. Neupro® also experienced supply issues in certain European countries. During 2009, most of these problems were resolved, and the product has been re-launched in the U.S.

Azilect<sup>®</sup> also competes with Comtan<sup>®</sup>, a COMT inhibitor, indicated only for adjunct therapy in moderate to advanced stages of the disease. Comtan<sup>®</sup> is also marketed as a fixed combination together with levodopa.

#### Women s Health

Our women s health products face competition, including our oral contraceptive products, Seasonique and loSeasonique, compete with Lybrel, an oral contraceptive product based on a 365 day regimen, and generic presentations of Seasonale, that, like Seasonale, are based on a 91 day regimen. Plan B, our one-step emergency oral contraception product, faces competition from a generic 2-dose emergency contraception product. Paragard competes with the hormonal IUD product, Mirena, and Enjuvia s main competitor is Premarifi tablets.

#### Operations and R&D

#### **Research and Development**

Our research and development efforts are integral to all of our operations. Research and development expenses increased 5.8% in 2009 to \$802 million from \$786 million in 2008 and up from \$581 million in 2007. Total gross research and development for 2009 reached \$923 million or 6.6% of sales.

Our Global Generic R&D is in charge of developing products that are equivalent to innovative pharmaceuticals. Its responsibilities include product formulation, chemical and physical (including shelf-life) testing, stability testing, bioequivalence (absorption and extent), blood level testing, clinical testing, registration and approval of a growing list of generic drugs for all of the markets where we operate. It continues to expand and enhance its capabilities beyond tablets, capsules, liquids, ointments and creams to other dosage delivery systems and dosage types, 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, drug device combinations and nasal delivery systems for generic drugs. The division operates from fifteen development centers located in the U.S., Israel, India, Mexico, Europe and Latin America, enabling us to take advantage of local expertise and costs as well as a more favorable patent law approach towards generics in some of these countries.

We develop a broad portfolio of generic products, including those that have one or more characteristics that we believe will make it difficult for others to develop competing generic products. The characteristics of the selected generic products we pursue may include one or more of the following:

those with complex formulation or development characteristics;

those requiring specialized manufacturing capabilities;

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those where sourcing the raw material may be difficult; and

those that must overcome unusual regulatory or legal challenges, including patent challenges.

Global Innovative R&D activities are conducted in Israel, the U.S., Canada, Hungary and several European countries. Our proprietary research and development pipeline focuses primarily on three niche specialty areas: neurological disorders, autoimmune diseases and oncology. In building our pipeline, we focus on products with meaningful differentiation from existing products in terms of clinical attributes, expected commercial value and benefit to patients and health insurers. In addition, we incorporate new technologies, such as biomarkers, early in the development process to reduce the risk at more advanced stages of R&D. Our proprietary pipeline is strengthened by the activities of our Innovative Ventures unit, which focuses on early identification and evaluation of potential proprietary compounds, primarily in the above niche areas, and invests directly in companies with promising products and technologies.

In conducting our research and development, we seek to manage our resources conservatively and to limit our risk exposure. At the drug discovery phase, we utilize our relationships with the Israeli and foreign academic community and start-up companies to gain early access to potential projects. Once these projects progress into the more costly clinical study phase, we explore corporate partnering options where needed, through which we can share financial and other risks.

We have innovative projects in various stages of development (both clinical and pre-clinical). While multiple sclerosis remains an important focus of our development efforts, as we continue to investigate potential improvement of Copaxone<sup>®</sup> and explore other molecules as future therapies for MS, we also have active projects in the areas of Crohn s disease, lupus/lupus nephritis, amyotrophic lateral sclerosis, oncology and asthma.

Below is a table listing selected pipeline products in clinical development:

Project / Compound Laquinimod (1)	Potential Indication Multiple sclerosis	Clinical Phase III	Project Partner Active Biotech	Formulation Oral
Talampanel	Amyotrophic lateral sclerosis (ALS)	II	Not applicable	Oral
Laquinimod (1)	Crohn s disease	II	Active Biotech	Oral
Pagoclone	Persistent developmental stuttering (PDS)	IIb in 2009	Endo Pharmaceuticals Inc.	Oral
Talampanel	Glioblastoma	II Completed	Not applicable	Oral
OGX-011/TV-1011	Metastatic Castrate Resistant Prostate Cancer and Lung Cancer	Phase III	OncoGenex Pharmaceuticals, Inc.	Intravenous
Adenovirus vaccines (2)	Respiratory diseases	Phase II/ III	U.S. Department of Defense	Oral

- (1) See below for further details.
- (2) We are developing adenovirus vaccines Type 4 and 7 under a \$79.5 million, multi-year development contract awarded in September 2001 by the U.S. Department of Defense ( DOD ). These are intended to be dispensed to armed forces personnel to prevent epidemics of an acute respiratory disease that has been a leading cause of hospitalizations of military trainees. We completed a Phase II/III clinical program in late

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2007 and filed a Biologic License Application (BLA) in 2008. Although the current BLA only covers the use of adenovirus vaccines in U.S. military recruit populations, the potential exists to develop and license the vaccines for additional indications in the U.S. or in international markets if a suitable at-risk population is identified. We are negotiating a production and supply contract with the DOD in anticipation of FDA approval of the BLA in 2010.

Laquinimod. In June 2004, we acquired from Active Biotech the exclusive rights to develop, register, manufacture and commercialize laquinimod worldwide, with the exception of the Nordic and Baltic countries. We made an upfront payment to Active Biotech and will conduct and fund further clinical development of laquinimod. Our agreement with Active Biotech also calls for us to make payments to Active Biotech upon the achievement of various sales targets and other milestones, with maximum payments of \$92 million. Active Biotech will also receive tiered double-digit royalties on sales of the product. In February 2010, we amended the agreement to acquire Active Biotech s marketing and distribution rights for laquinimod in the Nordic and Baltic regions in exchange for an increase in the royalties payable on sales in those regions.

Laquinimod is a novel once-daily, orally administered immunomodulatory compound that is being developed as a disease-modifying treatment for relapsing-remitting MS. A Phase IIb study in 306 patients demonstrated that an oral 0.6 mg dose of laquinimod, administered daily, significantly reduced MRI disease activity by a median of 60 percent versus placebo in RRMS patients. In addition, the study showed favorable effects on the reduction of annual relapse rates and the number of relapse-free patients compared with placebo. Treatment was well-tolerated, with only some transient and dose-dependent increases in liver enzymes reported. Over 1,000 MS patients have received laquinimod in various clinical trials. Study results were published in June 2008.

Following the results of this study, and after discussions with the FDA and the European Medicines Agency, we initiated a phase III clinical program. Laquinimod received fast track designation from the FDA in February 2009, which may allow this product to enter the market by 2012.

Two global Phase III clinical trials, BRAVO and ALLEGRO, have completed enrollment and are currently ongoing. ALLEGRO, a pivotal, placebo-controlled global, 24-month, double-blind, Phase III study is designed to evaluate the efficacy, safety and tolerability of laquinimod versus placebo in relapsing-remitting MS patients. Enrollment was completed in November 2008, after more than 1,000 patients were recruited at 152 sites in North America, Europe and Israel. The trial is currently ongoing, and results are expected in 2011. BRAVO, an additional pivotal, placebo-controlled, global, 24-month, double-blind, Phase III study, is designed to evaluate the efficacy, safety and tolerability of laquinimod versus placebo and to provide risk-benefit data for laquinimod versus interferon beta-1a IM (Avonex) in relapsing-remitting MS patients. Enrollment was completed in June 2009, after more than 1,200 patients were recruited at 156 sites in the U.S., Europe, Israel and South Africa. The trial is currently ongoing, and results are expected in 2011.

Laquinimod has demonstrated potent therapeutic efficacy in preclinical models of other autoimmune diseases such as rheumatoid arthritis, insulin-dependent diabetes mellitus, Guillain-Barré syndrome, lupus and inflammatory bowel disease. The broad profile of efficacy in animal models of inflammatory diseases suggests that laquinimod affects a specific pathway of autoimmunity. Laquinimod is currently in Phase II development for Crohn s disease, and clinical development for lupus is expected to be initiated soon.

**Biopharmaceutical R&D.** Teva s Biotechnology R&D group operates from three sites in the U.S., Lithuania and Israel specifically dedicated to the development of follow-on biosimilars. Teva s R&D capabilities cover all aspects of recombinant protein expression and production, including genetic engineering, microbial fermentation, mammalian cell culture, protein purification and analytical methods and formulations development.

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Teva s Biotechnology R&D group also has access to albumin fusion technology, allowing the half-life of many biopharmaceuticals to be significantly extended. Our pipeline of products is currently being developed internally and through Teva s joint venture with Lonza.

#### **Teva Innovative Ventures**

Teva Innovative Ventures seeks to increase and enhance our innovative pipeline through in-licensing and/or investing in pre-clinical stage products; developing such products through pre-clinical development until the clinical stage and investing in start-up companies having preclinical and clinical-stage products.

Teva Innovative Ventures sources potential products globally in both academia and early stage companies and has invested and continues to invest directly and/or through investment companies, in early stage companies that we believe have promising technologies or products. In some cases, in tandem with such investments, we will obtain strategic rights in a company or product. Examples of such rights received include an option to buy the entire company under certain circumstances at pre-negotiated prices/terms and/or an option to license a product or create a joint venture with the company on a particular product based on pre-negotiated terms.

Typically, our investment will be directed toward achieving certain milestones based on an agreed budget and development plan created with our assistance. Once a milestone is achieved, we will determine whether to exercise our option. If so, we will become much more actively involved in the company and its development, and the product will enter our pipeline.

Below is a table listing selected projects in which we have an interest:

Project Name StemEx® (1)	Potential Indication Hematological malignancies	Clinical Phase Phase III	Project Partner Gamida Cell Ltd.	<b>Total Investment</b> \$26.7 million
CT-011	Solid tumors and hematologic malignancies; Hepatitis C	Phase II (multiple trials ongoing)	Curetech Ltd.	\$14 million
Debrase® (2)	Removal of burn-injured tissue (eschar)	Successful Phase III in Europe completed	MediWound Ltd.	\$15 million
Diapep-277 (3)	Type I diabetes	Phase III	Andromeda Biotech Ltd.	\$13.5 million
MultiGeneAngio (4)	Critical limb ischemia	Phase I/II in US nearing completion; CLI Phase I/II in 2010	Multi Gene Vascular Systems Ltd.	\$4 million (4)

- (1) In February 2005, we signed a joint venture agreement with Gamida Cell Ltd. to develop and commercialize StemEx®, a novel cell therapy product containing expanded cord blood stem/progenitor cells for the treatment of hematological malignancies in patients who cannot find a matched donor. A Phase III pivotal study, which will enroll 100 patients in the U.S., Europe and Israel, was initiated in October 2007 and is scheduled to be completed in 2011.
- (2) Debrase® is an innovative product developed by MediWound for the enzymatic removal of burn-injured tissue (eschar). Debrase® may present an alternative to surgery and lengthy non-surgical procedures. Another benefit of Debrase® is its selective activity, which removes only the eschar without harming viable tissue. This minimizes the need for additional skin grafting surgery and increases the potential for

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- spontaneous healing of the burn wound. Currently, the product met the early stopping rules in its Phase III clinical study in the EU and is preparing a marketing authorization application for submission to the EMEA.
- (3) In February 2009, we exercised an option to enter into a license agreement with respect to Diapep-277, which is currently in a Phase III clinical study for Type I diabetes. In addition, a second phase III study is presently being initiated.
- (4) In December 2009, we invested \$4 million in Multi Gene Vascular Systems Ltd. to support development of MGA for the treatment of critical limb ischemia. MGA is a combined cell/gene product of autologous endothelial and smooth muscle cells, which support the growth of new arteries.

#### **Operations**

We believe that our global generic product infrastructure provides us with many advantages over our competitors, including the following:

global research and development facilities that enable us to have the broadest product line and the most extensive generic pipeline in the U.S., as well as a leading global generic pipeline;

finished-dose manufacturing facilities approved by the FDA and other regulatory authorities and located in countries around the world, which offer a broad range of production technologies and the ability to concentrate production to achieve economies of scale, thereby enabling us to achieve attractive profit margins in a highly competitive environment without compromising our commitment to excellence and product quality;

API 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 the means to respond on a global scale to a wide range of requirements (both therapeutic and commercial) of patients, customers and healthcare providers.

#### **Pharmaceutical Production**

We operate 38 finished dosage pharmaceutical plants, including in North America, Latin America, Europe and Israel. The plants manufacture solid dosage forms, injectables (sterile), liquids, semi-solids, inhalers and medical devices. During 2009, these plants produced approximately 54 billion tablets and capsules and over 490 million sterile units.

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 (Kfar Saba and Jerusalem) and in Hungary make up a significant percentage of our production capacity.

We maintain a uniform quality standard throughout our production facilities. 27 of our plants are FDA-approved. Achieving and maintaining quality standards in compliance with the current Good Manufacturing Practices (cGMP) regulations, as established by the FDA and other regulatory agencies worldwide, requires sustained effort and expenditures, and we have spent significant funds and dedicated substantial resources for this purpose.

We strive to optimize our manufacturing network, in order to maintain our goal of supplying high quality, cost-competitive products on a timely basis to all of our customers globally. As part of this effort, during 2009, we closed facilities in Congers, N.Y., Tlalpan, Mexico-City and Brno in the Czech Republic. The production activity of these facilities was transferred to other Teva facilities around the world.

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We have expanded the facilities in Opava, the Czech Republic, Jerusalem, Israel, Debrecen, Hungary and Eastbourn, U.K. for manufacturing and packaging of solid dosage forms, and in Godollo, Hungary, for sterile products manufacturing.

Our policy is to maintain multiple supply sources for our strategic products and API s 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 main pharmaceutical manufacturing facilities are listed below:

	Number of	
Facility Location	Employees	Principal Market(s) Served
Solid dose manufacturing sites:		
Forest, VA, U.S.	600	North America
Sellersville, PA, U.S.	530	North America
Cincinnati, Ohio, U.S.	480	North America
Stouffville& 30 Novo, Canada	650	North America
Maipu, Santiago, Chile	550	Latin America
Debrecen, Hungary	780	Europe and other non-U.S. markets
Zagreb, Croatia	1150	North America and other markets
Kfar Saba, Israel	850	North America, Europe and other markets
Jerusalem, Israel	600	North America
Sterile manufacturing sites:		
Irvine, CA, U.S.	680	North America
Runcorn, U.K.	320	North America, Europe and other markets
Godollo, Hungary	650	North America, Europe and other markets
Kfar Saba, Israel	400	North America, Europe and other markets
Respiratory manufacturing site:		
Waterford, Ireland	300	North America and other markets
Raw Materials for Pharmaceutical Production		

We source most of our active pharmaceutical ingredients from our own API manufacturing. Additional API materials are purchased from suppliers located in Europe, Asia and the U.S. 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 have 21 API production facilities located in Israel, Hungary, Italy, the U.S., the Czech Republic, India, Mexico, Puerto Rico, Spain, China and Croatia. We produce approximately 300 APIs covering a wide range of products, including respiratory, cardiovascular, anti-cholesterol, central nervous system, dermatological, hormones, anti-inflammatory, oncology, immunosuppressants and muscle relaxants. Our API intellectual property portfolio includes over 2,300 granted patents and pending applications worldwide.

We have expertise in a variety of production technologies, including chemical synthesis, semi-synthetic fermentation, enzymatic synthesis, high potent manufacturing, plant extract technology, synthetic peptides, vitamin D derivatives and prostaglandins. 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.

Our API facilities meet all applicable current Good Manufacturing Practices (cGMP) and quality standards promulgated by US Pharmacopoeia (USP), European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), and other applicable quality standards. Many of our products are produced in dedicated computer-controlled facilities

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to optimize quality and efficiency. Our API plants are regularly inspected by the FDA, the EMEA or other authorities as applicable. During 2009, all inspections of our API facilities worldwide found our manufacturing practices at all sites to be in compliance.

In certain of our products sold in the U.S., we utilize controlled substances and therefore must meet the requirements of the Controlled Substances Act and the related regulations administered by the Drug Enforcement Administration. These regulations include quotas on procurement of controlled substances and stringent requirements for manufacturing controls and security to prevent pilferage of or unauthorized access to the drugs in each stage of the production and distribution process. Quotas for controlled substances may from time to time limit our ability to meet demand for these products in the short run.

Our API R&D focuses on the development of processes for the manufacturing of API, including intermediates, chemical and biological (fermentation), which are of interest to the generic drug industry, as well as for our proprietary drugs. Our facilities include a large center in Israel (synthetic products and peptides), a large center in Hungary (fermentation and semi-synthetic products), and a facility in India and additional sites in Italy, Croatia, Mexico and the Czech Republic (development of high potency API). Our substantial investment in API R&D generates a steady flow of API products, enabling the timely introduction of pharmaceutical products to market. The API R&D division also seeks methods to continuously reduce API production costs, enabling us to improve our cost structure.

We also sell API to third parties, and are a leading global supplier of API to both generic and brand customers. In selling our API products, we compete globally with other specialty chemical producers. Our competitive advantages include quality, cost effective manufacturing costs, a wide portfolio of products, an understanding of patents globally, a high level of customer service, and an understanding of global regulatory requirements. Many of our customers market their products globally and thus would prefer to buy APIs from one vendor rather than multiple vendors. Our numerous facilities enable us to provide our customers flexibility in sourcing from multiple sites from one vendor, while our extensive portfolio, service level and compliance record, combined with the creation of intellectual property rights and our financial resources, strengthen our position as an industry leader.

#### **Environment**

As part of our overall corporate responsibility, we pride ourselves on our commitment to environmental, health and safety matters in all aspects of our business. As a vertically integrated pharmaceutical company with worldwide operations, we believe that our adherence to applicable laws and regulations, together with proactive management beyond mere compliance, enhances our manufacturing competitive advantage, minimizes business and operational risks and helps us to avoid adverse environmental effects in the communities where we operate. We believe that we are in substantial compliance with all applicable environmental, health and safety requirements.

Among our environmental initiatives in 2009 were (i) implementation of projects aimed at reducing the usage of energy resources; (ii) expansion of our waste recycling projects; (iii) further implementation of ISO 14001, an environmental management standard; and (iv) increased attention to the principles of green construction.

### Regulation

#### **United States**

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

All pharmaceutical manufacturers selling products in the U.S. are subject to extensive regulation by the U.S. federal government, principally by the FDA and the Drug Enforcement Administration, and, to a lesser extent, by state and local governments. The federal Food, Drug, and Cosmetic Act, the Controlled Substances Act and other

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federal statutes and regulations govern or influence the development, manufacture, testing, safety, efficacy, labeling, approval, storage, distribution, recordkeeping, advertising, promotion and sale of our products. Our major facilities and products 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 new drug applications and criminal prosecution. The FDA also has the authority to deny or revoke approvals of drug active ingredients and dosage forms 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 before a company may market new products. The FDA conducts pre-approval and post-approval reviews and plant inspections to implement these requirements. Generally the generic drug development and the ANDA review process can take three to five years.

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 submission and/or the approval of ANDAs. One such provision allows a five-year market exclusivity period for new drug applications (NDAs) involving new chemical entities and a three-year market exclusivity period for NDAs (including different dosage forms) containing new clinical trial data essential to the approval of the application. The Orphan Drug Act of 1983 grants seven years of exclusive marketing rights to a specific drug for a specific orphan indication. The term—orphan drug—refers to a product 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. Patent term extension and non-patent market exclusivity may delay the approval of other non-Teva drug applications (e.g. ANDAs and NDAs).

Under the Hatch-Waxman Act, a generic applicant 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 so-called Paragraph IV certification. As originally enacted, 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 180 days after the first commercial marketing of the drug by the first applicant. Submission of an ANDA with a Paragraph IV certification can result in protracted and expensive patent litigation. When this occurs, the FDA generally may not approve the ANDA until the earlier of thirty months or a court decision finding the patent invalid, not infringed or unenforceable.

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, final ANDA approval for a product subject to Paragraph IV patent litigation may be obtained upon the earlier of a favorable district court decision or 30 months from notification to the patent holder of the Paragraph IV filing, as was the case previously. However, exclusivity rights may be forfeited pursuant to the Medicare Modernization Act if the product is not marketed within 75 days of the final approval or if tentative approval is not received within 30 months of submission and under other specified circumstances. With the growing backlog of

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applications, and the resulting increase in the median time to approval of ANDAs, the number of forfeitures of exclusivity are likely to increase unless additional resources are provided within the FDA s Office of Generic Drugs.

The Best Pharmaceuticals for Children Act, signed into law in 2002, continues the so-called pediatric exclusivity program begun in the FDA Modernization Act of 1997. This pediatric exclusivity program provides a six-month extension both to listed patents and to regulatory exclusivities for all formulations of an active ingredient, if the sponsor performs and submits adequate pediatric studies on any one single dosage form. The effect of this program has been to delay the launch of numerous generic products by an additional six months.

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 current Good Manufacturing Practices (cGMP) standards or risk sanctions such as the suspension of manufacturing or the seizure of drug products and the FDA s refusal to approve additional ANDAs.

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 U.S. 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 drugs. Of this portfolio, only one, Tevtropin®, is sold in the U.S., while others are distributed outside of the U.S. We plan to introduce additional products into the U.S. marketplace, and recently filed our first BLA for one such product, Neutroval<sup>TM</sup>, but currently an abbreviated regulatory pathway, such as the Hatch-Waxman Act, does not exist for these products. In 2009, the legislative environment in the U.S. improved, as a Senate Committee considered legislation to create a regulatory pathway for biogeneric products, but no final legislation was enacted. We took an active role in the development and introduction of the proposed legislation, and believe a regulatory pathway will be created in the U.S. in the next several years.

#### **Government Reimbursement Programs**

The Medicare Modernization Act further expanded the scope of Medicare coverage for participants by creating what is known as the Medicare Part D prescription drug benefit. The Part D prescription drug benefit became available to Medicare beneficiaries on January 1, 2006. Medicare prescription drug coverage under Part D is insurance that covers the Medicare beneficiary s cost (subject to certain statutory purchasing thresholds, co-payments, insurance premiums, and deductibles) of prescription drugs at participating pharmacies. Medicare prescription drug coverage under the Part D benefit is available to all Medicare beneficiaries regardless of income and resources or health status. As a result, our products are, as of January 1, 2006, available for government-subsidized purchase by a larger market of Americans participating in government-sponsored third-party payor insurance programs. In addition, the structure of reimbursement under Medicare Part D includes a gap or doughnut hole in coverage, after the initial coverage limit is reached and before the catastrophic coverage benefit begins. To date, many benefit plans have utilized generic products to mitigate the impact of this gap.

The Center for Medicare and Medicaid Services is responsible for enforcing legal requirements governing rebate agreements between the federal government and pharmaceutical manufacturers. Drug manufacturers agreements with the Center provide that the drug manufacturer will remit to each state Medicaid agency, on a quarterly basis, the following rebates: for generic drugs marketed under ANDAs covered by a state Medicaid

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program, manufacturers are required to rebate 11% of the average manufacturer price (net of cash discounts and certain other reductions); for products marketed under NDAs, manufacturers are required to rebate the greater of 15.1% of the average manufacturer price (net of cash discounts and certain other reductions) or the difference between such average manufacturer price and the best price during a specified period. An additional rebate for products marketed under NDAs is payable if the average manufacturer price increases at a rate higher than inflation. We have such a rebate agreement in effect with the U.S. federal government. Federal and/or state governments have enacted and are expected to continue to enact measures, such as the Medicare Act, enacted in December 2003, or the current Health Care Reform proposals, which expanded the scope of Medicare coverage for drugs beginning in January 2006. These measures are aimed at reducing the costs to government third party insurers, such as Medicare and Medicaid, that dispense drugs to the public. We cannot predict the nature of such future measures or their impact on our sales or profitability.

In the United States, the Deficit Reduction Act of 2005 mandated a new regulation, which became effective in part on October 1, 2007, establishing the method by which pharmaceutical manufacturers, including us, must calculate average manufacturer price. The Act strongly encouraged state Medicaid programs to utilize this average manufacturer price in the future as the benchmark for prescription drug reimbursement in place of the previous, widely used benchmark of average wholesale price. The Act also changed the method used to determine the federal upper limit on payment for generic drugs. Payments to pharmacies for Medicaid-covered outpatient prescription drugs are set by the states. Federal reimbursements to states for the federal share of those payments are subject to this federal ceiling, which, effective January 1, 2007, was 250% of the average manufacturer price for generic drugs. This price limit may have the effect of reducing the reimbursement rates for certain medications that we currently sell. We are reviewing the potential impact of these provisions on our business and profitability and have not yet been able to draw conclusions, because the implementation of certain provisions of the final regulations promulgated under the Act has been stayed by litigation. We do not know how long the court-ordered stay will remain in effect or what the final outcome will be.

Various state Medicaid programs have in recent years adopted supplemental drug rebate programs that are intended to provide the individual states with additional manufacturer rebates that cover patient populations that are not otherwise included in the traditional Medicaid drug benefit coverage. These supplemental rebate programs are generally designed to mimic the federal drug rebate program in terms of how the manufacturer rebates are calculated, e.g., as a percentage of average manufacturer price. While some of these supplemental rebate programs are significant in size, they are dwarfed, even in the aggregate, by comparison to our quarterly Medicaid drug rebate obligations.

In late 2009, the U.S. government has sought to place health care reform at the forefront of the legislative agenda, calling for a comprehensive plan to decrease health care costs while improving the quality of patient care. Both the House and Senate have passed bills providing plans for reform. These bills seek to reduce the federal deficit and reduce the rate of growth in health care spending through, among other things, stronger prevention and wellness measures, increased access to primary care, changes in health care delivery systems, the creation of a health insurance exchange and improvements in Medicare payment accuracy. In addition, the proposals require the pharmaceutical industry to share in the costs of reform, such as by increasing Medicaid rebates, narrowing sales definitions for AMP purposes, expanding Medicaid rebates to dual eligible or Medicaid managed care and placing an excise tax on prescription programs. New regulations could be phased in over the coming years. As the passage of any healthcare reform legislation is uncertain, as well as the nature and provision of any such legislation, we are not able to draw conclusions as to the impact on our business.

## 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 is the national authority that evaluates and monitors the safety, effectiveness and quality of drugs, medical devices and other therapeutic products.

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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 on new chemical entities. The regulations prohibit generic companies from filing a generic submission using a new chemical entity as the Canadian reference or comparator product for six years following the receipt by a brand company of a Notice of Compliance for such new chemical entity. The Canadian generic industry trade association has opposed the application of these regulations in the courts. The trade association s application to the courts was dismissed by the lower court and is currently under appeal,

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 Therapeutic Products Directorate will not issue a Notice of Compliance if there are any patents relevant to the drug product listed in the Patent Register maintained by Health Canada. Generic pharmaceutical manufacturers can either wait for the patents to expire or serve a notice of allegation upon the brand company. If, as is frequently the case, litigation is commenced by the brand company in response to the notice of allegation, a Notice of Compliance will not be issued until the earlier of the expiration of a 24-month stay or resolution of the litigation in the generic company s favor.

Every province in Canada offers a comprehensive public drug program. Provincial governments control expenditures on therapeutic products by establishing formulary interchangeability and benefit lists and by only reimbursing for products that are listed therein. Many provinces are currently reforming their public drug programs and implementing new policies for the reimbursement of generic medications. In the province of Ontario, tenders for three products were issued but only one has been awarded. Other provinces are negotiating directly with pharmacy organizations for lower generic prices. Some provinces are requiring listing agreements or fees before they will add the product to their formularies. There is continued pressure on the prices that pharmacies are reimbursed for generic products. However, many of these governments acknowledge the need to limit extended brand patent monopolies and to speed the approval process for generic drugs.

#### **European Union**

The medicines legislation of the European Union requires that medicinal products, including generic versions of previously approved products and new strengths, dosage forms and formulations of previously approved products, shall have a marketing authorization before they are placed on the market in the European Union. Authorizations are granted after the assessment of quality, safety and efficacy by the respective health authorities. In order to obtain an authorization to place a medicinal product on the market, an application must be made 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 2009, we continued to register products in the European Union, 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. During 2009, the European Commission (EC) adopted the opinion of the committee for medicinal products for human use (CHMP) and granted us Europe-wide marketing authorizations for clopidogel bisulphate, irbesartan, irbesartan/hydrochlorothiazide, lamivudine, nevirapine, repaglinide, ribavarin, rivastigmine, sildenafil and topotecan. In addition, the CHMP adopted positive opinions (subject to ratification by the EC) recommending the granting of Europe-wide marketing authorizations for telmisartan, temozolomide and docetaxel. Due to historical court interpretations of essential similarity that have now been included in the new legislation, it has become possible to register generic drugs containing different salts of the active ingredient. We continue to invest in registration activities in the majority of countries in the European Union, including Hungary, the U.K., France, Germany, the Netherlands, Italy, the Czech Republic and Poland.

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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. In 2006, product specific guidelines were 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 European Union regulate the pricing of such products and in some cases limit the range of different forms of a drug available for prescription by national health services. These controls can result in considerable price differences among member states

The duration of certain pharmaceutical patents may be extended in the European Union by up to five years (with a Supplementary Patent Certificate) in order to extend effective patent life to fifteen years. Some older French and Italian patents were extended up to eight and eighteen years, respectively. Additionally, exclusivity provisions in the European Union may prevent companies from applying for a generic product for either six or ten years (the period is selected by each country) from the date of the first market authorization of the original product in the European Union. The legislation, applicable to all members of the European Union and effective as of November 2005, changes and harmonizes the exclusivity period for new products submitted after the effective date. The period before a generic application can be made will be eight years (from either six or ten years before) and allows the generic product to be marketed only after ten years from the first marketing authorization of the original product in the European Union, with the possibility of extending the exclusivity by one additional year under certain circumstances. Given that new products submitted after November 2005 will take at a minimum approximately one year to be assessed and approved, the new data exclusivity provisions of 8+2+1 years will affect only generic submissions from around the end of 2014 onwards. Subject to the respective Paediatric regulation, the holder of a Supplementary Patent Certificate may obtain a further extension of up to six months. This is separate but not in addition to the additional year of data exclusivity previously mentioned. The legislation also allows for research and development work during the patent term for the purpose of developing and submitting registration dossiers.

#### **Latin America**

The extension of patent protection to pharmaceutical products is a relatively new concept throughout much of Latin America, except Mexico, Brazil and Chile. Most local pharmaceutical companies in the region engage in the production of either copied versions of drugs still under patent in their countries of origin, or true off-patent drugs sold under a local brand-name, without bioequivalence testing in either case. Historically, registration has been simple, with no clinical studies required. In Mexico and Brazil, the regulatory requirements have changed dramatically. Bioequivalence studies performed by approved clinical research organizations and, given the climate zone, special stability studies are now required. In Mexico, bioequivalence studies are not only required for all new submissions, but also must be performed by February 2010 for all products registered before February 2005. Additionally, for products registered between February 2005 and February 2008 bioequivalence studies will be required at the time of the renewal, that is five years after the registration was granted. We expect to complete all such studies by the corresponding deadlines. In addition, Mexico abolished the plant requirement law so that companies no longer need to have an existing manufacturing plant in Mexico in order to obtain approval to register and sell their pharmaceutical drug products in the country. These new regulations could reduce competition from smaller, local companies and may provide an avenue for our Latin American operations to capitalize on products that we sell in other markets.

#### **Israel**

The Israeli Ministry of Health requires pharmaceutical companies to conform to internationally recognized standards. Other legal requirements prohibit the manufacturing, importation and marketing of any medicinal product unless it is duly approved in accordance with these requirements.

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In 2005, the Israeli parliament (Knesset) enacted new patent legislation that ensures that a patent term extension in Israel will terminate upon the earliest of the parallel patent term extension expiration dates in the U.S., Europe and several other countries. The Knesset also ratified legislation that provides for data exclusivity provisions, which may prevent the marketing of a generic product for a period of five and a half years measured from the first registration of the innovative drug product in any one of a number of specified Western countries.

Israeli pricing regulations mandate that the retail prices of pharmaceuticals in Israel should not exceed the lower of the average price in eight European markets or the price in The Netherlands. The eight reference European markets are the United Kingdom, Germany, France, Belgium, Spain, Portugal and Hungary (or Poland if the product does not exist in any of the last three countries). The addition of the last three countries, whose pharmaceutical prices are generally low, will have the effect of reducing the average prices.

#### 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 discharge of material into the environment.

As discussed above, 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.

#### **Organizational Structure**

Our worldwide operations are conducted through a network of global subsidiaries primarily located in North America, Europe, Asia, Latin America and Israel. We have direct operations in more than 60 countries, as well as 38 finished dosage pharmaceutical manufacturing sites in 17 countries and R&D centers in 18 countries. The following sets forth, as of December 31, 2009, our principal operating subsidiaries in terms of sales to third parties.

In North America United States: Teva Pharmaceuticals USA, Inc and Plantex USA, Inc.; Canada: Teva Canada Ltd. (formerly known as Novopharm Limited).

In Europe Hungary: TEVA Hungary Pharmaceutical Marketing Private Limited Company; United Kingdom: Teva U.K. Limited; The Netherlands: Teva Pharmaceuticals Europe B.V., Pharmachemie B.V., Plantex Chemicals B.V.; France: Teva Santé SAS; Croatia: Pliva Hrvatska d.o.o.; Germany: AWD Pharma GmbH & Co. KG; Poland: Teva Pharmaceuticals Polska sp. z o.o., Pliva Krakow S.A.; Italy: Teva Italia S.r.l.; Spain: Laboratorios Belmac S.L.; Czech Republic: Teva Czech Industries s.r.o., Teva Pharmaceuticals CR, s.r.o.; Russia: Teva Limited Liability Company, PLIVA RUS Limited Liability Company.

In Israel Assia Chemical Industries Ltd. and Salomon, Levin and Elstein Ltd.

*International Latin America*: Chile: Laboratorio Chile S.A.; Peru: Botica Torres de Limatambo S.A.C.; Mexico: Lemery S.A. de C.V.; Argentina: IVAX Argentina S.A., Teva Tuteur (joint venture).

In addition to the subsidiaries listed above, we have operations in various strategic and important locations, including China, India, Turkey, Japan and other emerging and smaller markets.

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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, 2009:

	Square Feet	
Facility Location	(in thousands)	Main Function
Israel		
Ramat Hovav	1,112	API (chemical) manufacturing and R&D
Jerusalem (3 sites)	541	Pharmaceutical manufacturing, research laboratories and offices
Kfar Saba	506	Pharmaceutical manufacturing, research laboratories and warehousing,
		including new parking lot of 14,860 sqm at end stage of building
Netanya (2 sites)	456	API (chemical) manufacturing, pharmaceutical warehousing, distribution
		center and offices
Petach Tikva	207	Corporate headquarters
Asia Petach Tikva	127	R&D
Ashdod	125	Manufacturing of hospital supplies
United States		
North Wales area, PA (4 sites)	808	Teva USA headquarters, warehousing and distribution center
St. Joseph, MO and Fort Dodge (8 sites)	515	Offices, distribution, R&D and warehouse
Forest, VA	427	Warehousing, manufacturing, packaging and distribution
Irvine, CA (2 sites)	342	Pharmaceutical manufacturing, R&D laboratories and warehousing
Cincinnati, OH	305	Pharmaceutical manufacturing, R&D laboratories, packaging and
		warehousing
Miami, FL (4 sites)	225	Manufacturing, R&D, warehousing and office space
Kutztown, PA	211	Warehouse
Sellersville, PA	206	Pharmaceutical manufacturing, R&D laboratories
Pomona, NY	181	Pharmaceutical manufacturing, R&D laboratories and warehousing
Guayama, Puerto Rico	170	API (chemical) manufacturing
Mexico, MO	150	API (chemical) manufacturing
East Hanover, NJ	135	Pharmaceutical manufacturing
Kansas City MO	117	Teva Neuroscience, office and R&D
Canada		
Toronto, Ontario	335	Canadian headquarters, pharmaceutical packaging, warehousing,
		distribution and laboratories
Stouffville, Ontario	155	Pharmaceutical manufacturing, R&D laboratories
Markham, Ontario	122	Pharmaceutical manufacturing and warehousing
Europe		
Zagreb, Croatia (4 sites)	1,983	Pharmaceutical manufacturing, packaging and warehousing, API
Zugreo, Crouna (1 sites)	1,503	(chemical) manufacturing, R&D laboratories
Debrecen, Hungary	1,681	Pharmaceutical manufacturing, API (chemical) manufacturing, R&D
Debleccii, Hungary	1,001	laboratories, warehousing
Opava, Czech Republic	1,322	Pharmaceutical and API (chemical) manufacturing, warehousing and
opara, ezecii republic	1,522	distribution
Krakow, Poland	948	Pharmaceutical manufacturing and warehousing
,	2.0	

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For the Armer	Square Feet	MIN
Facility Location	(in thousands)	Main Function  Pharmacoutical manufacturing hagnital counties manufacturing P&D
Gödöllő, Hungary	667	Pharmaceutical manufacturing, hospital supplies manufacturing, R&D
W. ( ) 1 1 1 (2 '.)	405	laboratories, distribution, packaging and warehousing
Waterford, Ireland (3 sites)	425	Pharmaceutical manufacturing, warehousing, packaging
Kutno, Poland	285	Pharmaceutical manufacturing, warehousing, packaging
Glasshoughton, England	257	Warehouse and distribution center
Brno, Czech Republic	252	Pharmaceutical manufacturing, R&D and warehousing
Zaragoza, Spain (2 sites)	239	Pharmaceutical manufacturing, R&D laboratories
Haarlem, The Netherlands	232	Pharmaceutical manufacturing, warehousing, packaging, offices and
		R&D laboratories
Bulciago, Italy	177	API (chemical) manufacturing
Rho, Villanterio, Setimo Milanese, Italy	165	API (chemical) manufacturing and R&D laboratories
Eastbourne, England	133	Warehousing and packaging
Runcorn, England	128	Pharmaceutical manufacturing, warehousing, office space and R&D
		laboratories
Rho, Villanterio, Setimo Milanese, Italy	165	API (chemical) manufacturing and R&D laboratories
Santhia, Italy	127	API (chemical) manufacturing, R&D laboratories and warehousing
Vilnius, Lithuania (2 sites)	95	Pharmaceutical manufacturing, R&D laboratories
Asia		
Gajraula (U.P.), India	356	API (chemical) manufacturing
Hangzhou, China	169	API (chemical) manufacturing
Malanpur, India	140	API (chemical) manufacturing
Greater Noida, Delhi, India	120	API R&D Laboratories
Latin America		
Santiago, Chile (2 sites)	550	Pharmaceutical manufacturing, warehousing and R&D laboratories
Mexico City, Mexico (4 sites)	375	Pharmaceutical manufacturing, API, distribution, warehousing and
•		R&D laboratories
Munro, Argentina	154	Pharmaceutical manufacturing, warehousing, R&D laboratories and packaging
Ramos Arizpe, Mexico	97	Pharmaceutical manufacturing

We lease certain of our facilities. In Israel, our principal executive offices and corporate headquarters in Petach Tikva are leased until December 2012. In North America, our principal leased properties are the facilities in North Wales, Pennsylvania, the initial term of which expires in 2011, and a new warehouse in New Britain, Pennsylvania, the initial term of which expires in 2013. We own and lease various other facilities worldwide.

#### ITEM 4A: UNRESOLVED STAFF COMMENTS

None.

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# ITEM 5: OPERATING AND FINANCIAL REVIEW AND PROSPECTS Introduction

We are a global pharmaceutical company that develops, produces and markets generic drugs covering all major treatment categories. We are the leading generic pharmaceutical company in the world, as well as in the U.S., in terms of both total and new prescriptions. We also have a significant and growing branded pharmaceutical product line, including Copaxone® for multiple sclerosis and Azilect® for Parkinson s disease, respiratory products and women s health products.

The generic pharmaceutical industry as a whole, and therefore our own operations, are affected by demographic trends such as an aging population and a corresponding increase in healthcare costs, governmental budget constraints and spending decisions of healthcare organizations, as well as broad economic trends. In each of our markets around the globe, governments as well as private insurers are working to control growing healthcare costs, and there is an increasing recognition of the importance of generics in providing access to affordable pharmaceuticals, although these conditions also enhance pressure on generic pricing. In addition, the generic pharmaceutical industry, particularly in the U.S., has been significantly affected by consolidation among managed care providers, large pharmacy chains, wholesaling organizations and other buyer groups. Generic pharmaceutical companies also face intense competition from brand-name pharmaceutical companies seeking to counter generic products. We believe that our broad pipeline and balanced business model, combining generic as well as branded generic, innovative, respiratory, API and women s health pharmaceutical products and biogenerics, coupled with our geographic diversity, are key strategic assets in addressing these trends.

#### **Highlights**

In 2009, our net sales grew to \$13.9 billion, an increase of approximately \$2,814 million, or 25%, over net sales in 2008. Our sales growth in 2009 was driven by the first time inclusion of Barr s sales and strong performance in all of our geographical areas, including higher generic sales in the U.S. and continued strong sales of Copaxone<sup>®</sup>.

Net income attributable to Teva in 2009 reached a record \$2,000 million, compared to \$609 million in 2008.

Among the significant highlights of 2009 were:

Record sales across all geographic regions, including the U.S., Europe and our International region;

North American sales increased by \$2,172 million, and benefited from increased sales of our generic and branded products, including Copaxone® and ProAir ;

Launches in the U.S. of three significant new generic products: the generic versions of Adderall® (amphetamine mixed salts), Eloxatin® (oxaliplatin solution for injection) and Ortho Tri-Cyclen® Lo (ethinyl estradiol and norgestimate);

Increased sales in Europe resulting from the first time inclusion of sales of Barr s subsidiary Pliva, partially offset by currency effects and adverse pricing pressure from governmental pricing regulation;

Increased sales in our International markets, including increased sales in Latin America and Russia as well as in Israel;

Copaxone® reinforced its position, both in the U.S. and globally, as the leading multiple sclerosis drug, with global sales growing by 25% over 2008, reaching total global in-market sales of \$2,826 million;

Global in-market sales of Azilect<sup>®</sup>, which reached \$243 million in 2009, an increase of 39% over 2008;

An increase of 15% in global sales of our respiratory product portfolio over 2008;

Gross profit of \$7,367 million, an increase of 23%, or \$1,399 million, compared to 2008;

Operating income of \$2,405 million, an increase of 110%, or \$1,260 million, compared to 2008 in which we recorded research and development in-process charges (totaling \$1,402 million), as a result of the Barr, Bentley and CoGenesys acquisitions;

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Taxes of \$166 million, or 8% of pre-tax income, as compared with \$184 million, or 23% of pre-tax income, in 2008;

Exchange rate differences had a negative effect on sales of \$572 million (approximately 4% of 2009 sales) and a minimal effect on operating income (approximately 1.5% of 2009 operating income) and net income; and

Financial debt to equity leverage as of December 31, 2009 of 23%, lower than the 34% at December 31, 2008. This improved financial ratio and our strong cash flow generation were factors in Moody s decision to raise our credit rating in January 2010 from Baa1 to A3.

Joint Ventures and Other Strategic Activity

#### Teva-Kowa

On December 24, 2009, Teva-Kowa Pharma Co., Ltd., the joint venture which we established in 2008 in Japan with Kowa Company Ltd., signed a definitive agreement to acquire a majority of the outstanding shares of Taisho Pharmaceutical Industries, Ltd. Through this transaction, which closed on December 28, 2009, Teva-Kowa Pharma acquired 68.9% of Taisho s outstanding shares. Additional acquisitions of shares from Taisho shareholders by Teva-Kowa Pharma since the closing of this transaction has brought Teva-Kowa Pharma s holdings in Taisho to approximately 74% as of February 11, 2010. Taisho manufactures and markets a portfolio of over 200 generic products to pharmacies, clinics, hospitals and wholesalers, through a well-established sales and marketing force. Taisho had revenues of over \$130 million for the twelve months ended September 30, 2009. We believe that this acquisition of a controlling interest in Taisho will further advance Teva-Kowa Pharma in its strategic objective to become the provider of choice of high-quality affordable generic medicine in the Japanese market, supporting the Japanese government s initiative to increase the use of generic pharmaceuticals.

#### Lonza

On January 20, 2009, we signed a definitive agreement with Lonza Group Ltd. to establish a joint venture to develop, manufacture and market a number of affordable, effective and safe generic equivalents of a selected portfolio of biologic pharmaceuticals. The joint venture, TL Biopharmaceuticals AG, began its collaboration and joint research and development in May 2009.

#### OncoGenex Pharmaceuticals

In December 2009, Teva and OncoGenex Pharmaceuticals, Inc. entered into a global license and collaboration agreement to develop and commercialize OGX-011, a Phase III cancer therapy designed to inhibit cancer treatment resistance. Teva and OncoGenex are expected to collaborate on a global Phase III clinical program, with two Phase III clinical trials expected to be initiated in 2010. As part of this transaction, we also agreed to purchase shares in OncoGenex.

Under the terms of the collaboration and share purchase agreements, we paid OncoGenex an initial cash payment of \$60 million, which included the equity investment in OncoGenex common stock and the upfront payment and prepayment for OncoGenex s contribution to the development costs of OGX-011. OncoGenex will be eligible to receive up to \$370 million in additional cash payments upon the achievement of various milestones, including regulatory milestones and sales targets. In addition, OncoGenex will receive tiered royalties on sales of the product, with the royalty percentage ranging from the mid-teens to the mid-twenties, depending upon the amount of net sales.

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## **Results of Operations**

The following table sets forth, for the periods indicated, certain financial data derived from our U.S. GAAP financial statements, presented as percentages of net sales, and the percentage change for each item as compared to the previous year.

	Percentage of Net Sales Year Ended December 31,			Percentage Change Comparison		
	2009 2008 2007			2009-2008	2008-2007	
	%	%	%	%	%	
Net sales	100.0	100.0	100.0	25	18	
Gross profit	53.0	53.8	51.8	23	22	
Research and development expenses	5.8	7.1	6.2	2	35	
Selling and marketing expenses	19.3	16.6	13.4	45	46	
General and administrative expenses	5.9	6.1	6.8	23	5	
Acquisition of research and development in process	0.1	12.6		(98)	N/A	
Legal settlements, impairment, restructuring and acquisition costs	4.6	1.1		415	N/A	
Operating income	17.3	10.3	25.4	110	(52)	
Financial expenses net	1.5	3.1	0.9	(41)	279	
Income before income taxes	15.8	7.2	24.5	175	(65)	
Provision for income taxes	1.2	1.6	4.1	(10)	(52)	
Share in losses of associated companies net	0.2	*	0.1	3,200	(67)	
Net income attributable to non-controlling interests	*	0.1	*	(33)	500	
Net income attributable to Teva	14.4	5.5	20.3	228	(68)	

<sup>\*</sup> Less than 0.05%.

Formerly, we reported two operating segments, our pharmaceutical business and our active pharmaceutical ingredients (API) business. These two segments were managed separately. In 2009, following the acquisition of Barr at the end of 2008, we re-evaluated our organizational structure under a notion of One Teva with functional based units of a front-end (products offerings) and back-end (operations and R&D) unified organization. Accordingly, API is no longer managed separately and is now managed under the pharmaceutical business. Following such changes, we reassessed our operating segments and concluded that Teva has one operating segment.

#### Sales General

### Sales by Geographical Areas

						Percent Change	
Sales for the Period	2009 U.S. do	2008 ollars in mi	2007	% of 2009	% of 2008	2009 from 2008	2008 from 2007
North America	8,585	6,413	5,428	62%	58%	34%	18%
Europe*	3,271	2,976	2,645	23%	27%	10%	13%
International	2,043	1,696	1,335	15%	15%	20%	27%
Total	13,899	11,085	9,408	100%	100%	25%	18%

<sup>\*</sup> All members of the European Union as well as Switzerland and Norway.

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#### Sales by Product Line

				~ .	~ 4	Percent C 2009	2008
Sales for the Period	2009	2008	2007	% of 2009	% of 2008	from 2008	from 2007
	U.S. do	llars in mi	illions				
Generics and other	9,340	7,719	7,024	67%	70%	21%	10%
Innovative: Copaxone® and Azilect®	2,665	1,922	1,031	19%	17%	39%	86%
Specialty respiratory products	898	778	742	6%	7%	15%	5%
API	565	603	561	4%	5%	(6)%	7%
Proprietary women s health products	357			3%	NA	NA	NA
BioGenerics	74	63	50	1%	1%	18%	27%
Total	13,899	11,085	9,408	100%	100%		

#### Sales

#### **North America**

In 2009, our sales in North America amounted to \$8,585 million, an increase of 34% over 2008. The growth in sales was attributable to:

The first time inclusion of the Barr products, including its line of women s health products;

The launch of new generic products, the most significant of which were the generic versions of Adderall® (amphetamine mixed salts) pursuant to an agreement with Shire Plc, Eloxatin® (oxaliplatin solution for injection) and Ortho Tri-Cyclen® Lo (ethinyl estradiol and norgestimate), which we sold under our own brand Tri-Lo Sprinte®. We launched Tri-Lo Sprinte® in 2009 and reached a subsequent agreement with Ortho-McNeil Janssen Pharmaceuticals, Inc. to cease sales until December 31, 2015 or earlier in certain circumstances;

The launch of 16 other new generic products in the U.S. (a total of 19), as described above under Item 4: Information on the Company Product Offering Generic Products North America;

Strong sales of Lotrel® (amlodipine benazepril), which was initially launched in the second quarter of 2007; Protonix® (pantoprazole), which was initially launched in the fourth quarter of 2007; Yasmin® (drospirenone and ethinyl estradiol marketed by Teva as Ocella®), which Barr launched in the second quarter of 2008 pursuant to an agreement with Bayer AG and Pulmicort® (budesonide inhalation), which was initially launched in the fourth quarter of 2008 and relaunched in December 2009 pursuant to a settlement agreement with Astra Zeneca;

Growth of generic sales were offset in part by the decreased sales of Lamictal® (lamotrigine), Wellbutrin  $XL^{\$}$  (buproprion 150mg) launched pursuant to an agreement with Anchen Pharmaceuticals Inc. and Impax Laboratories, Inc. and Risperdal® (risperidone) which lost exclusivity in 2008, as well as decreased sales of other previously sold products;

Continued growth in sales of Copaxone<sup>®</sup>, which increased in-market sales by \$534 million in 2009. We benefited from record in-market sales of Copaxone<sup>®</sup> in the U.S. due to price increases and, to a lesser extent, volume growth, as well as the full year impact of the takeover of distribution activities from sanofi-aventis;

Increased sales of ProAir  $\,$ , which grew by 35% over 2008, driven by a full year effect of the CFC to HFA conversion, continued strong market share and a significant flu season, as well as 22% growth in Qvar®, our inhaled corticosteroid; and

Increased in-market sales of Azilect®, which grew by 49% over 2008.

In 2009, following the Barr acquisition, we expanded our leadership position in the U.S. both in total prescriptions and new prescriptions, with total generic prescriptions increasing from approximately 475 million

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in 2008 to approximately 599 million in 2009 after the Barr acquisition, representing 22% of total U.S. generic prescriptions. We expect that our U.S. market leadership will continue to increase as a result of our ability to introduce new generic equivalents for brand-name products on a timely basis, our emphasis on regulatory compliance and customer service, the breadth of our product line and our cost-effective production.

We expect that our revenue stream in North America will continue to be fueled by our strong U.S. generic pipeline, which, as of February 5, 2010, had 216 product registrations awaiting FDA approval (including some products through strategic partnerships), including 43 tentative approvals. Collectively, the branded versions of these 216 products had U.S. sales in 2009 exceeding \$113 billion. Of these applications, 140 were Paragraph IV applications challenging patents of branded products. We believe we are the first to file with respect to 89 of these products, the branded versions of which had U.S. sales of more than \$55 billion in 2009. IMS reported branded product sales are one of the many indicators of the potential future value of a launch, but equally important is the mix and timing of competition, as well as cost-effectiveness. The potential advantages of being the first filer with respect to some of these products may be subject to forfeiture.

In Canada, in local currency terms, we increased our sales in 2009. However, the 7% decline of the Canadian dollar against the U.S. dollar caused our U.S. dollar sales to remain flat as compared to 2008. In Canada, as of December 31, 2009, we had 67 product registrations awaiting approval by the Therapeutic Products Directorate of Health Canada. Collectively, the branded versions of these products had Canadian sales in 2009 of approximately \$4.2 billion.

On July 31, 2009, Teva and the FDA entered into a consent decree with respect to the operations of Teva Animal Health. As a result of the consent decree, the FDA mandated that all Teva Animal Health products be recalled and all finished goods inventory be disposed of. Such activities have resulted in a write-off of \$82 million, consisting primarily of inventory and recall reserves, as well as an impairment of certain fixed assets and intangibles related to the closure of the Fort Dodge facility. Remediation of the remaining facilities is expected to continue in 2010. There have not been any sales by Teva Animal Health since August 2009. As of December 31, 2009 we had \$112 million of intangible assets and fixed assets relating to acquired product rights of Teva s U.S. Animal Health products line. Due to the inherent uncertainties relating to the future ability of Teva Animal Health to produce and sell its products, the impairment of the above assets is monitored periodically. In 2009, sales of Teva Animal Health in the U.S. amounted to \$24 million. Teva s Animal Health sales in the U.S. for 2008 were approximately \$85 million.

In 2008, our sales in North America amounted to \$6,413 million, representing an increase of 18% over 2007. The increase in sales was attributable to:

The launch of four significant new generic products with exclusivity: generic versions of Lamictal® (lamotrigine), Wellbutrin XL® (bupropion 150 mg), Pulmicort® (budesonide) and Risperdal® (risperidone);

The launch of 24 other new products in the U.S.;

The continuation of strong sales of Protonix<sup>®</sup> (pantoprazole), which was initially launched late in the fourth quarter of 2007;

Continued growth in sales of Copaxone<sup>®</sup>, which increased in-market sales by 28% over 2007;

Increased sales of Azilect®, which grew by 19% over 2007; and

Increased sales of ProAir, which grew by 13% over 2007.

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#### **Europe**

Total sales in Europe in 2009 amounted to \$3,271 million, an increase of 10% compared to 2008, despite the negative impact of European currencies against the U.S. dollar. In local currency terms, we increased our sales 22%. The main contributors to this increase was the first time inclusion of sales from Barr s European subsidiary, Pliva (mainly in Germany, Poland, and the Czech Republic), a full year of generic sales in Spain (following our acquisition of Bentley in July 2008), strong sales in France, as well as an increase in the sales of Copaxone® and Azilect®. During 2009, most European currencies declined in value against the U.S. dollar (on an annual average compared to annual average basis).

Our 2009 European results were impacted by pricing pressure from governmental action and pharmaceutical buying groups. Certain European governments, which view generics as an opportunity to lower healthcare costs significantly, pursued various reforms in 2009. In the U.K., the government initiated the next stage of its reform of pharmacy remuneration, which resulted in further price reductions of generic products. Price levels for generic pharmaceuticals in Germany were adversely affected by the on-going implementation of a tender system. France had some of the lowest pharmaceutical prices in the region largely due to aggressive pharmacist buying groups and to the government s efforts to control healthcare costs by imposing significant price decreases. The tender like system introduced in the Netherlands gave pharmaceutical companies an incentive to reduce prices by becoming exclusive suppliers to health insurers for a six-month to one-year period. In the Czech Republic, new governmental reforms reduced the reimbursement level of low-priced products in favor of high-priced new products, resulting in a shift of demand to newer and more expensive pharmaceuticals.

Among the most significant products we sold in Europe in 2009 were generic versions of the following branded products (listed in the order of launch): Vancenase® (beclomethasone dipropionate), Losec®/Prilosec® (omeprazole), Ventolin® (salbutamol sulfate), Neurontin® (gabapentin), Eloxatin® (oxaliplatin), Casodex® (bicalutamide), Rhinocort® (budesonide), Effexor® (venlafaxine HCl), Protonix® (pantoprazole sodium), Temesta® (lorazepam), Dostinex®/Cabaser® (cabergoline), Camptosar® (irinotecan HCl), Neupogen® (filgrastim), Gemzar® (gemcitabine HCl), Femara® (letrozole), Plavix® (clopidogrel hydrobromide), and Hyzaar® (losartan potassium/HCTZ).

During 2009, we received 1,035 generic approvals in Europe relating to 164 compounds in 324 formulations, including 12 European Commission (or EMEA) approvals valid in all EU member states. In addition, we have the broadest generic pipeline in Europe with approximately 3,143 marketing authorization applications pending approval in 30 European countries, relating to 241 compounds in 485 formulations, including nine applications pending with the EMEA. During the course of 2009, we continued to register products in the European Union, 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. During 2009, the European Commission (EC) adopted the opinion of the committee for medicinal products for human use (CHMP) and granted us Europe-wide marketing authorizations for clopidogel bisulphate, irbesartan, irbesartan/hydrochlorothiazide, lamivudine, nevirapine, repaglinide, ribavarin, rivastigmine, sildenafil and topotecan. In addition, the CHMP adopted positive opinions (subject to ratification by the EC) recommending the granting of Europe-wide marketing authorizations for telmisartan, temozolomide and docetaxel.

Teva Europe s market position in key markets nevertheless grew or remained strong, despite this increasingly challenging competitive environment. Highlights for 2009 in Europe included:

*France:* We continued to experience significant growth in sales in France, both for our generic products and respiratory products. In 2009, the retail market in France for the existing, or base, products remained unchanged and the market growth was achieved from the introduction of new products. Teva remained the third largest generic pharmaceutical company in France, but with a slight increase in our market share.

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Germany: Sales in Germany increased in 2009 primarily as a result of the inclusion of Pliva's sales. Germany became one of our main markets in Europe. We had strong sales in the retail branded market as well as sales in the hospitals market. As a result of legislative changes introduced in 2007 favoring the use of tenders, two distinguishable generic markets in Germany emerged: a branded market and a tender-based generic market with a very competitive pricing environment. In the tender-based generic market, state health insurers may enter into direct rebate agreements with multiple pharmaceutical manufacturers, or enter in direct agreements with pharmaceutical manufacturers through portfolio contracts. Under this tender-based system, pharmacists are obliged to dispense products of pharmaceutical manufacturers that hold such rebate contracts with the patient shealth insurer, except in cases where the physician has specifically ruled out substitution. While we experienced pricing pressure from the tender system, we benefited from some of the brand products that Pliva had introduced into the German market.

*Hungary:* The decline of the Hungarian forint against the U.S. dollar caused our U.S. dollar sales to decrease in 2009. In local currency (Hungarian forint) terms, we increased our sales in 2009 and maintained our market share. In 2009, we were the third largest generic company. Government measures to manage the budget deficit are ongoing, and in 2009 included measures to manage pharmaceutical spending by reducing reimbursement and publishing quarterly reimbursement price lists.

*Italy:* As a result of regulations effective from May 2009 until year end, aimed at reduction of prices and regulation of rebates, we reduced prices of our products and consequently witnessed a decrease in our sales, as well as a decline in our market share. Despite these measures we were the leading generic company in Italy in 2009.

**Netherlands:** In the Netherlands, where we are the leading generic company, our sales decreased due to the exchange rate effect. We increased our respiratory product sales and grew our generic market share, despite a new expanded tender like system, as detailed in Item 4: Pharmaceutical Product Offering Generic Products Europe. In local currency terms sales increased.

**Poland:** Increased sales in Poland in 2009 were mainly attributable to the addition of sales from Pliva. In 2009, we became the third-largest generic pharmaceutical company in Poland in terms of retail sales, and maintained our leading position in terms of OTC sales.

*Spain:* We built on our mid 2008 acquisition of Bentley to increase sales and establish our position in the Spanish market. Our market share increased during 2009, as Teva became the third-largest generic pharmaceutical company in Spain in terms of sales.

*U.K.*: In the U.K., where we are the largest pharmaceutical company in terms of sales. In 2009, sales in U.S. dollar terms decreased due to the exchange rate effect. We recorded an increase in sales in local currency terms despite unfavorable market conditions, including reduced reimbursement by the government and price pressure due to competition. We increased our sales of generic and respiratory products. The increase of our respiratory sales was due to higher sales of HFA-based products, which was partly offset by erosion and the phase-out of CFC-based inhalers. The CFC phase-out continued during 2009; however, approximately 20% of the patients previously using CFC inhalers continue to use them.

Total sales in Europe in 2008 amounted to \$2,976 million, an increase of 13% compared to 2007, reflecting higher generic sales in Spain following our acquisition of Bentley in July 2008, France, Italy and Hungary, as well as an increase in the sales of Copaxone® and Azilect®. In 2008:

*France:* We continued to experience significant growth in sales in France, outperforming market growth and reaching a market share of approximately 10%.

Germany: Sales in Germany increased in 2008.

Hungary: Despite continuing price decreases, we maintained our market share and slightly increased sales.

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Italy: We increased sales in the generic market as a result of new product launches and an agreement with a leading wholesaler.

The Netherlands: We increased our market share to 34% of the generic market in the Netherlands.

Spain: As a result of our mid-2008 acquisition of Bentley, our retail generic market share increased to nearly 10% by the end of the year.

*U.K.*: We recorded a decrease in sales as well as slight decrease in sales in local currency terms due primarily to unfavorable market conditions.

#### International

Our International group includes all countries other than the U.S., Canada, EU member states, and other Western European countries. Our sales in these countries reached an aggregate of \$2,043 million in 2009, an increase of 20% as compared to 2008. In local currency terms, sales grew by 32%. Approximately 37% of our International sales were generated in Latin America, 24% in Israel, 25% in Russia and other Eastern European markets and 14% in all other markets.

In most international markets, our products are marketed and sold as branded generics. Sales of branded generic products usually generate higher gross margins but also involve considerably higher marketing expenditures than do non-branded generic products (such as those sold in the United States and certain Western European countries).

During 2009, 152 new products were launched in the International group. Among the most significant products we sold in the International markets were: Copaxone®, Zithromax® (azithromycin), Alfa DR (alfacalcidol), Advil® (ibuprofen), Mucinex® (guaifenesin), Beclovent® (beclomethasone), Tylenol® (paracetamol), Trasylol® (aprotinin), L-carnitine® (carnitine), Tantum® (benzydamine HCL), Tegretol® (carbamazepine), and Intron A® (interferon Alfa-2B). In Latin America, sales grew 8% over 2008 sales in U.S. dollar terms and by 15% in local currency terms. We increased our market share in Mexico and maintained our market share in all other Latin American markets. In Argentina and Mexico, sales increased due to both unit growth and a rise in prices.

Sales in our International group during 2008 amounted to \$1,696 million, an increase of 27% compared to 2007.

In Eastern Europe, sales grew by 11% in local currency terms in 2009. During the year we successfully integrated Pliva, primarily in countries such as Russia and Croatia. Market shares in most major markets in Eastern Europe were increased or maintained during 2009, despite the global economic environment. In Croatia, following the Barr acquisition, we became one of the leading generic companies in the market. In March 2009, according to the new national reimbursement list, prices were reduced. In Russia, our sales nearly doubled, mainly due to the Barr acquisition but also due to growth in sales of generics, mainly antibiotics.

Sales in Israel increased mainly due to the increase of revenue from the distribution of third-party products and medical device sales. Azilect<sup>®</sup> was approved to be included in the Israeli national list of registered drugs for 2010.

On January 29, 2009, we sold our Israeli animal health product line to Phibro Animal Health Corporation for total consideration of approximately \$47 million.

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#### **Global Branded Products**

#### **Innovative Products:**

**Copaxone®.** In 2009, Copaxone® continued to be the leading multiple sclerosis therapy in the U.S. and globally. Global in-market sales grew by 25% over 2008, reaching \$2.83 billion. Price increases, offset by negative currency effects, accounted for 13% of the increase, and unit growth accounted for the remainder. Sales also increased substantially in Europe due to unit growth.

U.S. in-market Copaxone® sales increased 39% to \$1,917 million, and non-U.S. in-market sales increased by 3% to \$909 million, compared to 2008. Growth in U.S. sales of Copaxone® was driven by price increases in January and April and to a lesser extent by increases in unit sales, whereas the increase in sales outside the U.S. was driven primarily by unit growth, partially offset by adverse currency effect. In local currency terms, in-market sales outside the U.S. grew by 12%. Markets outside the U.S. with substantial unit growth included Germany, Italy, Spain, U.K., and Turkey, U.S. sales accounted for 68% of global Copaxone® sales in 2009, compared with 61% in 2008.

In April 2008, we assumed the distribution of Copaxone<sup>®</sup> in the U.S. and Canada from our partner, sanofi-aventis. Under the terms of our agreements with sanofi-aventis, sanofi-aventis is entitled to receive payment from us of previously agreed-upon termination consideration of 25% of the in-market sales in the U.S. and Canada through March 31, 2010, which is recorded under selling and marketing expenses. Sanofi-aventis also ceased sharing our Copaxone<sup>®</sup> sales and marketing expenses in North America that were recorded against selling and marketing in previous quarters. This change has resulted in increases in our net sales, gross profit and gross profit margin as well as an increase in selling and marketing expenses, resulting in a minimal negative effect on operating income in 2009.

We have an additional collaborative agreement with sanofi-aventis for the marketing of Copaxone® in Europe and other markets. Under the terms of this agreement, Copaxone® is co-promoted with sanofi-aventis in Germany, the U.K., France, Spain, the Netherlands and Belgium and is marketed solely by sanofi-aventis in the rest of the European markets, Australia and New Zealand. Commencing in 2009 and to a greater extent by 2012, we are gradually assuming marketing responsibilities for Copaxone® in territories covered under this additional agreement. Sanofi-aventis is entitled to pre-specified residual payments for a period of two years, following a pattern similar to that under the North America agreement described above, but with substantially lower payments.

To date, Copaxone® has been approved for marketing in 52 countries worldwide, including the U.S., Canada, Israel, all EU countries and other countries. U.S. market shares in terms of new and total prescriptions were 36.9 % and 38.6%, respectively, according to December 2009 IMS data

In 2008, in-market global sales of Copaxone® amounted to \$2.26 billion, an increase of 32% over 2007. U.S. sales in 2008 accounted for 61% of global sales of Copaxone®. The growth of in-market sales of Copaxone® in the U.S. in 2008 also reflected the impact of two price increases of 12.5% and 9.9%.

Azilect<sup>®</sup>. Azilect<sup>®</sup> (rasagiline tablets), our once-daily treatment for Parkinson's disease, continued to establish itself in the U.S. and Europe. Global in-market sales in 2009 reached \$243 million compared to \$175 million in 2008, an increase of 39%. The increase in sales is attributable primarily to a global volume growth and to a lesser extent due to price increases in the U.S. Azilect<sup>®</sup> also benefited from, increased sales outside the U.S., mainly in Spain and Italy as well as in Turkey. In local currency terms, in-market sales of Azilect<sup>®</sup> grew 44%. Azilect<sup>®</sup> is now approved for marketing in 45 countries.

**Respiratory Products.** Our global respiratory product portfolio recorded a 15% increase in sales in 2009, reaching a record \$898 million. Not included in this figure are our sales in the U.S. of budesonide, which were reported as part of our generic drug sales. Sales in the U.S. grew to \$568 million, a 30% increase over 2008,

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driven by greater sales of ProAir (albuterol HFA), which maintained its market leadership with an average market share of 57% in the fourth quarter of 2009, in the short-acting beta agonist (SABA) market, and higher sales of Qvar®, which increased its market share in the U.S. and is now second in terms of new and total prescriptions in the inhaled corticosteroid category.

In Europe, increased sales in local currencies in France of 29% and in the U.K. 9% were offset by the decrease in sales of CFC products compared to 2008. Sales of Qvar® increased in the main markets in Europe as well, most notably in the U.K.

All of our asthma products sold in Europe (except for beclomethasone in the U.K.) and in the U.S. are free of CFC propellants, which are being phased out worldwide under the Montreal Protocol, a 1987 international treaty to eliminate the production and use of ozone-depleting chemicals, and which may not be sold in the U.S. after December 31, 2008. Our current inhaler products contain the ozone-friendly propellant hydrofluoroalkane (HFA) in place of CFC.

Women s Health. Our women s health business reached sales of \$357 million, an increase of 12% from \$319 million sold by Barr in 2008. Sales of all promoted products increased in 2009. These sales figures represent proprietary women s health products only, and include different products than the sales reported by Barr as its overall proprietary sales. In 2009, our original two-pill dosage emergency contraception product, Plan B<sup>®</sup>, encountered generic competition. We have since refocused our marketing efforts on Plan B<sup>®</sup> One-Step, a single pill dosage version of this emergency contraceptive.

**Biogenerics and Biopharmaceuticals.** During 2009, sales of biosimilar pharmaceuticals reached \$74 million, as compared with \$63 million in 2008 and \$50 million in 2007. Over 60% of the sales in 2009 were from products sold in U.S. and European markets, whereas most of sales in 2008 were from sales outside the U.S. and Europe. We currently sell human growth hormone in the U.S. and granulocyte colony stimulating factor (GCSF) in Europe and intend to launch additional biopharmaceutical products in the coming years in the U.S., European and International markets.

Following the September 2008 grant of marketing authorization by the European Commission s Directorate General for Enterprise and Industry for our GCSF product, we launched our biosimilar GCSF under the brand name TevaGrastim® in several EU countries, including the U.K., Germany, Portugal and Greece. We expect to launch it in additional EU and International markets over time. In December 2009, we submitted a Biologic License Application (BLA) for this product with the U.S. FDA. The brand product, Neupogen® filgrastim, had sales of \$1.3 billion globally in the twelve months ended September 30, 2009. On February 2, 2010, the FDA accepted our BLA filing for this product. Our proposed trade name for the product is Neutroval .

In January 2009, we signed a definitive agreement with Lonza Group Ltd., the world s largest producer of biological API, to establish a joint venture to develop, manufacture and market a number of affordable, effective and safe generic equivalents of a selected portfolio of biologic pharmaceuticals. The joint venture, TL Biopharmaceuticals AG, began research and development activities in May 2009.

It is expected that the biopharmaceutical market will make up nearly 23% of the total pharmaceutical market by 2014, up from 17% in 2008, reflecting an anticipated compound annual growth rate of 8% for the period, as compared to a compound annual growth rate of 1% for small molecule pharmaceuticals. In addition, during the next 10 years, products constituting over 85% of current biopharmaceuticals sales may face biosimilar competition.

#### Active Pharmaceutical Ingredient (API) Sales to Third Parties

API sales to third parties in 2009 amounted to \$565 million, a decrease of 6% compared to 2008. The decrease in third party sales is mainly in the European and North American markets, and partly offset by higher sales in our International markets.

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The business environment for third party sales remained very competitive in 2009, with the main factors being the ongoing consolidation of customers and competitors. Sales of active pharmaceutical ingredients to third parties in 2008 amounted to \$603 million, an increase of 7% over 2007.

### **Other Income Statement Line Items**

#### **Gross Profit**

In 2009, gross profit amounted to \$7,367 million, an increase of 23%, or \$1,399 million compared to 2008. The higher gross profit was mainly a result of our higher sales.

Gross profit margins were 53.0% in 2009, compared with 53.8% in 2008 and 51.8% in 2007. The lower margins in 2009 reflect higher inventory step-up expenses and higher amortization of product rights in connection with the Barr acquisition.

Inventory step-up expenses in 2009 were \$302 million related to the Barr acquisition, compared with \$5 million in 2008 related to the Bentley acquisition. Amortization of product rights under the cost of sales reached \$450 million in 2009, compared with \$152 million in 2008.

The decrease in gross profit margins was partially offset by the assumption of the distribution activities of Copaxone® in North America, as well as a favorable product mix, many of which are vertically integrated. In addition, changes in foreign exchange rates had a negative impact on our gross profit and also a negative effect on our sales, resulting in a favorable impact on our gross margin.

# Research and Development (R&D) Expenses

Net R&D spending for 2009 grew by 2% over 2008 and reached \$802 million. As a percentage of sales, R&D spending decreased from 7.1% in 2008 to 5.8% in 2009, due to cost savings and synergies from the integration with Barr as well as an increase in third parties participation in R&D.

In 2009, we recorded increases in R&D spending in generic R&D activities as well as in our branded R&D, including research and development of respiratory projects and of women shealth products following the Barr acquisition. Approximately 63% of our 2009 R&D expenditures were for generic R&D, and the balance was for our innovative products, respiratory products, women shealth products and biogenerics.

The Teva-Lonza joint venture commenced activities in 2009. In connection with the joint venture, Teva was reimbursed \$59 million for related R&D efforts incurred both prior to the formation of the joint venture and following its formation as part of the joint activity. This reimbursement has been recorded as a reduction in research and development expenses. The Teva share in the joint venture s expenses approximately \$30 million is reflected in the income statement under share in losses of associated companies net.

In 2009, expenses recovered from third parties that were recorded as a reduction to R&D significantly increased as compared to 2008. These were mainly due to reimbursements associated with the Teva-Lonza joint venture as well as other third party reimbursements and grants for certain R&D efforts.

Taking into account R&D expenditures included in joint ventures, as well as third party participations in our R&D efforts, our gross R&D expenditures in 2009 amounted to approximately 6.6% of sales.

Research and development expenses increased in 2008 to \$786 million from \$581 million in 2007, an increase of 35%.

# Research and Development In-Process (IPR&D)

IPR&D expenses in 2009 were \$23 million, attributable to the OncoGenex collaboration and share purchase agreement to develop and commercialize OGX-011, a Phase III cancer therapy designed to inhibit cancer treatment resistance. IPR&D write-offs in 2008 were \$1,402 million and were attributable to the acquisitions of Barr, CoGenesys and Bentley. According to the new accounting rules, commencing 2009, only IPR&D purchased in an asset deal are expensed immediately.

# Selling and Marketing (S&M)

S&M expenses in 2009 amounted to \$2,676 million, an increase of 45% over 2008. As a percentage of sales, S&M expenses increased to 19.3% for 2009 from 16.6% for 2008. The increase is primarily due to the higher S&M expenses of certain parts of Barr s businesses, higher net payments to sanofi-aventis due to our assumption of the distribution activities of Copaxone® in the U.S. and Canada as of April 1, 2008 (in 2009 we had four full quarters of payments to sanofi-aventis and in 2008 we had only three an effect of approximately \$196 million), as well as higher sales of Copaxone®, higher royalty payments regarding products sold in the U.S., primarily related to the re-launch of Pulmicort® (budesonide), Adderall XR® (amphetamine mixed salts), Yasmin® (drospirenone and ethinyl estradiol marketed as Ocella®), all partially offset by changes in foreign exchange rates that reduced our expenses in U.S. dollar terms.

The increase in the S&M expenses as a percentage of sales is primarily due to the our assumption of the distribution activities of Copaxone<sup>®</sup> in the U.S. and Canada as of April 1, 2008, a larger proportion of innovative and branded products in our overall sales, including respiratory products and women s health care products, as well as branded generics in many of our international markets, which have higher associated selling costs.

S&M expenses in 2008 amounted to \$1,842 million, an increase of 46% over 2007, and as a percentage of sales, S&M expenses increased to 16.6% for 2008 from 13.4% for 2007.

# General and Administrative Expenses (G&A)

G&A expenses in 2009 amounted to \$823 million compared with \$669 million in 2008, an increase of 23% over 2008. The increase in G&A expenses is mainly due to the Barr acquisition, partially offset by synergies and expense control initiatives.

As a percentage of sales, G&A expenses decreased to 5.9% for 2009 from 6.0% for 2008. The decrease is primarily due to our expense control initiatives.

G&A expenses in 2008 amounted to \$669 million, an increase of 5% over 2007, and as a percentage of sales, G&A expenses decreased to 6.0% for 2008 from 6.8% for 2007.

# Legal Settlements, Impairment, Restructuring and Acquisition Costs

Legal settlements for 2009 include mainly settlements in connection with drug pricing lawsuits and intellectual property litigation.

Our 2009 results include restructuring expenses of \$90 million, consisting principally of employee termination payments. These expenses relate to cost reduction initiatives to meet the challenges of our changing business environment and future opportunities. The cost reduction program included the closure of several manufacturing and R&D facilities and streamlining of staff functions and work force.

In February 2010, we announced that we had reached a settlement in principle to resolve claims brought by Ven-A-Care of the Florida Keys, Inc. on behalf of the United States, Texas, Florida, and California under federal and state False Claims Acts. Together with many other pharmaceutical manufacturers, Teva is named in numerous civil lawsuits that relate to drug price reporting by manufacturers in about 15 states. The cases, which are pending in federal and state courts, generally allege that the prices reported by pharmaceutical companies caused governments to pay inflated reimbursements for drugs under Medicaid or other programs. Teva denies the allegations. Upon execution of definitive settlement documents and certain government and court approvals, the settlement will resolve a lawsuit relating to federal contributions to all state Medicaid programs and claims of Texas, Florida, and California relating to their Medicaid programs. The settlement will eliminate the majority of the alleged damages asserted against us in the various drug pricing litigations. We recorded a charge of approximately \$315 million in our fourth quarter, 2009 results. This charge includes both the settlement in principle and a reserve for the remaining drug pricing lawsuits to which we are a party.

# **Financial Expenses**

In 2009, financial expenses amounted to \$202 million, compared with expenses of \$345 million during 2008. The 41% decrease in financial expenses is primarily attributable to net impairment of financial assets booked in 2008, partially offset by higher interest expenses and lower financial income. Our financing of the Barr acquisition increased our borrowing level and reduced cash levels, thereby increasing interest charges and reducing financial income.

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In 2008, we had a write-down of \$343 million in the carrying value of our portfolio of auction rate securities as a result of what was considered an other-than-temporary reduction of the fair market value of these securities. Those write-downs were partially offset by \$100 million received in connection with a settlement agreement during 2008 with an institution related to our investment in auction rate securities. In addition to these items, financial expenses were impacted by a write-off of approximately \$40 million of other financial assets to their fair market value in 2008. In 2009, we received \$14 million in income from sales of securities from our portfolio of auction rate securities, partially offset by a write-down of \$6 million in the carrying value of specific securities within this portfolio.

# **Tax Rate**

The provision for taxes amounted to \$166 million, or 8% of pre-tax income of \$2,203 million in 2009. In 2008, the provision for taxes amounted to \$184 million, or 23% of pre-tax income of \$800 million. In 2007, the provision for taxes amounted to \$386 million, or 17% of pre-tax income of \$2,304 million. The lower tax rate in 2009 was primarily due to legal settlements, restructuring and impairment charges, which reduced pre-tax income in jurisdictions of subsidiaries whose tax rates are above Teva s average tax rate. The higher tax rate in 2008 was mainly affected by a non tax-deductible write-off of in-process R&D related to the acquisitions of Barr and Cogenesys reduced Teva s pre-tax income during the period.

The statutory Israeli corporate tax rate was 26% in 2009, compared to 27% in 2008 and 29% in 2007. This rate is currently scheduled to decrease as follows: to 25% in 2010, 24% in 2011, 23% in 2012, 22% in 2013, 21% in 2014, 20% in 2015 and 18% in 2016. However, these decreases are expected to have a relatively small impact on our provision for taxes, as our effective consolidated tax rates have historically been considerably lower, because a major portion of our income is derived from approved enterprises in Israel (as more fully described in Item 10: Additional Information Israeli Taxation below) and from certain locations outside of Israel, where we have enjoyed lower tax rates.

Most of our investments in Israel were granted approved enterprise status, which confers certain tax benefits. These benefits include a long-term tax exemption for undistributed income generated by such projects, and lower rates of tax on dividends distributed from other projects, the source of which is approved enterprise income, for the periods set forth in the law, as described in Item 10: Additional Information Israeli Taxation. Concurrently, we enjoy investment-related and R&D-related tax incentives in many of our facilities around the world.

In the future, the effective tax rate is expected to fluctuate as a result of various factors, including the constant changes in the products and geographical mix of our sales, the effect of any mergers and acquisitions as well as statute of limitations and settlements.

# **Net Income and Earnings Per Share**

Net income attributable to Teva in 2009 was \$2,000 million. Diluted earnings per share reached \$2.23 in 2009, an increase of 197% compared to diluted earnings per share of \$0.75 in 2008. Net income attributable to Teva totaled \$609 million in 2008 a year in which we recorded research and development in-process write offs, as a result of the Barr, Bentley and CoGenesys acquisitions, as compared with \$1,914 million in 2007, and diluted earnings per share amounted to \$0.75 and \$2.36 in 2008 and 2007, respectively.

During 2007, we spent \$152 million to repurchase approximately 4 million of our shares at an average price of \$34.73 per share, pursuant to an authorization in November 2006 by the board of directors to repurchase up to \$600 million of our securities.

The share count used for the fully diluted calculation for 2009, 2008 and 2007 was 896 million, 820 million and 830 million shares, respectively.

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During 2009, \$965 million principal amount of convertible senior debentures were converted, comprised of: \$412 million principal amount of our 0.5% convertible senior debentures due 2024 and \$553 million principal amount of our 0.25% convertible senior debentures due 2024.

During 2008, \$89 million principal amount of convertible debentures, acquired in connection with the Ivax acquisition, were converted.

#### 2010 Known Trends

The following factors are expected to have an effect on our 2010 results:

Commencing April 1, 2010, we cease to make further payments to sanofi-aventis with respect to North American sales of Copaxone®, which to date have been equal to 25% of our Copaxone® North American in-market sales.

We expect significant variance between the first quarter and the rest of the year, resulting from the timing of our key business drivers during the year new launches of Paragraph IV products in the U.S. market, the termination of Copaxone royalty payments to sanofi-aventis described above, as well as our regular seasonality.

Amortization of approximately \$470 million dollars recorded under the cost of sales line resulting from past acquisitions.

Net R&D expenses in the range of 6% and 6.5% of net sales.

Selling and marketing expenses in the range of 16% to 18%. This number does not include amortization of approximately \$40 million.

General and administrative expenses are anticipated in the range of 5%-5.5% of sales.

In 2010, our financial expenses are expected to decline as a result of lower borrowing levels due to the debt reduction in 2009 and the higher cash level generated from expected positive cash flow in 2010. Financial expenses in 2010 are expected to reach a level of \$150-\$170 million.

In 2010, we expect to record share in losses of associated companies of approximately \$40 million primarily arising from our joint venture with Lonza.

We believe that the fully diluted number of shares in 2010 should be approximately 925 million, and the add-back for the EPS calculation is expected to be \$45 million.

Future acquisition could affect the above numbers.

# **Supplemental Non-GAAP Income Data**

The tables below present supplemental data, in U.S. dollar terms, as a percentage of sales and the increase/decrease by item as a percentage of the amount for the comparable period which we believe facilitates an understanding of the factors affecting our business. In these tables, we exclude the below:

In 2009:

\$485 million in charges relating to amortization of purchased intangible assets;						
\$434 million expenses relating to legal settlements;						
\$302 million in charges relating to inventory step-up;						
\$110 million in charges relating to impairment of long lived assets;						
\$94 million of restructuring and acquisition costs;						
\$23 million related to purchased in-process R&D, in connection with the OncoGenex collaboration agreement;						
\$6 million in charges relating a credit loss impairment of financial assets;						
\$14 million in income relating to the sale of auction rate securities; net of corresponding tax effect of \$411 million.						

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In 2008:

\$1,402 million related to a write-off of in-process R&D, which was primarily in connection with the acquisitions of Barr and CoGenesys;

\$375 million in charges relating to other than temporary impairment of financial assets (mainly auction rate securities);

\$180 million charges related to amortization of purchased intangible assets;

\$107 million in charges relating to impairment of intangible and fixed assets;

\$100 million income in connection with a settlement agreement with an institution related to Teva s auction rate securities;

\$17 million expenses relating to five different legal settlements, partially offset by income received from an additional settlement;

\$5 million in charges relating to an inventory step-up; net of corresponding tax effect of \$102 million.

The data so presented after these exclusions are the results used by management and our board of directors to evaluate our operational performance, to compare against work plans and budgets, and ultimately to evaluate the performance of management. For example, each year we prepare detailed work plans for the next three succeeding fiscal years. These work plans are used to manage the business and are the plans against which management s performance is measured. All of such plans are prepared on a basis comparable to the presentation below, in that none of the plans take into account those elements that are factored out in our non-GAAP presentations. In addition, at quarterly meetings of the Board at which management provides financial updates to the Board, presentations are made comparing the current fiscal quarterly results against: (a) the comparable quarter of the prior year, (b) the immediately preceding fiscal quarter and (c) the work plan. Such presentations are based upon the non-GAAP approach reflected in the table below. Moreover, while there are always qualitative factors and elements of judgment involved in the granting of annual cash bonuses, the principal quantitative element in the determination of such bonuses is performance targets tied to the work plan, and thus tied to the same non-GAAP presentation as is set forth below.

In arriving at our non-GAAP presentation, we have in the past factored out items, and would expect in the future to continue to factor out items, that either have a non-recurring impact on the income statement or which, in the judgment of our management, are items that, either as a result of their nature or size, could, were they not singled out, potentially cause investors to extrapolate future performance from an improper base. While not all inclusive, examples of these items include: legal settlements, including principally settlements in connection with intellectual property lawsuits, purchase accounting adjustments related to acquisitions, including adjustments for write-offs of R&D in-process, amortization of intangible assets and inventory—step-ups—following acquisitions; restructuring charges related to efforts to rationalize and integrate operations on a global basis; material tax and other awards or settlements—both in terms of amounts paid or amounts received; impairment charges related to intangible and other assets such as intellectual property, product rights or goodwill; and the income tax effects of the foregoing types of items when they occur.

This data are non-GAAP financial measures and should not be considered replacements for GAAP results. We provide such non-GAAP data because management believes that such data provide useful information to investors. However, investors are cautioned that, unlike financial measures prepared in accordance with GAAP, non-GAAP measures may not be comparable with the calculation of similar measures for other companies. These non-GAAP financial measures are presented solely to permit investors to more fully understand how management assesses our performance. The limitations of using these non-GAAP financial measures as performance measures are that they provide a view of our results of operations without including all events

during a period, such as the effects of acquisition, merger-related, restructuring and other charges, and may not provide a comparable view of our performance to other companies in the pharmaceutical industry.

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

	2009	Year Ended December 31, 2009 2008 2007 U.S. dollars and		Percentage of Net Year Ended Decen 2009 2008				ge Change parison 2008-2007	
shares in millions									
	(except p	(except per share amounts)			%	%	%	%	
Supplemental non-GAAP income data:									
Net sales	13,899	11,085	9,408	100.0	100.0	100.0	25	18	
Gross profit	8,119	6,125	5,027	58.4	55.3	53.4	33	22	
Operating income	3,853	2,856	2,616	27.7	25.8	27.8	35	9	
Income before income taxes	3,643	2,786	2,525	26.2	25.1	26.8	31	11	
Provision for income taxes	577	286	436	4.2	2.6	4.6	102	(34)	
Net income attributable to Teva	3,029	2,493	2,085	21.8	22.5	22.2	22	20	
Diluted earnings per share	3.37	3.03	2.57				11	18	
Weighted average number of shares	912	837	830						

For 2009 and 2008, the difference between the reported and the non-GAAP diluted weighted average number of shares represents potential dilution of convertible senior debentures, which had an anti-dilutive effect on the reported earnings per share while being dilutive on the non-GAAP basis.

The below table provides a reconciliation of our U.S. GAAP reported results and these supplemental non-GAAP data:

	2009	2008	2007	
	U.S.	U.S. dollars in millions		
	(except	(except per share amounts)		
Reported net income attributable to Teva	\$ 2,000	\$ 609	\$ 1,914	
Acquisition of research and development in process	23	1,402		
Inventory step-up	302	5		
Impairment of assets	110	107		
Restructuring and acquisition costs	94			
Legal settlements	434	17		
Settlement with an institution relating to auction rate securities		(100)		
Impairment of financial assets-net	(8)	375		
Amortization of purchased intangible assets	485	180	221	
Related tax effect	(411)	(102)	(50)	
Non-GAAP net income	\$ 3,029	\$ 2,493	\$ 2,085	
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Diluted earnings per share:				
Reported (\$)	2.23	0.75	2.36	
Non-GAAP (\$)	3.37	3.03	2.57	
Add back for diluted earnings per share calculation:	3.37	3.03	2.57	
Reported (\$)	1	5	47	
reported ( $\phi$ )	1	3	<del>-1</del> /	

Year Ended December 31,

Non-GAAP (\$) 43 46 47

For 2009 and 2008, the difference between the add back for diluted earnings per share calculations represents potential dilution of convertible senior debentures, which had an anti-dilutive effect on the reported earnings per share while being dilutive on the non-GAAP basis.

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# **Impact of Currency Fluctuations and Inflation**

Because our results are reported in U.S. dollars, changes in the rate of exchange between the U.S. dollar and the local currencies in the markets in which we operate (primarily the euro, pound sterling, Hungarian forint, Israeli shekel, Canadian dollar and Russian ruble) affect our results. During 2009, the main currencies relevant to our operations declined in value against the U.S. dollar: the pound sterling by 15%, the Hungarian forint by 15%, the euro by 5%, the Russian ruble by 22%, the Polish zloty by 23%, the Israeli shekel by 9%, and the Canadian dollar by 7% (on an annual average compared to annual average basis).

The devaluation of non-U.S. currencies during 2009 in comparison with 2008 negatively impacted overall sales by approximately 4% of 2009 sales. We also recorded lower expenses due to these currency fluctuations and, as a result overall, changes in the exchange rates had negligible negative effect on our operating income (approximately 1.5% of 2009 operating income) and net income.

# **Critical Accounting Policies**

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the accompanying consolidated financial statements and related footnotes. Actual results may differ from these estimates. To facilitate the understanding of our business activities, certain accounting policies that are more important to the portrayal of our financial condition and results of operations and that require management subjective judgments are described below. We base our judgments on our experience and on various assumptions that we believe to be reasonable under the circumstances. Please refer to Note 1 to our consolidated financial statements included in this annual report for a summary of all of our significant accounting policies.

#### Revenue Recognition and Sales Reserves and Allowances ( SR&A )

**Revenue** is recognized generally when title and risk of loss for the products is transferred to the customer. Provisions for sales reserves and allowances are established concurrently with the recognition of revenue. Accordingly, and in compliance with accounting guidance which relates to customer payments and incentives, reported net sales is presented net of those deductions. These provisions primarily relate to sales of pharmaceutical products in the North American marketplace, principally the United States.

Provisions for chargebacks, returns, rebates, other promotional items and price protection provisions are included in Sales reserves and allowances under the heading of current liabilities on our balance sheet included in the accompanying financial statements. Prompt pay discount provisions are netted against. Accounts receivable. We adjust these provisions in the event that it appears that the actual amounts may differ from the estimated provisions. The following briefly describes the nature of each deduction and how provisions are estimated in our financial statements.

Chargebacks. We have arrangements with various third parties, such as managed care organizations and drug store chains, establishing prices for certain of our products. While these arrangements are made between us and the customers, the customers independently select a wholesaler from which they purchase the products. Alternatively, certain wholesalers may enter into agreements with the customers, with our concurrence, which establishes the pricing for certain products which the wholesalers provide. Under either arrangement, we will issue a credit (referred to as a chargeback) to the wholesaler for the difference between the invoice price to the wholesaler and the customer's contract price.

Provisions for chargebacks are the largest single component of our SR&A process, involving estimates of contract prices across in excess of 1,000 products and multiple contracts with multiple wholesalers. The provision for chargebacks varies in relation to changes in product mix, pricing and the level of inventory at the wholesalers and therefore will not necessarily fluctuate in proportion with an increase or decrease in sales.

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Provisions for estimating chargebacks are calculated using historical chargeback experience, or expected chargeback levels for new products. Chargeback provisions are compared to externally obtained distribution channel reports for reasonableness. We regularly monitor the provision for chargebacks and make adjustments when we believe that actual chargebacks may differ from estimated provisions. In addition, we consider current and expected price competition when evaluating the provision for chargebacks.

Returns. Returns primarily relate to customer returns for expired products which the customer has the right to return up to one year following the expiration date. Such returned products are destroyed, and credits and/or refunds are issued to the customer for the value of the returns. We record a reserve for estimated sales returns in accordance with the Revenue Recognition When Right of Return Exists FASB pronouncement. The returns provision is estimated by applying a historical return rate to the amounts of revenue estimated to be subject to returns. Revenue subject to returns is estimated based on the lag time from time of sale to date of return. The estimated lag time is developed by analyzing historical experience. Lag times during 2009 and 2008 were estimated at approximately 24 months from the date of sale. Additionally, we consider specific factors such as levels of inventory in the distribution channel, product dating and expiration, size and maturity of launch, entrance of new competitors, changes in formularies or packaging and any changes to customer terms for determining the overall expected levels of returns.

Shelf Stock Adjustments. The custom in the pharmaceutical industry is generally to grant customers a shelf stock adjustment based on the customers existing inventory contemporaneously with decreases in the market price of the related product. The most significant of these relate to products for which an exclusive or semi-exclusive period exists. Provisions for price reductions depend on future events, including price competition, new competitive launches and the level of customer inventories at the time of the price decline. We regularly monitor the competitive factors that influence the pricing of our products and customer inventory levels and adjust these estimates where appropriate.

Customer Volume Rebates. Rebates are primarily related to volume incentives and are offered to key customers to promote loyalty. These rebate programs provide that, upon the attainment of pre-established volumes or the attainment of revenue milestones for a specified period, the customer receives a rebate. Since rebates are contractually agreed upon, they are estimated based on the specific terms in each agreement. Externally obtained inventory levels are evaluated in relation to estimates made for rebates payable to indirect customers.

Medicaid and Other Governmental Rebates. Pharmaceutical manufacturers whose products are covered by the Medicaid program are required to rebate to each state a percentage of their average manufacturer s price for the products dispensed. Many states have also implemented supplemental rebate programs that obligate manufacturers to pay rebates in excess of those required under federal law. We estimate these rebates based on historical trends of rebates paid as well as on changes in wholesaler inventory levels and increases or decreases in sales.

*Other Promotional Arrangements.* Other promotional or incentive arrangements are periodically offered to customers specifically related to the launch of products or other targeted promotions. Provisions are made or expenses recorded in the period for which the customer earns the incentive in accordance with the contractual terms.

**Prompt Pay Discounts.** Prompt pay discounts are offered to most customers to encourage timely payment. Discounts are estimated at the time of invoice based on historical discounts in relation to sales. Prompt pay discounts are almost always utilized by customers. As a result, the actual discounts do not vary significantly from the estimated amount.

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Sales reserves and allowances (SR&A) for third-party sales of pharmaceutical products to U.S. customers at December 31, 2009 and 2008 were as set forth in the below table. Such sales reserves and allowances to U.S. customers comprised over 90% of our total sales reserves and allowances as of December 31, 2009, with the balance primarily in Canada and the U.K.

	Sales Reserves and Allowances								
	Reserves included in Accounts Receivable, net	Cha	rgebacks (U.		eturns ars in mill	Oth Rese Allo	bates & ner Sales erves and owances	Total	
Balance at December 31, 2007	\$ 96	\$	700	\$	222	\$	637	\$ 1,655	
Provisions related to sales made in current year period	213		3,022		155		1,508	4,898	
Provisions related to sales made in prior periods	(4)		20		(10)		(32)	(26)	
Credits and payments	(189)		(2,758)		(107)		(1,163)	(4,217)	
Barr s purchase accounting	15		106		116		144	381	
Balance at December 31, 2008	\$ 131	\$	1,090	\$	376	\$	1,094	\$ 2,691	
Provisions related to sales made in current year period	286		3,649		239		2,088	6,262	
Provisions related to sales made in prior periods	(3)		6		(33)		6	(24)	