

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. See "Forward-Looking Statements" on page 1.

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

Our financial results depend, to a significant degree, upon our ability to successfully commercialize additional generic and innovative pharmaceutical products as well as active pharmaceutical ingredients. We must develop, test and manufacture generic products as well as prove that our generic products are the bio-equivalent of their branded counterparts. All of our products must meet and continue to comply with regulatory and safety standards and receive regulatory approvals; we may be forced to withdraw a product from the market if health or safety concerns arise with respect to such product. 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 successfully and profitably produce and market such products. 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 may depend upon our ability to successfully challenge patent rights held by branded companies or otherwise develop non-infringing products. The continuous introduction of new pharmaceutical products as well as active pharmaceutical ingredients is critical to our business.

Our revenues and profits from generic pharmaceutical products generally decline as competitors introduce their own generic equivalents.

Net selling prices of generic drugs typically decline, sometimes dramatically, especially as additional companies receive approvals and enter the market for a given product and competition intensifies. In particular, we are facing increasing competition from brand-name companies in addition to local and foreign generic companies. Our ability to sustain our sales and profitability on any product over time is dependent on both the number of new companies selling such product and the timing of approvals of those products. Our overall profitability depends on, among other things, our ability to continuously and timely introduce new products.

Our revenues and profits are closely tied to our success in obtaining 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 market exclusivity for 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 the equivalent product. For example, our 2007 operating results included major contributions from products sold with U.S. market exclusivity, such as pantoprazole. Our ability to achieve sales growth and profitability is dependent on our success in challenging patents and/or developing non-infringing products and launching products with U.S. market exclusivity. In addition, the flow of potential new generic products with exclusivity and the size of the product opportunities vary significantly from year-to-year, or even from quarter-to-quarter. Failure to continue to obtain such market exclusivities could have a material adverse effect on our sales and profitability.

If we elect to sell a generic product prior to the final resolution of outstanding patent litigation, 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 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 Allegra®, Neurontin®, Lotrel® and Protonix®, despite the fact that litigation with the companies that sell these branded products is still pending.

To the extent we elect to proceed in this manner, and the final court decision is adverse to us, we could be required to cease selling the infringing products, causing us to lose future sales revenue from such products and to face substantial liability 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 and not based on the profits we earned. 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.

Although we currently have insurance coverage for certain of the specified types of damage described above, we may be subject to claims that are subject to our deductible, involve a co-insurance participation, exceed our policy limits or relate to damages that are not covered by our policy. In addition, there is a very limited market for such insurance coverage.

Our revenues and profits from generic pharmaceutical products may decline as a result of intense competition from brand-name companies that are under increased pressure to counter generic products.

Our generic pharmaceutical products face intense competition from brand-name companies that have taken aggressive steps to thwart competition from generic companies. In particular, brand-name companies continue to sell or license their products directly or through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called “authorized generics”). No significant regulatory approvals are required for a brand-name company to sell directly or through a third party to the generic market, and brand-name companies do not face any other significant barriers to entry into such market. In addition, such companies continually seek to delay generic introductions and to decrease the impact of generic competition, using tactics which include:

- obtaining new patents on drugs whose original patent protection is about to expire;
- filing patent applications that are more complex and costly to challenge;
- filing suits for patent infringement that automatically delay approval of the U.S. Food and Drug Administration (“FDA”);
- filing citizens’ petitions with the FDA contesting approval of the generic versions of products due to alleged health and safety issues;
- developing controlled-release or other “next-generation” products, 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 as over-the-counter products those branded products which are about to face generic competition; and

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- making arrangements with managed care companies and insurers to reduce the economic incentives to purchase generic pharmaceuticals.

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 sales of innovative products, especially Copaxone®, 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 substantial revenues and profits. To date, we and our marketing partners have been successful in our efforts to establish Copaxone® as a 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® and Tysabri®. We may also face competition from additional products in development, including an orally administered treatment for multiple sclerosis. In addition, the exclusivity protections afforded us in the United States through orphan drug status for Copaxone® expired on December 20, 2003. If our patents on Copaxone® are successfully challenged, we may also face generic competition for this product.

Sales of our products may be adversely affected by the continuing consolidation of our U.S. distribution network, seasonality, other pricing factors, financial constraints of pharmaceutical distributors and the concentration of our customer base.

A significant proportion of our sales are made to relatively few U.S. retail drug chains, wholesalers, managed care purchasing organizations, mail order distributors and hospitals. These customers, which represent an essential part of the distribution chain of pharmaceutical products, are continuing to undergo significant consolidation. This consolidation may provide our customers with additional purchasing leverage and consequently increase the pricing pressures that we face. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions enable those groups to extract price discounts on our products.

Our net sales and quarterly growth comparisons may be affected by fluctuations in the buying patterns of retail chains, major distributors and other trade buyers. These fluctuations may result from seasonality, pricing, wholesaler buying decisions or other factors. In addition, many of the major pharmaceutical distributors have experienced downturns and financial constraints, which may impact both our sales and the collectibility of our receivables and result in even greater consolidation among our customers. These developments may have a material adverse effect on our business, financial condition and results of operations.

Changes in the regulatory environment may prevent us from utilizing the exclusivity periods that are important to the success of our generic products.

The Medicare Prescription Drug Act provides that the 180-day market exclusivity period provided under the Hatch-Waxman Act is only triggered by commercial marketing of the product. However, the Medicare Act also contains forfeiture provisions which would deprive the first "Paragraph IV" filer (as described under "Regulation" in Item 4 below) of exclusivity if certain conditions are met. Accordingly, we may face the risk of forfeiture and therefore may not be able to exploit a given exclusivity period for specific 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.

We are subject to extensive pharmaceutical industry regulations in countries where we operate. We cannot predict the extent to which we may be affected by legislative and other regulatory developments concerning our products.

We are dependent on obtaining timely approvals before marketing most of our products. In the United States, any manufacturer failing to comply with FDA or other applicable regulatory agency requirements may be unable to obtain approvals for the introduction of new products and, even after approval, initial product shipments may be delayed. The FDA also has the authority to revoke drug approvals previously granted and remove from the market previously approved drug products containing ingredients no longer approved by the FDA. Our major facilities, both within and outside the United States, and our products are periodically inspected by the FDA, which has extensive enforcement powers over the activities of pharmaceutical manufacturers, including the power to seize, force to recall and prohibit the sale or import of non-complying products, and to halt operations of and criminally prosecute non-complying manufacturers. In addition, we are subject in the U.S. to other regulations, including those related to quotas for controlled substances, which may from time to time limit our ability to meet demand for products containing such substances.

In the European Union ("EU") and Israel, the manufacture and sale of pharmaceutical products is regulated in a manner substantially similar to that in the United States. Legal requirements generally prohibit the handling, manufacture, marketing and importation of any pharmaceutical product unless it is properly registered in accordance with applicable law. The registration file relating to any particular product must contain medical data related to product efficacy and safety, including results of clinical testing and references to medical publications, as well as detailed information regarding production methods and quality control. Health ministries are authorized to cancel the registration of a product if it is found to be harmful or ineffective or manufactured and marketed other than in accordance with registration conditions.

Data exclusivity provisions exist in many countries where we operate, although their application is not uniform. In general, these exclusivity 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 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, primarily relating to patents and data exclusivity provisions. Modifications of this legislation or court decisions regarding this legislation may adversely affect us and may prevent us from exporting 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 provisions 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, significant investments in our ability to develop and produce biotechnology-based products, most recently including our acquisition for \$400 million of CoGenesys Inc. Although some of these products may be sold as branded, 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 clear 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.

The manufacture of our products is highly complex, and sometimes single-sourced, and a supply interruption or delay could adversely affect our business, financial condition or results of operations.

The products we market, distribute and sell are either manufactured at our own manufacturing facilities or, in certain cases, through supply agreements with third parties. Many of our products are the result of complex manufacturing processes, and are sometimes dependent on highly specialized raw materials. In addition, for certain of our products, and certain key raw materials, we have only a single source of supply. As a result, we can provide no assurances that supply sources will not be interrupted from time to time. For these same reasons, the volume of production of any product cannot be rapidly altered. As a result, if we fail to accurately predict market demand for any of our products, we may not be able to produce enough of the product to meet that demand, which could affect our business, financial condition or results of operations.

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

In the past, we have grown, in part, through a number of significant acquisitions, including our acquisitions of 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 and active pharmaceutical ingredients businesses and seek to integrate them into our own operations.

Future 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 enable us to execute our business strategy.
- We compete with others to acquire companies. 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 successfully integrate acquisitions in accordance with our business strategy.
- 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.

We may be susceptible to product liability claims that are not covered by insurance, including potential claims relating to products that we previously sold or currently sell and that are not covered by insurance.

Our business inherently exposes us to claims relating to the use of our products. We sell, and will continue to sell, 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 as well as claims that exceed our policy limits. Additional products for which we currently have coverage may be excluded in the future. 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.

Reforms in the healthcare industry 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 currently operate, pharmaceutical prices are subject to regulation. In the United States, numerous proposals that would effect changes in the U.S. 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 and certain countries in Central and Eastern Europe. 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." 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.

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.

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.

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

We are a global pharmaceutical company with worldwide operations. Over 80% of our sales are in North America and Western Europe. However, 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.

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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 should occur in the Middle East or trade between Israel and its present trading partners should be curtailed, including as a result of acts of terrorism in the United States or elsewhere.

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

Over 40% of our revenues is from sales outside of the United States. As a result, we are subject to significant foreign currency risk, including foreign currency payment 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 local currency devaluations or fluctuations. We may also be exposed to credit risks in some of these less developed markets.

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, 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.

In recent years, the operations of all companies have become subject to increasingly stringent legislation and regulation related to occupational safety and health, product registration and environmental protection. Such legislation and regulations are complex and constantly changing, and we cannot assure you that future changes in laws or regulations would not require us to install additional controls for certain of our emission sources, to undertake changes in our manufacturing processes or to remediate soil or groundwater contamination at facilities where such clean-up is not currently required.

An increasing amount of intangible assets and goodwill on our books may 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 for impairment 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, primarily as a result of our recent acquisitions. Impairment testing under U.S. GAAP may lead to further impairment charges in the future. Any significant impairment charges could have a material adverse effect on our results of operations. For a discussion of how we determine whether an impairment has occurred and what factors could result in an impairment, see "Item 5. Operating and Financial Review and Prospects—Critical Accounting Policies" and "Item 18. Financial Statements—Note 1."