[Table of Contents](#)

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. Commercialization requires that we successfully develop, test and manufacture both generic and innovative products. All of our products must meet, and continue to comply with, regulatory and safety standards as well as receive regulatory approval; 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 generic products also depends upon our success in challenging patent rights held by third parties or in developing non-infringing products. Due to the emergence and development of competing products over time, 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 product portfolio.

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

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 and enforcing new patents on drugs whose original patent protection is about to expire;
- 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;

- 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 actions may increase the costs and risks associated with our efforts to introduce generic products and may delay or prevent such introduction altogether.

In addition, 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 recent years, the rise of low-cost generic pharmaceutical producers based in China and India has increased the level of competition we face.

The intense pressure of government authorities, particularly in highly regulated European markets, to lower health care budgets has resulted in lower pharmaceutical pricing, causing lower revenues and profits.

Sales of our innovative products, especially Copaxone®, could be adversely affected by competition, including potential generic versions.

Our innovative products face or may face intense competition from competitors' products, which may adversely affect our sales and profitability. Copaxone®, our leading innovative product, was responsible for approximately 18% of our net sales in 2010 and contributed disproportionately to our profits and cash flows. To date, we 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 injectable products, such as Avonex®, Betaseron®, Rebif®, Extavia® and Tysabri®. In addition, competition from the rapidly developing market segment of oral treatments, such as Gilenya®, which was recently introduced by Novartis, is expected to be especially intense in light of the substantial convenience afforded by oral products in comparison to injectables such as Copaxone®.

Our patents on Copaxone® have been challenged, and we may face generic competition prior to 2014, when the U.S. Orange Book patents covering Copaxone® would otherwise expire. We also recently received notification of several challenges to our patents covering Azilect®. Thus, we may face generic competition prior to the expiration of the Orange Book patents for these products. The success of Copaxone®, Azilect® and our other innovative products depends substantially on our ability to enforce the patents covering these products.

Any substantial decrease in the profits derived from our innovative products would have an adverse effect on our results of operations.

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 in the U.S., Europe and other markets where we do business.

Our ability to introduce new products depends in large part upon the success of our challenges to patent rights held by brand companies or our ability to develop non-infringing products. Based upon a variety of legal and commercial factors, we may elect to sell a generic product even though patent litigation is still pending, whether before any court decision is rendered or while an appeal of a lower court decision is pending. The outcome of such patent litigation could, in certain cases, materially adversely affect our business. For example, we launched, and continue to sell, generic versions of Neurontin® (gabapentin), Lotrel® (amlodipine benazepril), and Protonix® (pantoprazole), despite the fact that litigation with the companies that sell the brand versions of these products is still pending. Although the case remains on appeal, we received an adverse decision in the pantoprazole litigation in 2010.

If we sell products prior to a final court decision either in the U.S. Europe or elsewhere, and such decision is adverse to us, we could be required to cease selling the infringing products, causing us to lose future sales revenue from such products and to face substantial liabilities for patent infringement, in the form of either payment for the innovator's lost profits or a royalty on our sales of the infringing products. These damages may be significant, and could materially adversely affect our business. In the 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. In addition, even if we do not suffer damages, we may incur significant legal and related expenses in the course of successfully defending against infringement claims.

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

Our ability to achieve continued 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. The failure to continue to develop such opportunities could have a material adverse effect on our sales and profitability.

To the extent that we succeed in being the first to market a generic version of a significant product, and particularly if we are the only company authorized to sell during 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 2010 operating results included contributions from products launched with U.S. market exclusivity, or with otherwise limited competition, such as venlafaxine, losartan and amlodipine benazepril. Even after the exclusivity period ends, we frequently benefit from the continuing effect of being the first generic in the market.

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. Additionally we increasingly share the 180-day exclusivity period with other generic competitors, which diminishes the commercial value of the exclusivity.

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

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

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.

Recently, there has been increasing regulatory scrutiny of pharmaceutical manufacturers, resulting in product recalls, plant shutdowns and other required remedial actions. Our U.S. injectable products facility and animal health facilities have been the subject of recent regulatory action, requiring substantial expenditures of resources to ensure compliance with more stringently applied production and quality control regulations. In addition, we recently received a warning letter from the FDA relating to our oral solid dose facility in Jerusalem. If any regulatory body were to require one or more of our significant manufacturing facilities, such as the Jerusalem site, to cease or limit production, our business could be adversely affected. In addition, because regulatory approval to manufacture a drug is site-specific, the delay and cost of remedial actions, or obtaining approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations.

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

A core part of our strategy has been, and remains, growth through acquisitions. For example, we acquired the ratiopharm-Merckle Group in August 2010, Barr Pharmaceuticals, Inc. in December 2008, IVAX Corporation in January 2006 and Sicor Inc. in January 2004, among others. 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.

Our reliance on acquisitions as a means of growth involves 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 seeking to expand into or enter 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, and as a result, or for other reasons, we may fail to consummate an announced acquisition.
- Potential acquisitions may divert management's attention away from our existing business operations, resulting in the loss of key customers and/or personnel and exposing us to unanticipated liabilities.
- We may fail to integrate acquisitions successfully in accordance with our business strategy or achieve expected synergies.
- We may not be able to retain experienced management and skilled employees from the businesses we acquire and, if we cannot retain such personnel, we may not be able to attract new skilled employees and experienced management to replace them.
- We may purchase a company that has excessive known or unknown contingent liabilities, including, among others, patent infringement or product liability claims.

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

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, in-licensing and acquisition of products from or with third parties. The development of innovative drugs involves different processes and expertise than we have historically relied upon in the development of generic drugs, which increases the risks of failure that we face. For example, 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.

Because of the amounts required to be invested in augmenting our innovative pipeline, we are increasingly reliant on partnerships and joint ventures with third parties, and consequently face the risk that some of these third parties may fail to perform their obligations, or fail to reach the levels of success that we are relying on to meet our revenue and profit goals. There is a trend in the innovative pharmaceutical industry of seeking to effectively “outsource” drug development by acquiring companies with promising drug candidates, and we face substantial competition from historically innovative companies for such acquisition targets. Accordingly, our investment in research and development of innovative products can involve significant costs with no assurances of future revenues or profits.

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 currently facing patent challenges.

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.

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

As our business continues to evolve beyond generic pharmaceuticals, we face intense competition in our respiratory and women’s health specialty businesses, which contributed significantly to our revenues and profits in 2010 and which we have targeted for significant growth by 2015. Our competitors in these product categories typically have substantially greater experience in the marketing and sale of branded, innovative and consumer-oriented products. They may be able to respond more quickly to new or emerging market preferences or to devote greater resources to the development and marketing of new products and/or technologies than we can. As a result, any products and/or innovations that we develop may become obsolete or noncompetitive before we can recover the expenses incurred in connection with their development. In addition, for these product categories we must demonstrate to physicians, patients and third-party payors the benefits of our products relative to competing products that are often more familiar or otherwise 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.

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.

Regulations to permit the sale of biotechnology-based products as 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 biosimilar generic versions of currently marketed biotechnology products. To date, in many markets, 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 healthcare reform legislation recently adopted in the U.S., 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 FDA is in the process of establishing regulations relating to biosimilars to implement the new healthcare legislation. These regulations, when ultimately adopted, could further complicate the process of bringing biosimilar products to market on a timely basis and could thus adversely affect our ability to develop a successful biosimilars business.

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 (including products sold by companies we have acquired), we have experienced a significant increase in both the number of product liability claims asserted against us and the number of products attracting personal injury claims, and we expect that trend to continue. In 2010, a jury awarded damages in excess of $500 million against us and our distributor in a case involving our propofol product. While we are appealing the ruling, we have been required to post a bond of over $580 million to stay execution of the judgment pending the appeal, which has added to our financing costs. In the event of additional judgments of similar magnitude, our financial results, financial condition and access to sources of liquidity could be materially adversely affected.

Moreover, we sell, and will continue to sell, certain pharmaceutical products 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. 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.

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 previously announced.

The U.S. 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.

Although we have recorded reserves related to certain 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 35% of our revenues comes from sales outside of the U.S., a percentage we expect to increase as we expand our non-U.S. operations. As a result, we are subject to significant foreign currency risks, 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.

In particular, although the majority of our net sales and operating costs is recorded in, or linked to, the U.S. dollar, our reporting currency, in 2010 we recorded sales and expenses in over 30 other currencies. Approximately 60% of our operating costs in 2010 was incurred in currencies other than the U.S. dollar, particularly in euros, Israeli shekels, Hungarian forints, Canadian dollars and the British pound. As a result, fluctuations in exchange rates between the currencies in which such costs are incurred and the U.S. dollar may have a material adverse effect on our results of operations, the value of balance sheet items denominated in foreign currencies and our financial condition.

We use derivative financial instruments to manage some of our net exposure to currency exchange rate fluctuations in the major foreign currencies in which we operate. We do not use derivative financial instruments or other “hedging” techniques to cover all of our potential exposure, and some elements of our financial statements, such as our equity position or operating profit, are not fully protected against foreign currency exposures. Therefore, we cannot assure you 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, particularly as government revenues have decreased in recent years. Both private and governmental entities are seeking ways to reduce or contain healthcare costs. In many countries and regions where we operate, including the U.S., Western Europe, Israel, Russia, certain countries in Central and Eastern Europe and several countries in Latin America, pharmaceutical prices are subject to new government policies. 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.

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.

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

We are a global pharmaceutical company with worldwide operations. Although over 85% 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 U.S. 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 the brand—generic 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.

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 continuing through 2010, 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. There is a risk that the increased scrutiny of the European pharmaceutical sector may lead to changes in the regulation of our business that would have an adverse impact on our results of operations in Europe.

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

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

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

In addition, we rely on complex information technology systems, including Internet-based systems, to support our supply-chain processes as well as internal and external communications. The size and complexity of our systems make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes that may result in the loss of key information or the impairment of production and other supply chain processes. Such disruptions and breaches of security could adversely affect our business.

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 2010 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.

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 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. Heightened regulatory scrutiny in recent years has resulted in substantial additional compliance costs. Under certain circumstances, 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 generally 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 noncompliant 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.

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. Currently pending Israeli legislation may effect the duration of data exclusivity provisions as well as patent term extension provisions.

The increased amount of intangible assets and goodwill recorded on our balance sheet 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. In process research and development and 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 as a result of our recent acquisitions, and may 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 may lead to further impairment charges in the future. In addition, we may from time to time sell assets that we determine are not critical to our strategy or execution. Future events or decisions may lead to asset impairments and/or related charges. Certain non-cash impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment. Any significant impairment charges could have a material adverse effect on our results of operations.

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.

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 Israeli and other government programs and tax benefits that generally carry conditions that we must meet in order to be eligible to obtain such benefits.

If we fail to meet the conditions upon which certain favorable tax treatment is based, we would not be able to claim future tax benefits and could be required to refund tax benefits already received. Additionally, some of these programs and the related tax benefits are available to us for a limited number of years, and these benefits expire from time to time.

Any of the following could have a material effect on our overall effective tax rate:

- some government programs may be discontinued,
- 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.

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

Given the increasing size, complexity and global reach of our business and our multiple areas of focus, each of which would be a significant stand-alone company, we are especially reliant upon our ability to recruit and retain highly qualified management and other employees. In addition, the success of our research and development activities depends on our ability to attract and retain sufficient numbers of skilled scientific personnel. Any loss of service of key members of our organization, or any diminution in our ability to continue to attract high-quality employees, may delay or prevent the achievement of major business objectives.

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.