

## RISK FACTORS

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

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

Our financial results depend upon our ability to commercialize additional generic and specialty pharmaceutical products, particularly during this period of transition when our leading specialty medicine, Copaxone®, faces increasing competition. Commercialization requires that we successfully develop, test and manufacture both generic and specialty products. All of our products must receive regulatory approval and meet (and continue to comply with) regulatory and safety standards; if health or safety concerns arise with respect to a product, we may be forced to withdraw it from the market.

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

***Our leading specialty medicine, Copaxone®, faces increasing competition, including from orally-administered therapies and potential generic versions.***

Any substantial decrease in the revenues derived from our specialty medicines would have an adverse effect on our results of operations, several of which currently face, or will soon face, intense competition. Our multiple sclerosis franchise includes our Copaxone® products and laquinimod (a developmental compound for the treatment of MS). The profitability of our multiple sclerosis franchise is comprised of Copaxone® revenues and cost of goods sold as well as S&M and R&D expenses related to our MS franchise. It does not include G&A expenses, amortization and non-recurring items. Our MS franchise profitability was \$3.3 billion, \$3.0 billion and \$2.8 billion in 2013, 2012 and 2011, respectively. Profitability of our multiple sclerosis franchise as a percentage of Copaxone® revenues was 76%, 74% and 79% in 2013, 2012 and 2011, respectively.

Although Copaxone® remains the leading therapy for multiple sclerosis to date, it faces intense competition from existing injectable products, such as Avonex®, Betaseron®, Extavia®, Rebif® and Tysabri®, and from oral treatments, such as Gilenya®, which was introduced in 2010 by Novartis, Genzyme’s Aubagio®, which was introduced in 2012, and Biogen’s Tecfidera®, which was introduced in 2013. These new oral treatments provide especially intense competition in light of their substantial convenience in comparison to injectables such as Copaxone®. Also, our patents on Copaxone® have been challenged, and as a result we may face generic competition in the United States as early as May 2014. In addition, our business strategy for Copaxone® relies heavily on the successful introduction of a three-times-a-week product and the migration of a substantial percentage of current daily Copaxone® patients to this new version. The failure to achieve our objectives for the new version would likely have a material adverse effect on our financial results and cash flow.

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

We are required to comply with the U.S. Foreign Corrupt Practices Act (the “FCPA”) and similar anti-corruption laws in other jurisdictions around the world where we do business. Compliance with these laws has been subject to increasing focus and activity by regulatory authorities in recent years. Actions by our employees,

---

## Table of Contents

or third-party intermediaries acting on our behalf, in violation of such laws, whether carried out in the United States or elsewhere in connection with the conduct of our business (including our business practices currently under investigation, as described below) may expose us to liability for violations of the FCPA or other anti-corruption laws and accordingly may have a material adverse effect on our reputation and our business, financial condition or results of operations.

Beginning in 2012, we received subpoenas and informal document requests from the SEC and the Department of Justice ("DOJ") to produce documents with respect to compliance with the FCPA in certain countries. We have provided and will continue to provide documents and other information to the SEC and the DOJ, and are cooperating with the government in their investigations of these matters. We are also conducting a voluntary worldwide investigation into certain business practices that may have FCPA implications and have engaged independent counsel to assist in the investigation. In the course of our investigation, which is continuing, we have identified issues in Russia, certain Eastern European countries, certain Latin American countries and other countries where we conduct business that could rise to the level of FCPA violations and/or violations of local law. We have brought these issues to the attention of the SEC and the DOJ.

Our internal investigation is not complete and additional issues or facts could become known to management as the investigation continues, which may expand the scope or severity of the potential violations and/or extend to additional jurisdictions beyond those described above. Our investigation is expected to continue through the end of 2014 and may continue beyond that date.

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

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

We must invest increasingly significant resources to develop specialty medicines, (including our strategic focus on developing new therapeutic entities, as well as the development of complex generics), both through our own efforts and through collaborations and in-licensing or acquisition of products from or with third parties. The development of specialty medicines involves processes and expertise different from those used in the development of generic medicines, which increases the risks of failure that we face. For example, the time from discovery to commercial launch of a specialty medicine can be 15 years or even longer, and involves multiple stages: not only intensive preclinical and clinical testing, but also highly complex, lengthy and expensive approval processes which can vary from country to country. The longer it takes to develop a product, the less time there will be for us to recover our development costs and generate profits.

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

insufficient clinical trial data to support the safety or efficacy of the product candidate; and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured.

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

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

In December 2012, we announced a cost reduction program intended to result in \$2 billion in cost reductions by the end of 2017, with half of that targeted by the end of 2014. As part of this program, we are reducing our employee headcount by approximately 10%. This program, the first of its magnitude in our history, is a significant pillar of our strategy, with much of the expected savings targeted for reinvestment in our business. The announced plan for headcount reductions has generated intense governmental and union opposition in Israel and may generate similar opposition in European countries and other locations where we have significant numbers of unionized employees. If such opposition limits our ability to carry out workforce-related aspects of our cost savings program or causes us to grant significant financial concessions, our ability to achieve planned cost reductions will be further impacted. If we are unable to achieve our cost reduction targets during the expected timeframes, our results of operations will be negatively affected and our ability to execute other aspects of our strategy may be slowed or undermined.

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

As a key part of our strategy, we continue to be engaged in various stages of evaluating or pursuing potential acquisitions, collaborations and licenses, among other transactions. Our reliance on acquisitions and other transactions as a means of growth involves risks that could adversely affect our future revenues and operating results. For example:

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

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

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

In recent years, there has been increasing regulatory scrutiny of pharmaceutical manufacturers, resulting in product recalls, plant shutdowns and other required remedial actions. We have been subject to increasing scrutiny of our manufacturing operations, and several of our facilities have been the subject of significant regulatory actions requiring substantial expenditures of resources to ensure compliance with more stringently applied production and quality control regulations. These regulatory actions also adversely affected our ability to supply various products worldwide and to obtain new product approvals at such facilities. If any regulatory body were to require one or more of our significant manufacturing facilities to cease or limit production, our business could be adversely affected. In addition, because regulatory approval to manufacture a drug is site-specific, the delay and cost of remedial actions, or obtaining approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations.

***We may be susceptible to significant product liability claims that are not covered by insurance.***

Our business inherently exposes us to claims for injuries allegedly resulting from the use of our products. As 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. For example, during 2010 and 2011, juries awarded approximately \$800 million in compensatory and punitive damages against us and our distributors related to claims involving our propofol product. We expect the potential for product liability claims to increase further if recently proposed regulations that permit companies to change the labeling of their generic products take effect.

Many of the products we sell are not covered by insurance, and even those that are covered are subject to a very high deductible and/or self-insured retention. Product liability coverage for pharmaceutical companies, including us, continues to become more expensive and increasingly difficult to obtain and accordingly the trend is to seek coverage only for catastrophic liability. In addition, where claims are made under insurance policies, insurers may reserve the right to deny coverage on various grounds.

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

We have been involved in numerous litigations involving challenges to the validity or enforceability of listed patents (including our own), and therefore settling patent litigations has been and is likely to continue to be an important part of our business. Parties to such settlement agreements in the U.S., including us, are required by law to file them with the Federal Trade Commission ("FTC") and the Antitrust Division of the DOJ for review.

## [Table of Contents](#)

The FTC has publicly stated that, in its view, some of the brand-generic settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies, including us, that have entered into such agreements. Accordingly, we may receive formal or informal requests from the FTC for information about a particular settlement agreement, and there is a risk that the FTC may commence an action against us alleging violations of the antitrust laws. See “Competition Matters” in Note 14 to our consolidated financial statements.

Such settlement agreements may further expose us to claims by purchasers of the products for unlawfully inhibiting competition. We are currently defendants in private antitrust actions involving numerous settlement agreements, and in 2013 we recorded a provision of \$495 million in connection with certain modafinil antitrust litigation, including amounts paid to settle certain of the claims. However, there can be no assurance that such amount will be sufficient to settle the matter with the remaining plaintiffs.

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

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

In 2013, over 48% of our revenues came from sales outside the United States, a percentage that 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, Central and Eastern European countries and Asia, is recorded in local currencies, which exposes us to the direct risk of devaluations, hyperinflation or exchange rate fluctuations. 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 2013 we recorded sales and expenses in 37 other currencies. Approximately 55% of our operating costs in 2013 were incurred in currencies other than the U.S. dollar, particularly in euros, Israeli shekels, Hungarian forints, Canadian dollars, Japanese yen and the British pound. As a result, fluctuations in exchange rates between the currencies in which such costs are incurred and the U.S. dollar may have a material adverse effect on our results of operations, the value of balance sheet items denominated in foreign currencies and our financial condition.

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

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

The success of our specialty medicines depends substantially on our ability to obtain patents and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products identical or similar to ours. We have been issued numerous patents covering

our specialty medicines, and have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the United States. Currently pending patent applications may not result in issued patents or be approved on a timely basis or at all. Any existing or future patents issued to or licensed by us may not provide us with any competitive advantages for our products or may be challenged or circumvented by competitors.

We are currently engaged in lawsuits challenging the validity and/or enforceability of the patents covering Copaxone®, our leading specialty medicine, Azilect®, Fentora®, Nuvigil®, ProAir® HFA and Treanda®. While we intend to defend the validity of these patents vigorously, and will seek to use all appropriate methods to prevent their infringement, such efforts are expensive and time consuming. Due to the nature of litigation, there can be no assurance that such efforts will be successful. Our ability to enforce our patents also depends on the laws of individual countries and each country's practices regarding the enforcement of intellectual property rights. The loss of patent protection or regulatory exclusivity on these or other specialty medicines could materially impact our business, results of operations, financial conditions or prospects.

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

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

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

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

In addition, "tender systems" for generic pharmaceuticals have been implemented (by both public and private entities) in a number of significant markets in which we operate, including Germany and Russia, in an effort to lower prices. Under such tender systems, manufacturers submit bids that establish prices for generic

pharmaceutical products. These measures impact marketing practices and reimbursement of drugs and may further increase pressure on 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 effect on our business, financial position and results of operations.

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

We operate around the world in complex legal and regulatory environments, and any failure to comply with applicable laws, rules and regulations may result in civil and/or criminal legal proceedings. As those rules and regulations change or as interpretations of those rules and regulations evolve, our prior conduct or that of companies we have acquired may be called into question. In the United States, we are currently responding to federal investigations into our marketing practices with regard to several of our specialty pharmaceutical products, which could result in civil litigation brought on behalf of the federal government. Responding to such investigations is costly and involves a significant diversion of management's attention. Such proceedings are unpredictable and may develop over lengthy periods of time. Future settlements may involve large cash penalties. In addition, government authorities have significant leverage to persuade pharmaceutical companies to enter into corporate integrity agreements, which can be expensive and disruptive to operations. See "Government Investigations, Pricing and Other Investigations" in Note 14 to our consolidated financial statements.

***Uncertainties related to our recent management changes may adversely affect our business, strategy and financial results.***

In January 2014, we announced the appointment of Erez Vigodman as our President and Chief Executive Officer, effective February 11, 2014. Mr. Vigodman is our fifth CEO since 2007 and the fourth since 2012. As a result of these frequent management transitions, we may face uncertainties regarding our future business strategy and direction. These uncertainties may cause or result in disruption of our business or distraction of our employees and management; difficulty in recruiting, hiring, motivating, and retaining talented and skilled personnel, including current members of management; and difficulty in negotiating, maintaining, or consummating business or strategic relationships or transactions. If we are unable to mitigate these or other potential risks, our revenue, operating results, and financial condition may be adversely impacted.

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

Over the last eight years, our short- and long-term indebtedness has increased from approximately \$2.1 billion to approximately \$12.2 billion. As a result, our principal and interest payment obligations have increased substantially, as have our costs relating to financing activities. The degree to which we are leveraged could affect our ability to obtain additional financing for working capital, acquisitions, refinancing of existing debt or other purposes and could make us more vulnerable to industry downturns and competitive pressures as well as interest rate and other refinancing risks. In addition, due in part to the continuing effects of the unstable economic environment, capital markets have been more volatile in recent times. Such volatility may adversely affect our ability to obtain financing on favorable terms at a time when we face the need to access the capital markets regularly. Our ability to refinance existing debt and meet our debt service obligations will be dependent upon our future performance and access to the capital markets, which will be subject to financial, business and other factors affecting our operations (including our long-term unsecured credit ratings), many of which are beyond our control.

***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 2013, we added new senior management personnel,



including a new strategy officer, among others, and in early 2014 we named a new chief executive officer, who is the fourth person to lead our company since 2012. In addition, the success of our research and development activities depends on our ability to attract and retain sufficient numbers of skilled scientific personnel. Any loss of service of key members of our organization, or any diminution in our ability to continue to attract high-quality employees, may delay or prevent the achievement of major business objectives. In addition, there is a risk that we will not strike the appropriate balance between retaining existing managerial talent and achieving the targets of the cost reduction program mentioned above.

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

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

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

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

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

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

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.



***Significant disruptions of our information technology systems or breaches of our data security could adversely affect our business.***

A significant invasion, interruption, destruction or breakdown of our information technology systems and/or infrastructure by persons with authorized or unauthorized access could negatively impact our business and operations. We could also experience business interruption, information theft and/or reputational damage from cyber attacks, which may compromise our systems and lead to data leakage either internally or at our third party providers. Our systems have been, and are expected to continue to be, the target of malware and other cyber attacks. Although we have invested in measures to reduce these risks, we cannot assure you that these measures will be successful in preventing compromise and/or disruption of our information technology systems and related data.

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

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

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

Furthermore, brand pharmaceutical companies continue to defend their products vigorously. For example, brand companies often sell or license their own generic versions of their products, either directly or through other generic pharmaceutical companies (so-called “authorized generics”). No significant regulatory approvals are required for authorized generics, and brand companies do not face any other significant barriers to entry into such market. Brand companies may seek to delay introductions of generic equivalents through a variety of commercial and regulatory tactics. These actions may increase the costs and risks of our efforts to introduce generic products and may delay or prevent such introduction altogether.

***Our specialty pharmaceuticals business faces intense competition from companies that have greater resources and capabilities.***

We face intense competition in our specialty pharmaceutical business. Many of our competitors are larger and/or have substantially greater experience in the development and marketing of branded, innovative and consumer-oriented products. They may be able to respond more quickly to new or emerging market preferences or to devote greater resources to the development and marketing of new products and/or technologies than we can. As a result, any products and/or innovations that we develop may become obsolete or noncompetitive before we can recover the expenses incurred in connection with their development. In addition, for these product categories we must demonstrate to physicians, patients and third-party payors the benefits of our products relative to competing products that are often more familiar or otherwise 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 increased focus on innovative and specialty pharmaceuticals requires much greater use of a direct sales force than does our core generic business. Our ability to realize significant revenues from direct marketing and sales activities depends on our ability to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. We may also need to enter into co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or

sufficiently well-aligned to achieve maximum penetration in the market. Any failure to attract or retain qualified sales personnel or to enter into third-party arrangements on favorable terms could prevent us from successfully maintaining current sales levels or commercializing new innovative and specialty products.

***Decreased opportunities to obtain U.S. market exclusivity for generic versions of significant products may adversely affect our revenues and profits.***

Our ability to achieve continued growth and profitability through sales of generic pharmaceuticals is dependent on our success in challenging patents, developing non-infringing products or developing products with increased complexity to provide opportunities with U.S. market exclusivity or limited competition. The failure to continue to develop such opportunities could adversely affect our sales and profitability.

To the extent that we succeed in being the first to market a generic version of a 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, as provided under the Hatch-Waxman Act, our sales, profits and profitability can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of an equivalent product. Even after the exclusivity period ends, there is often continuing benefit from being the first generic product in the market.

However, the number of significant new generic products for which Hatch-Waxman exclusivity is available, and the size of those product opportunities, has decreased in recent years, and patent challenges have become more difficult. Additionally, increasingly we share the 180-day exclusivity period with other generic competitors, which diminishes the commercial value of the exclusivity.

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

***We have sold and may in the future elect to sell generic products prior to the final resolution of outstanding patent litigation, and, as a result, we could be subject to liability for damages in the U.S., Europe and other markets where we do business.***

Our ability to introduce new products depends in large part upon the success of our challenges to patent rights held by third parties or our ability to develop non-infringing products. Based upon a variety of legal and commercial factors, we may elect to sell a generic product even though patent litigation is still pending, either before any court decision is rendered or while an appeal of a lower court decision is pending. The outcome of such patent litigation could, in certain cases, materially adversely affect our business. For example, we launched a generic version of Protonix® (pantoprazole), despite the fact that litigation with the company that sells the brand versions was still pending at the time. In 2013, we settled the pantoprazole litigation and recorded aggregate charges of \$1.6 billion in 2012 and 2013 related to this matter.

If we sell products prior to a final court decision, whether in the United States, Europe or elsewhere, and such decision is adverse to us, we could be required to cease selling the infringing products, causing us to lose future sales revenue from such products and to face substantial liabilities for patent infringement, in the form of either payment for the innovator's lost profits or a royalty on our sales of the infringing products. These damages may be significant, and could materially adversely affect our business. In the United States, in the event of a finding of willful infringement, the damages 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.

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

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

***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 2013 accounted for 17% 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.

***The large amount of intangible assets and goodwill recorded on our balance sheet may continue to lead to significant impairment charges in the future.***

We regularly review our long-lived assets, including identifiable intangible assets and goodwill, for impairment. Goodwill and acquired indefinite life intangible assets are subject to impairment review on an annual basis and whenever potential impairment indicators are present. Other long-lived assets are reviewed when there is an indication that an impairment may have occurred. The amount of goodwill and identifiable intangible assets on our consolidated balance sheet has increased significantly in recent years to \$25.5 billion as a result of our acquisitions, and may increase further following future acquisitions. For example, in 2013, we recorded identifiable intangible assets impairment charges of \$393 million. Changes in market conditions or other changes in the future outlook of value may lead to further impairment charges in the future. In addition, we may from time to time sell assets that we determine are not critical to our strategy or execution. Future events or decisions may lead to asset impairments and/or related charges. Certain non-cash impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment. Any significant impairment charges could have a material adverse effect on our results of operations.

***Our tax liabilities could be larger than anticipated.***

We are subject to tax in many jurisdictions, and significant judgment is required in determining our provision for income taxes. Likewise, we are subject to audit by tax authorities in many jurisdictions. In such audits, our interpretation of tax legislation might be challenged and tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions under our inter-company agreements. For example, in 2013, we paid the Israeli tax authorities approximately \$790 million in additional income taxes, applying the provisions of Amendment 69 to the Israeli Law for the Encouragement of Capital Investments, 1959 to certain previously tax-exempt profits, as well as to settle tax assessments for the years 2005 to 2007. Although we believe our estimates are reasonable, the ultimate outcome of such audits and related litigation could be different from our provision for taxes and might have a material adverse effect on our consolidated financial statements.

***The termination or expiration of governmental programs or tax benefits, or a change in our business, could adversely affect our overall effective tax rate.***

Our tax expenses and the resulting effective tax rate reflected in our consolidated financial statements are likely to increase over time as a result of changes in corporate income tax rates, other changes in the tax laws of the various countries in which we operate or changes in our product mix or the mix of countries where we generate profit. We have benefited, and currently benefit, from a variety of Israeli and other government programs and tax benefits that generally carry conditions that we must meet in order to be eligible to obtain such benefits. If we fail to meet the conditions upon which certain favorable tax treatment is based, we would not be able to claim future tax benefits and could be required to refund tax benefits already received. Additionally, some of these programs and the related tax benefits are available to us for a limited number of years, and these benefits expire from time to time.

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

- some government programs may be discontinued, or, as is the case in Israel from 2014 and on, the applicable tax rates may increase;
- we may be unable to meet the requirements for continuing to qualify for some programs;
- these programs and tax benefits may be unavailable at their current levels;
- upon expiration of a particular benefit, we may not be eligible to participate in a new program or qualify for a new tax benefit that would offset the loss of the expiring tax benefit; or
- we may be required to refund previously recognized tax benefits if we are found to be in violation of the stipulated conditions.

***Because our facilities are located throughout the world, we are subject to varying patent laws that may adversely affect our ability to manufacture our products.***

We are subject to legislation in all countries where we have manufacturing facilities relating to patents. Modifications of such legislation or court decisions regarding such legislation may adversely affect us and may impact our ability to export product-manufactured in any such country in a timely fashion. Additionally, the existence of third-party patents in such countries, with the attendant risk of litigation, may cause us to move production to a different country (with potentially serious timing delays) or otherwise adversely affect our ability to export certain products from such countries.

***Our failure to comply with applicable environmental laws and regulations worldwide could adversely impact our business and results of operations.***

We are subject to laws and regulations concerning the environment, safety matters, regulation of chemicals and product safety in the countries where we manufacture and sell our products or otherwise operate our business. These requirements include regulation of the handling, manufacture, transportation, storage, use and disposal of materials, including the discharge of pollutants into the environment. In the normal course of our

---

[Table of Contents](#)

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.