

### **3.D. Risk factors**

You should carefully consider all of the information set forth in this Form 20-F and the following risk factors that we face and that are faced by our industry. The risks below are not the only ones we face. Additional risks not currently known to us or that we presently deem immaterial may also affect our business operations. Our business, financial condition or results of operations could be materially or adversely affected by any of these risks. This Form 20-F 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 we face as described below and elsewhere. See "Forward-Looking Statements."

#### **RISKS RELATING TO OUR COMPANY AND OUR BUSINESS**

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

Our future results of operations depend, to a significant degree, upon our ability to successfully develop and commercialize additional products in our Pharmaceutical Services and Active Ingredients, Global Generics and Proprietary Products segments. We must develop, test and manufacture generic products as well as prove that our generic products are bio-equivalent or bio-similar to their branded counterparts, either directly or in partnership with contract research organizations. The development and commercialization process, particularly with respect to proprietary 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 or meet our standards of safety and efficacy. Necessary regulatory approvals may not be obtained in a timely manner, if at all, and we may not be able to successfully and profitably produce and market such products. Our approved products may not achieve expected levels of market acceptance.

**If we fail to comply fully with government regulations or to maintain continuing regulatory oversight applicable to our research and development activities or regarding the manufacture of our products, or if a regulatory agency amends or withdraws existing approvals to market our products, it may delay or prevent us from developing or manufacturing our products.**

Our research and development activities are heavily regulated. If we fail to comply fully with applicable regulations, then there could be a delay in the submission or approval of potential new products for marketing approval. In addition, the submission of an application to a regulatory authority does not guarantee that approvals required to market the product will be granted. Each authority may impose its own requirements and/or delay or refuse to grant approval, even when a product has already been approved in another country. In the United States, as well as many of the international markets into which we sell our products, the approval process for a new product is complex, lengthy and expensive. The time taken to obtain approval varies by country but generally takes from six months to several years from the date of application. This approval process increases the cost to us of developing new products and increases the risk that we will not be able to successfully sell such new products.

Regulatory agencies may at any time reassess the safety and efficacy of our products based on new scientific knowledge or other factors. Such reassessments could result in the amendment or withdrawal of existing approvals to market our products, which in turn could result in a loss of revenue, and could serve as an inducement to bring lawsuits against us. In our bio-generics business, due to the intrinsic nature of biologics, our bio-similarity claims can always be contested by our competitors, the innovator company and/or the applicable regulators.

Additionally, governmental authorities, including among others the U.S. Food and Drug Administration ("U.S. FDA") and the U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA"), heavily regulate the manufacturing of our products, including manufacturing quality standards. Periodic audits are conducted on our manufacturing sites, and if the regulatory and quality standards and systems are not found adequate, it could result in an audit observation (on Form 483, if from the U.S. FDA), or a subsequent investigative letter which may require further corrective actions. If we or our third party suppliers fail to comply fully with such regulations or to take corrective actions which are mandated, then there could be a government-enforced shutdown of our production facilities or a Detention Without Physical Examination ("DWPE") import ban (e.g., see the description in Item 4.a. below of the June 2011 DWPE import ban for our manufacturing facility at Cuernavaca, Mexico), which in turn could lead to product shortages that delay or prevent us from fulfilling our obligations to customers, or we could be subjected to government fines. Failure to comply fully with such regulations could also lead to a delay in the approval of our new products.

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An increasing portion of our portfolio are “biologic” products. Unlike traditional “small-molecule” drugs, biologic drugs cannot be manufactured synthetically, but typically must be produced from living plant or animal micro-organisms. As a result, the production of biologic drugs that meet all regulatory requirements is especially complex. Even slight deviations at any point in the production process may lead to batch failures or recalls. In addition, because the production process is based on living micro-organisms, the process could be affected by contaminants that could impact those micro-organisms. In such an event, production shutdowns and extensive and extended decontamination efforts may be required.

The regulatory requirements are still evolving in many developing markets where we sell or manufacture products, including our bio-similar products. In these markets, the regulatory requirements and the policies and opinions of regulators may at times be unclear, inconsistent or arbitrary due to absence of adequate precedents or for other reasons. As a result, there is increased risk of withholding or delay of regulatory approvals for new products or government-enforced shutdowns and other sanctions. And, in some cases, there is increased risk of our inadvertent non-compliance with such regulations.

**There has been a trend of increased regulatory review of over-the-counter products for safety and efficacy questions, which could potentially affect our over-the-counter products business.**

Our over-the-counter products business sells over-the-counter medicines. In recent years, significant questions have arisen regarding the safety, efficacy and potential for misuse of certain over-the-counter medicine products. As a result, health authorities around the world have begun to re-evaluate some important over-the-counter products, leading to restrictions on the sale of some of them and even the banning of certain products. For example, in 2010, the U.S. FDA undertook a review of one cough medicine ingredient to consider whether over-the-counter sales of the ingredient remained appropriate. While the U.S. FDA has not, to date, changed the ingredient’s status, further regulatory or legislative action may follow, and litigation sometimes follows actions such as these, particularly in the United States. Additional actions and litigation regarding over-the-counter products are possible in the future. If the U.S. FDA or another regulator were to review one or more of our over-the-counter products for such purposes, it could have a significant adverse effect on our sales of such over-the-counter products and, thus, our overall profitability.

**Risks from operations in certain countries susceptible to political or economic instability.**

We are a global pharmaceutical company. Although a significant proportion of our sales are in North America (the United States and Canada) and Western Europe, we expect to derive an increasing portion of our sales and future growth from other regions, such as Latin America, Russia and other countries of the former Soviet Union, Central Europe, Eastern Europe and South Africa, all of which may be more susceptible to political or economic instability.

We monitor significant political, legal and economic developments in these regions and attempt to mitigate our exposure where possible. However, mitigation is not always possible, and our international operations could be adversely affected by political, legal and economic developments, such as changes in capital and exchange controls; expropriation and other restrictive government actions; intellectual property protection and remedy laws; trade regulations; procedures and actions affecting approval, production, pricing and marketing of, reimbursement for and access to our products; and intergovernmental disputes, including embargoes and/or military hostilities.

In addition, in many less-developed markets, we rely heavily on third-party distributors and other agents for the marketing and distribution of our products. Although our policies prohibit these third parties from making improper payments or otherwise engaging in improper activities to influence the procurement decisions of government agencies, physicians, pharmacies, hospitals or other health care professionals, we may not be able to effectively manage these third parties. Many of these third parties do not have internal compliance resources comparable to ours. Business activities in many of these markets have historically been more susceptible to corruption. If our efforts to screen third-party agents and detect cases of potential misconduct fail, we could be held responsible and subjected to civil and criminal penalties for the noncompliance of these third parties under applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act, which may have a material adverse effect on our reputation and our business, financial condition or results of operations.

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Significant portions of our operations are conducted outside the markets in which our products are sold, and accordingly we often import a substantial number of products into such markets. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship products from any of our sites as a result of 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.

**If we are sued by consumers for defects in our products, it could harm our reputation and thus our profits.**

Our business inherently exposes us to potential product liability claims, and the severity and timing of such claims are unpredictable. Notwithstanding pre-clinical and clinical trials conducted during the development of potential products to determine the safety and efficacy of products for use by humans following approval by regulatory authorities, unanticipated side effects may become evident only when drugs and bio-similars are introduced into the marketplace. Due to this fact, our customers and participants in clinical trials may bring lawsuits against us for alleged product defects. In other instances, third parties may perform analyses of published clinical trial results which raise questions regarding the safety of pharmaceutical products, and which may be publicized by the media. Even if such reports are inaccurate or misleading, in whole or in part, they may nonetheless result in claims against us for alleged product defects.

Historically, in the event a patient or group of patients suffered adverse events from taking the generic version of a branded drug in the United States, generic pharmaceutical manufacturers relied on U.S. laws which permitted them to pass that liability back to the innovator pharmaceutical company that originally brought the branded drug to market. However in recent years, courts across the United States have begun to hold the generic manufacturers directly responsible for the safety of their drugs and have found them to be strictly liable for injuries emanating from the use of generics.

Product liability claims, regardless of their merits or the ultimate success of the defense against them, are costly. Although we have obtained product liability coverage with respect to products that we manufacture and the clinical trials that we conduct, if any product liability claim sustained against us is not covered by insurance or exceeds the policy limits, it could harm our business and financial condition.

This risk is likely to increase as we develop our own new-patented products in addition to making generic versions of drugs that have been in the market for some time. In addition, the existence or even threat of a major product liability claim could also damage our reputation and affect consumers' views of our other products, thereby negatively affecting our business, financial condition and results of operations.

Product liability insurance coverage for pharmaceutical companies is becoming more expensive and, from time to time, the pharmaceutical industry has experienced difficulty in obtaining desired amounts of product liability insurance coverage. As a result, it is possible that, in the future, we may not be able to obtain the type and amount of coverage we desire at an acceptable price and self-insurance may become the sole commercially reasonable means available for managing the product liability risks of our business.

**Reforms in the health care industry and the uncertainty associated with pharmaceutical pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for our products.**

Our success will depend in part on the extent to which government and health administration authorities, private health insurers and other third-party payors will pay for our products. Increasing expenditures for health care has been the subject of considerable public attention in almost every jurisdiction where we conduct business. Both private and governmental entities are seeking ways to reduce or contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products. These pressures are particularly strong given the lingering effects of the recent global economic and financial crisis, including the ongoing debt crisis in certain countries in Europe. In many countries in which we currently operate, including India, pharmaceutical prices are subject to regulation. The existence of government-imposed price controls and mandatory discounts and rebates can limit the revenues we earn from our products. We expect these efforts to continue in the year ended March 31, 2013 as healthcare payors around the globe—in particular government-controlled health authorities, insurance companies and managed care organizations—step up initiatives to reduce the overall cost of healthcare.

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In the United States, numerous proposals that would affect changes in the health care system have been introduced in Congress and in some state legislatures, including the enactment in December 2003 of expanded Medicare coverage for drugs, which became effective in January 2006. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA"), were signed into law. The PPACA is one of the most significant healthcare reform measures in the United States in decades, and is expected to significantly impact the U.S. pharmaceutical industry. We may see an increase in revenues by virtue of the PPACA's anticipated extension of health insurance to tens of millions of previously uninsured Americans and the prohibitions on denials of health insurance coverage due to pre-existing diseases and on lifetime value limits on insurance policy coverage. However, the PPACA contains various provisions which could adversely affect our business, including the following:

- The PPACA imposes on pharmaceutical manufacturers a variety of additional rebates, discounts and fees. Among other things, the PPACA includes annual, non-deductible fees for entities that manufacture or import certain prescription drugs and biologics. The first year for which the fee applies is calendar year 2011, and the fee is due by September 30 of the following calendar year (i.e., 2012). This fee is calculated based upon each organization's percentage share of total branded prescription drug and biologics sales to U.S. government programs (such as Medicare, Medicaid and Veterans' Affairs and Public Health Service discount programs), and authorized generic products are generally treated as branded products. The manufacturer must have at least \$5 million in sales of branded prescription drugs or biologics in order to be subject to the fee.

In April 2012, we received an invoice from the United States Internal Revenue Service (the "IRS") estimating our liability for the manufacturers' fee for calendar year 2011 to be \$92,696, based upon our calendar year 2010 sales of branded and authorized generic prescription drugs and biologics. We expect our sales of brand and authorized generic products during calendar year 2011 to be below the threshold limit of \$5 million, and thus we may not be subject to the fee for calendar year 2012, based on our calendar year 2011 sales.

- In addition, the PPACA changed the computations used to determine Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program by redefining the average manufacturer's price ("AMP"), effective October 1, 2010, and by using 23.1% instead of 15% of AMP for most branded drugs and 13% instead of 11% of AMP for generic drugs, effective January 1, 2010. The PPACA also increased the number of healthcare entities eligible for discounts under the Public Health Service pharmaceutical pricing program.
- The PPACA has pro-generic provisions that could increase competition in the generic pharmaceutical industry and therefore adversely impact our selling prices or costs and reduce our profit margins. Among other things, the PPACA creates an abbreviated pathway to U.S. FDA approval of "biosimilar" biological products and allows the first interchangeable bio-similar biological product 18 months of exclusivity, which could increase competition for our bio-generics business. Conversely, the PPACA has some anti-generic provisions that could adversely affect our bio-generics business, including provisions granting the innovator of a biological drug product 12 years of exclusive use before generic drugs can be approved based on being biosimilar.
- The PPACA makes several important changes to the federal anti-kickback statute, false claims laws, and health care fraud statutes that may make it easier for the government or whistleblowers to pursue such fraud and abuse violations. In addition, the PPACA increases penalties for fraud and abuse violations. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and our financial results.
- To further facilitate the government's efforts to coordinate and develop comparative clinical effectiveness research, the PPACA establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in such research. The manner in which the comparative research results would be used by third-party payors is uncertain.
- On January 27, 2012, The Centers for Medicare and Medicaid Services ("CMS") issued its long awaited proposed rule implementing the Medicaid pricing and reimbursement provisions of PPACA and related legislation. CMS accepted comments on this proposed rule through April 2, 2012, and we are waiting for CMS to issue a final rule.

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On June 28, 2010 the Departments of Health and Human Services, Labor, and the Treasury jointly issued interim final regulations to implement the provisions of PPACA that prohibit the use of preexisting condition exclusions, eliminate lifetime and annual dollar limits on benefits, restrict contract rescissions, and provide patient protections.

During the year ended March 31, 2011, the PPACA's changes to manufacturer rebates under the Medicaid Drug Rebate Program impacted our U.S. Generics business, but the impact was not material.

On June 28, 2012, the U.S. Supreme Court ruled on certain challenged provisions of the PPACA. The U.S. Supreme Court generally upheld the constitutionality of the PPACA, including its individual mandate that requires most Americans to buy health insurance starting in 2014, and ruled that the Anti-Injunction Act did not bar the court from reviewing that PPACA provision. However, the U.S. Supreme Court struck down the PPACA's provisions requiring each state to expand its Medicaid program or lose all federal Medicaid funds. The Court did not invalidate the PPACA's expansion of Medicaid for states that voluntarily participate; it only held that a state's entire Medicaid funding cannot be withheld due to its failure to participate in the expansion.

Pending full implementation of the PPACA, we are continuing to evaluate all potential scenarios surrounding its implementation and the corresponding impact on our financial condition, results of operations and cash flow.

In Germany, an important market for us, the government has introduced several healthcare reforms in order to control healthcare spending and promote the prescribing of generic drugs. As a result, the prices of generic pharmaceutical products in Germany have declined, impacting our revenues, and may further decline in the future. Furthermore, the shift to a tender (i.e., competitive bidding) based supply model in Germany has led to a significant decline in the prices for our products and impacted our market opportunities in that country. Similar developments may take place in our other key markets. We cannot predict the nature of the measures that may be adopted or their impact on the marketing, pricing and demand for our products.

During the year ended March 31, 2012, Russia introduced Federal Law # 323, titled "On the Foundations of Healthcare for Russian Citizens". Portions of this new law became effective on November 23, 2011 and the remainder became effective on January 1, 2012. This new law imposes stringent restrictions on interactions between (i) healthcare professionals, pharmacists, healthcare management organizations, opinion leaders (both governmental and from the private sector) and certain other parties (collectively referred to as "healthcare decision makers"), and (ii) companies that produce or distribute drugs or medical equipment and any representatives or intermediaries acting on their behalf, (collectively referred to as "medical product representatives"). Some of the key provisions of this law are prohibitions on:

- one-on-one meetings and communications between healthcare decision makers and medical product representatives, except for participation in clinical trials, pharmacovigilance, group educational events and certain other limited exceptions;
- the acceptance by a healthcare decision maker of compensation, gifts or entertainment paid by medical product representatives;
- the agreement by a healthcare decision maker to prescribe or recommend drug products or medical equipment; or
- the engagement by a healthcare decision maker in a "conflict of interest" transaction with a medical product representative, unless approved by regulators pursuant to certain specified procedures.

Although certain of the above prohibitions technically restrict only the actions of healthcare decision makers, liability for non-compliance with such restrictions nonetheless extends to both the healthcare decision maker and the medical product representative. Penalties for non-compliance with this new law have not yet been clarified.

During the year ended March 31, 2012, the Department of Pharmaceuticals under the ministry of Chemicals and Fertilizers in India proposed a revised national Pharmaceutical Pricing policy. The draft policy, as published, proposed to apply price controls to 348 drugs listed in the National List of Essential Medicines (as opposed to the 74 drugs currently subject to price control in India), and to revise the price control mechanism by benchmarking the prices based on market dynamics and eliminating the current cost-based model. Pending finalization of the policy, its impact on our business cannot be ascertained.

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In addition, governments throughout the world heavily regulate the marketing of products. Most countries also place restrictions on the manner and scope of permissible marketing to government agencies, physicians, pharmacies, hospitals and other health care professionals. Although our company policies prohibit our employees and third party distributors from violating such regulations, we may not be able to effectively prevent this, especially in markets that have historically been more susceptible to corruption. The effect of such regulations may be to limit the amount of revenue that we may be able to derive from a particular product. Moreover, if we or our third party distributors fail to comply fully with such regulations, then civil or criminal actions could be brought against us, which may have a material adverse effect on our reputation and our business, financial condition or results of operations.

**If we are unable to patent new products and processes or to protect our intellectual property rights or proprietary information, or if we infringe on the patents of others, our business may be materially and adversely impacted.**

Our overall profitability depends, among other things, on our ability to continuously and timely introduce new generic as well as proprietary products. Our success will depend, in part, on our ability in the future to obtain patents, protect trade secrets, intellectual property rights and other proprietary information and operate without infringing on the proprietary rights of others. Our competitors may have filed patent applications, or hold issued patents, relating to products or processes that compete with those we are developing, or their patents may impair our ability to successfully develop and commercialize new products.

Our success with our proprietary products depends, in part, on our ability to protect our current and future innovative products and to defend our intellectual property rights. If we fail to adequately protect our intellectual property, competitors may manufacture and market products similar to ours. We have been issued patents covering our innovative products and processes and have filed, and expect to continue to file, patent applications seeking to protect our 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 even be challenged, invalidated 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.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation that we seek to protect, in part by confidentiality agreements with licensees, suppliers, employees and consultants. It is possible that these agreements will be breached and we will not have adequate remedies for any such breach. 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.

**If pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and other efforts, our sales of generic products may suffer.**

Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

- pursuing new patents for existing products that may be granted just before the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;
- selling the brand product as an authorized generic, either by the brand company directly, through an affiliate or by a marketing partner;
- using the Citizen Petition process to request amendments to U.S. FDA standards or otherwise delay generic drug approvals;

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- seeking changes to U.S. Pharmacopeia, an organization that publishes industry recognized compendia of drug standards;
- attaching patent extension amendments to non-related federal legislation;
- engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing; and
- seeking patents on methods of manufacturing certain active pharmaceutical ingredients.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products may decline. If we experience a material decline in generic product sales, our results of operations, financial condition and cash flows will suffer.

**If competitors are successful in limiting competition for certain authorized generic products through their legislative, regulatory and litigation efforts, our sales of certain generic products may suffer.**

Recently, some U.S. generic pharmaceutical companies who obtained rights to market and distribute a generic alternative of a brand product (i.e., an “authorized generics” arrangement) under the brand manufacturer’s new drug application (“NDA”) have experienced challenges to their ability to distribute authorized generics during a competitors’ 180-day period of abbreviated new drug application (“ANDA”) exclusivity under the Hatch-Waxman Act. These challenges have come in the form of Citizen Petitions filed with the U.S. FDA, lawsuits alleging violation of the antitrust and consumer protection laws, and seeking legislative intervention. For example, in February 2011, legislation was introduced in both the U.S. Senate and the U.S. House of Representatives that would prohibit the marketing of authorized generics during the 180-day period of ANDA exclusivity under the Hatch-Waxman Act. If distribution of authorized generic versions of brand products is otherwise restricted or found unlawful, our results of operations, financial condition and cash flows could be materially adversely affected.

**If we are unable to defend ourselves in patent challenges, we could be subject to injunctions preventing us from selling our products, resulting in a decrease in revenues, or we could be subject to substantial liabilities that would lower our profits.**

There has been substantial patent related litigation in the pharmaceutical industry concerning the manufacture, use and sale of various products. In the normal course of business, we are regularly subject to lawsuits and the ultimate outcome of litigation could adversely affect our results of operations, financial condition and cash flow. Regardless of regulatory approval, lawsuits are periodically commenced against us with respect to alleged patent infringements by us, such suits often being triggered by our filing of an application for governmental approval, such as an ANDA. The expense of any such litigation and the resulting disruption to our business, whether or not we are successful, could harm our business. The uncertainties inherent in patent litigation make it difficult for us to predict the outcome of any such litigation.

If we are unsuccessful in defending ourselves against these suits, we could be subject to injunctions preventing us from selling our products, resulting in a decrease in revenues, or to damages, which may be substantial. An injunction or substantial damages resulting from these suits could adversely affect our consolidated financial position, results of operations or liquidity.

**If we elect to sell a generic product prior to the final resolution of outstanding patent litigation, we could be subject to liabilities for damages.**

At times we seek approval to market generic products before the expiration of patents for those products, based upon our belief that such patents are invalid, unenforceable, or would not be infringed by our products. As a result, we are involved in patent litigation, the outcome of which could materially adversely affect our business. Based upon a complex analysis of a variety of legal and commercial factors, we may elect to market a generic product even though litigation is still pending. This could be before any court decision is rendered or while an appeal of a lower court decision is pending. To the extent we elect to proceed in this manner, if the final court decision is adverse to us, we could be required to cease the sale of the infringing products and face substantial liability for patent infringement. These damages may be significant as they may be measured by a royalty on our sales or by the profits lost by the patent owner and not by the profits we earned. Because of the discount pricing typically involved with generic pharmaceutical products, patented brand products generally realize a significantly higher profit margin than generic pharmaceutical products. In the case of a willful infringer, the definition of which is unclear, these damages may even be trebled.



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For example, in April 2006, we launched, and continue to sell fexofenadine, the generic version of Allegra®, despite the fact that litigation with the company that holds the patents for and sells this branded product is still ongoing. In Canada, we continue to sell olanzapine tablets (the generic version of Eli Lilly's Zyprexa® tablets) through a partnership with Pharmascience, Inc., despite the fact that Pharmascience has agreed to pay damages if Eli Lilly is successful in its olanzapine patent litigation against Novopharm, and our partnership arrangement with Pharmascience would require us to share a portion of any such damages obligation realized by Pharmascience.

Furthermore, there may be risks involved in entering into in-licensing arrangements for products, which are often conditioned upon the licensee's sharing in the patent-related risks.

For business reasons, we continue to examine such product opportunities (i.e., involving non-expired patents) going forward and this could result in patent litigation, the outcomes of which may impact our profitability.

**If we fail to comply with environmental laws and regulations, or face environmental litigation, our costs may increase or our revenues may decrease.**

We may incur substantial costs complying with requirements of environmental laws and regulations. In addition, we may discover currently unknown environmental problems or conditions. In all countries where we have production facilities, we are subject to significant environmental laws and regulations that govern the discharge, emission, storage, handling and disposal of a variety of substances that may be used in or result from our operations. 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 that could require remediation of contaminated soil and groundwater, which could cause us to incur substantial remediation costs that could adversely affect our consolidated financial position, results of operations or liquidity.

If any of our plants or the operations of such plants are shut down, it may severely hamper our ability to supply our customers and we may continue to incur costs in complying with regulations, appealing any decision to close our facilities, maintaining production at our existing facilities and continuing to pay labor and other costs, which may continue even if the facility is closed. As a result, our overall operating expenses may increase and our profits may decrease.

**We operate in a highly competitive and rapidly consolidating industry.**

Our products face intense competition from products commercialized or under development by competitors in all of our business segments based in India and overseas. Many of our competitors have greater financial resources and marketing capabilities than we do. Our competitors may succeed in developing technologies and products that are more effective, more popular or cheaper than any we may develop or license, thus rendering our technologies and products obsolete or uncompetitive, which would harm our business and financial results.

In our proprietary products business, many of our competitors have greater experience than we do in clinical testing, human clinical trials, obtaining regulatory approvals and in the marketing and sale of brand, innovative and consumer-oriented products. They may be able to respond more quickly to new or emerging market preferences or to devote greater resources to the development and marketing of new products and/or technologies than we can. As a result, any products and/or innovations that we develop may become obsolete or noncompetitive before we can recover the expenses incurred in connection with their development. In addition, for these product categories we need to emphasize to physicians, patients and third-party payors the benefits of our products relative to competing products that are often more familiar or otherwise more well-established. If competitors introduce new products or new variations on their existing products, our marketed products, even those protected by patents, may be replaced in the marketplace or we may be required to lower our prices.

In our generics business, to the extent that we succeed in being the first to market a generic version of a significant product, and particularly if we obtain the 180-day period of market exclusivity in the United States provided under the Hatch-Waxman Act of 1984, as amended, our sales and profit can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of the equivalent product or the launch of an authorized generic. Prices of generic drugs typically decline, often dramatically, especially as additional generic pharmaceutical companies (including low-cost generic manufacturers based in India and China) receive approvals and enter the market for a given product and competition intensifies. Consequently, our ability to sustain our sales and profitability of any product over time is dependent on both the number of new competitors for such product and the timing of their approvals.



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The number of significant new generic products for which Hatch-Waxman exclusivity is available, and the size of those product opportunities, varies significantly over time and may decrease in future years in comparison to those available in the past. Patent challenges have become more difficult in recent years. Additionally, we increasingly share the 180-day exclusivity period with other generic competitors, which diminishes the commercial value of the exclusivity.

Our generics business is also facing increasing competition from brand-name manufacturers who do not face any significant regulatory approvals or barriers to entry into the generics market. These brand-name companies sell generic versions of their products to the market directly or by acquiring or forming strategic alliances with our competitor generic pharmaceutical companies or by granting them rights to sell "authorized generics." Moreover, brand-name companies continually seek new ways to delay the introduction of generic products and decrease the impact of generic competition, such as filing new patents on drugs whose original patent protection is about to expire, developing patented controlled-release products, changing product claims and product labeling, or developing and marketing as over-the-counter products those branded products that are about to face generic competition.

Our competitors, which include major multinational corporations, are consolidating, and the strength of the combined companies could affect our competitive position in all of our business areas. Furthermore, if one of our competitors or their customers acquires any of our customers or suppliers, we may lose business from the customer or lose a supplier of a critical raw material.

**If we have difficulty in identifying candidates for or consummating acquisitions and strategic alliances, our competitiveness and our growth prospects may be harmed.**

In order to enhance our business, we frequently seek to acquire or make strategic investments in complementary businesses or products, or to enter into strategic partnerships or alliances with third parties. It is possible that we may not identify suitable acquisition, strategic investment or strategic partnership candidates, or if we do identify suitable candidates, we may not complete those transactions on terms commercially acceptable to us. We compete with others to acquire companies, and we believe that this competition has intensified and may result in decreased availability or increased prices for suitable acquisition candidates. Even after we identify acquisition candidates and/or announce that we plan to acquire a company, we may ultimately fail to consummate the acquisition. For example, we may be unable to obtain necessary regulatory approvals, including the approval of antitrust regulatory bodies.

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

- We may fail to successfully integrate our acquisitions in accordance with our business strategy.
- The initial rationale for the acquisition may not remain viable due to a variety of factors, including unforeseen regulatory changes and market dynamics after the acquisition, and this may result in a significant delay and/or reduction in the profitability of the acquisition.
- We may not be able to retain the skilled employees and experienced management that may be necessary to operate the businesses we acquire. If we cannot retain such personnel, we may not be able to locate or hire new skilled employees and experienced management to replace them.
- We may purchase a company that has contingent liabilities that include, among others, known or unknown patent or product liability claims or environmental liability claims.
- We may purchase companies located in jurisdictions where we do not have operations and as a result we may not be able to anticipate local regulations and the impact such regulations have on our business.

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In addition, if we make one or more significant acquisitions in which the consideration includes equity shares or other securities, equity interests in us held by holders of the equity shares may be significantly diluted and may result in a dilution of earnings per equity share. If we make one or more significant acquisitions in which the consideration includes cash, we may be required to use a substantial portion of our available cash or incur a significant amount of debt or otherwise arrange additional funds to complete the acquisition, which may result in a decrease in our net income and a consequential reduction in our earnings per equity share.

**If, as we expand into new international markets, we fail to adequately understand and comply with the local laws and customs, these operations may incur losses or otherwise adversely affect our business and results of operations.**

Currently, we operate our business in certain countries through subsidiaries and equity investees or through supply and marketing arrangements with our alliance partners. In those countries where we have limited experience in operating subsidiaries and in reviewing equity investees, we are subject to additional risks related to complying with a wide variety of national and local laws, including restrictions on the import and export of certain intermediates, drugs and technologies. There may also be multiple, and possibly overlapping, tax structures. In addition, we may face competition in certain countries from companies that may have more experience with operations in such countries. We may also face difficulties integrating new facilities in different countries into our existing operations, as well as integrating employees that we hire in different countries into our existing corporate culture. If we do not effectively manage our operations in these subsidiaries and review equity investees effectively, or if we fail to manage our alliances, we may lose money in these countries and it may adversely affect our business and results of operations.

**If we improperly handle any of the dangerous materials used in our business and accidents result, we could face significant liabilities that would lower our profits.**

We handle dangerous materials including explosive, toxic and combustible materials such as sodium azide, acrolein and acetyl chloride. If improperly handled or subjected to the wrong conditions, these materials could hurt our employees and other persons, cause damage to our properties and harm the environment. Also, increases in business and operations in our plants, and the consequent hiring of new employees, can pose increased safety hazards. Such hazards need to be addressed through training, industrial hygiene assessments and other safety measures and, if not carried out, can lead to industrial accidents. Any of the foregoing could subject us to significant litigation or adversely impact our other litigation matters then outstanding, which could lower our profits in the event we were found liable, and could also adversely impact our reputation. In a worst case scenario, this could also result in a government forced shutdown of our manufacturing plants, which in turn could lead to product shortages that delay or prevent us from fulfilling our obligations to customers and would harm our business and financial results.

**If there is delay and/or failure in supplies of materials, services and finished goods from third parties or failure of finished goods from our key manufacturing sites, it may adversely affect our business and results of operations.**

In some of our businesses, we rely on third parties for the timely supply of active pharmaceutical ingredients ("API"), specified raw materials, equipment, formulation or packaging services and maintenance services, and in some cases there could be a single source of supply. For instance, we rely on third party manufacturers for a major part of the supply of finished dosages sold in Germany. Although, we actively manage these third party relationships to ensure continuity of supplies and services on time and to our required specifications, events beyond our control could result in the complete or partial failure of supplies and services or in supplies and services not being delivered on time.

In the event that we experience a shortage in our supply of raw materials, we might be unable to fulfill all of the API needs of our Global Generics segment, which could result in a loss of production capacity for this segment. Moreover, we may continue to be dependent on vendors, strategic partners and alliance partners for supplies of some of our existing products and new generic launches. Any unanticipated capacity or supply related constraints affecting such vendors, strategic partners or alliance partners can adversely affect our business or results of operations. Our key generics manufacturing sites also may have capacity constraints and, at times, we may not be able to generate sufficient supplies of finished goods.

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If any of the foregoing delays or prevents us from timely delivering our products to our customers, our relationships with the adversely affected customers could be harmed and we could be subject to contractually imposed financial penalties and/or lawsuits, any of which may adversely affect our business or results of operations.

### **Fluctuations in exchange rates and interest rate movements may adversely affect our business and results of operations.**

Our principal subsidiaries are located in the United States, the United Kingdom, Germany, Switzerland, Mexico and Russia, and each has significant local operations. A significant portion of our revenues are in currencies other than the Indian rupee, especially the U.S. dollar, the Euro, the Russian rouble and the U.K. pound sterling, while a significant portion of our costs are in Indian rupees. As a result, if the value of the Indian rupee appreciates relative to these other currencies, our revenues measured in Indian rupees may decrease and our financial performance may be adversely impacted. This also exposes us to additional risks in the event of devaluations, hyperinflation or restrictions on the conversion of foreign currencies.

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. Therefore, we are subjected to exchange rate fluctuations that could significantly affect our financial results.

### **Our success depends on our ability to retain and attract key qualified personnel and, if we are not able to retain them or recruit additional qualified personnel, we may be unable to successfully develop our business.**

We are highly dependent on the principal members of our management and scientific staff, the loss of whose services might significantly delay or prevent the achievement of our business or scientific objectives. In India, it is not our practice to enter into employment agreements with our executive officers and key employees that are as extensive as are generally used in the United States, and each of those executive officers and key employees may terminate their employment upon notice and without cause or good reason. Currently, we are not aware of any executive officer's or key employee's departure that has had, or planned departure that is expected to have, any material impact on our operations. Competition among pharmaceutical companies for qualified employees is intense, and the ability to retain and attract qualified individuals is critical to our success. There can be no assurance that we will be able to retain and attract such individuals currently or in the future on acceptable terms, or at all, and the failure to do so would have a material adverse effect on our business, financial condition and results of operations. In addition, we do not maintain "key person" life insurance on any officer, employee or consultant.

### **We have grown at a very rapid pace. Our inability to properly manage or support this growth may have a material adverse effect on our business.**

We have grown very rapidly over the past few years, including growth through our acquisitions of companies and brands. This growth has significantly increased demands on our processes, systems and people. We have been making additional investments in personnel, systems and internal control processes to help manage our growth. Attracting, retaining and motivating key employees in various departments and locations to support our growth is critical to our business, and competition for these people can be intense.

To facilitate our growth, we are carrying out reorganizations and deploying initiatives to improve our focus on delivery, to build decisive competitive advantages or/and to build sustainable cost structures. There is also an increasing need to manage information and asset related security.

If we are unable to hire and retain qualified employees, or if we do not invest in systems and processes to manage and support our rapid growth, the failure to do so may have a material adverse effect on our business, financial condition and results of operations.

### **Fluctuations in our quarterly revenues, operating results and cash flows may adversely affect the trading price of our shares and ADSs.**

Our quarterly revenues, operating results and cash flows have fluctuated significantly in the past and may fluctuate substantially from quarter to quarter in the future. Such fluctuations result from a variety of factors, including but not limited to changes in demand for our products, timing of regulatory approvals and of launches of new products by us and our competitors (particularly where we obtain the 180-day period of market exclusivity in the United States provided under the Hatch-Waxman Act of 1984), and timing of our retailers' promotional programs. Such fluctuations may result in volatility in the price of our equity shares and our ADSs. In such an event, the trading price of our shares and ADSs may be adversely affected.

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

Our business is dependent upon increasingly complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses. Any such disruption may result in the loss of key information and/or disruption of production and business processes, which could materially and adversely affect our business.

In addition, our systems are potentially vulnerable to data security breaches, whether by employees or others, that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others. Such breaches of security could have a material adverse effect on our business, financial condition and results of operations.

**Increasing use of social media could give rise to liability or breaches of data security.**

We and our business associates are increasingly relying on social media tools as a means of communications. To the extent that we seek as a company to use these tools as a means to communicate about our products or about the diseases our products are intended to treat, there are significant uncertainties as to either the rules that apply to such communications, or as to the interpretations that health authorities will apply to the rules that exist. As a result, despite our efforts to comply with applicable rules, there is a significant risk that our use of social media for such purposes may cause us to nonetheless be found in violation of them. In addition, because of the universal availability of social media tools, our associates may make use of them in ways that may not be sanctioned by us, and that may give rise to liability, or that could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others. In either case, such uses of social media could have a material adverse effect on our business, financial condition and results of operations.

**A relatively small group of products may represent a significant portion of our net revenues, gross profit or net earnings from time to time.**

Sales of a limited number of products may represent a significant portion of our net revenues, gross profit and net earnings. If the volume or pricing of our largest selling products declines in the future, our business, financial position and results of operations could be materially adversely affected.

**Changes in Indian tax regulations may increase our tax liabilities and thus adversely affect our financial results.**

Currently, we enjoy various tax benefits and exemptions under Indian tax laws. Any changes in these laws or their application in matters such as tax exemption on exportation income, research and development spending and transfer pricing, may increase our tax liability and thus adversely affect our financial results.

**We operate in jurisdictions that impose transfer pricing and other tax-related regulations on our intercompany arrangements, and any failure to comply could materially and adversely affect our profitability.**

We are required to comply with various transfer pricing regulations in India and other countries. Failure to comply with such regulations may impact our effective tax rates and consequently affect our net margins. Additionally, we operate in numerous countries and our failure to comply with the local and municipal tax regimes may result in additional taxes, penalties and enforcement actions from such authorities. Although our intercompany arrangements are based on accepted tax standards, tax authorities in various jurisdictions may disagree with and subsequently challenge the amount of profits taxed in such jurisdictions, which may increase our tax liabilities and could have a material adverse effect on the results of our operations.

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**We enter into various agreements in the normal course of business which periodically incorporate provisions whereby we indemnify the other party to the agreement.**

In the normal course of business, we periodically enter into agreements with vendors, customers, alliance partners, innovators and others that incorporate terms for indemnification provisions. Our indemnification obligations under such agreements may be unlimited in duration and amount. We maintain insurance coverage that we believe will effectively mitigate our obligations under certain of these indemnification provisions (for example, in the case of outsourced clinical trials). However, should our obligations under an indemnification provision exceed our coverage or should coverage be denied, it could have a material adverse impact on our business, financial position and results of operations.

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

In recent years, the global economy has experienced volatility and an unfavorable economic environment, and these trends may continue in the future. Reduced consumer spending, or shifting concentrations of payors and their preferences, may force our competitors and us to reduce prices. We have exposure to many different industries and counterparties, including our partners under our alliance, research and promotional services agreements, suppliers of raw materials, drug wholesalers and other customers, who may be unstable or may become unstable in the current economic environment.

Significant changes and volatility in the consumer environment and in the competitive landscape may make it increasingly difficult for us to predict our future revenues and earnings.

**We are subject to the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws, which impose restrictions and may carry substantial penalties.**

The U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business. These laws may require not only accurate books and records, but also sufficient controls, policies and processes to ensure business is conducted without the influence of bribery and corruption. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties including fines, criminal prosecution and potential debarment from public procurement contracts. Failure to comply may also result in reputational damages. Given the high level of complexity of these laws, however, there is a risk that some provisions may be inadvertently breached, for example through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements or otherwise. Any violation of these laws or allegations of such violations, whether or not merited, could have a material adverse effect on our reputation and could cause the trading price of our ordinary shares and ADSs to decline.

In addition, in many less-developed markets, we rely heavily on third-party distributors and other agents for the marketing and distribution of our products. Many of these third parties do not have internal compliance resources comparable to ours. Business activities in many of these markets have historically been more susceptible to corruption. If our efforts to screen third-party agents and detect cases of potential misconduct fail, we could be held responsible for the noncompliance of these third parties under applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act, which may have a material adverse effect on our reputation and our business, financial condition or results of operations.

Finally, we operate in certain jurisdictions that have experienced governmental corruption to some degree or are found to be low on the Transparency International Corruption Perceptions Index and, in some circumstances, anti-bribery laws may conflict with some local customs and practices. As a result of our policy to comply with the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws in jurisdictions that have experienced higher levels of bribery and corruption.

**Risks from disruption to production, supply chain or operations from natural disasters could adversely affect our business and operations and cause our revenues to decline**

If flooding, droughts, earthquakes, volcanic eruptions or other natural disasters were to directly damage, destroy or disrupt our manufacturing facilities, it could disrupt our operations, delay new production and shipments of existing inventory or result in costly repairs, replacements or other costs, all of which would negatively impact our business. A significant portion of our manufacturing facilities are situated around Hyderabad, India, a region that has experienced earthquakes, floods and droughts in the past.

Even if we take precautions to provide back-up support in the event of such a natural disaster, the disaster may nonetheless affect our facilities, harming production and ultimately our business. And, even if our manufacturing facilities are not directly damaged, a large natural disaster may result in disruptions in distribution channels or supply chains. The impact of such occurrences depends on the specific geographic circumstances but could be significant.

In addition, there is increasing concern that climate change is occurring and may have dramatic effects on human activity without aggressive remediation steps. A modest change in temperature may cause a rising number of natural disasters. We cannot predict the economic impact, if any, of natural disasters or climate change.

**If the world economy is affected due to terrorism, wars or epidemics, it may adversely affect our business and results of operations.**

Several areas of the world, including India, have experienced terrorist acts and retaliatory operations in recent years. If the economy of our key markets (including but not limited to the United States, the United Kingdom, Germany and, among the emerging markets, India and Russia) is affected by such acts, our business and results of operations may be adversely affected as a consequence.

In recent years, Asia experienced outbreaks of avian influenza and Severe Acute Respiratory Syndrome, or "SARS". In addition, a rising death toll in Mexico from a new strain of Swine Flu led the World Health Organization to declare a public health emergency of international concern. If the economy of our key markets is affected by such outbreaks or other epidemics, our business and results of operations may be adversely affected as a consequence.

**Our principal shareholders have significant control over us and, if they take actions that are not in the best interests of our minority shareholders, the value of their investment in our ADSs may be harmed.**

Our full time directors and members of their immediate families, in the aggregate, beneficially owned 25.61% of our issued shares as at March 31, 2012. As a result, these people, acting in concert, are likely to have the ability to exercise significant control over most matters requiring approval by our shareholders, including the election and removal of directors and significant corporate transactions. This significant control by these directors and their family members could delay, defer or prevent a change in control of us, impede a merger, consolidation, takeover or other business combination involving us, or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, even if that was in our best interest. As a result, the value of the ADSs of our minority shareholders may be adversely affected or our minority shareholders might be deprived of a potential opportunity to sell their ADSs at a premium.

**RISKS RELATING TO INVESTMENTS IN INDIAN COMPANIES**

We are an Indian company. Our headquarters are located in India, a substantial part of our operations are conducted in India and a significant part of our infrastructure and other assets are located in India. In addition, a substantial portion of our total revenues for the year ended March 31, 2012 continued to be derived from sales in India. As a result, the following additional risk factors apply that are not specific to our company or industry.

**A slowdown in economic growth in India may adversely affect our business and results of operations.**

Our performance and the quality and growth of our business are necessarily dependent on the health of the overall Indian economy. The Indian economy has grown significantly over the past few years. Any future slowdown in the Indian economy could harm us, our customers and other contractual counterparties. In addition, the Indian economy is in a state of transition. The share of the services sector of the Indian economy is rising while that of the industrial, manufacturing and agricultural sector is declining. It is difficult to gauge the impact of these fundamental economic changes on our business.

**If communal disturbances or riots erupt in India, or if regional hostilities increase, this would adversely affect the Indian economy, which our business depends upon.**

India has experienced communal disturbances, terrorist attacks and riots during recent years. For example, Mumbai, India's commercial capital, was the target of serial railway bombings in July 2006 as well as the "26/11" attacks on November 26, 2008. Hyderabad, the city in which we are headquartered, was also subjected to terrorist acts in May and August 2007.

During the year ended March 31, 2010, the state of Andhra Pradesh, where our headquarters is located, experienced political disruption relating to a separatist movement seeking to bifurcate the existing state of Andhra Pradesh into two separate states of "Telangana" and "Andhra". Due to civil disturbances and "Bandhs" (i.e., political protests in the form of worker strikes) called for, several productive days were lost from forced or precautionary closures of our production units and offices. If there are further strikes, political protests or civil unrest, our business and results of operations may be adversely affected as a consequence.

Additionally, India has from time to time experienced hostilities with neighboring countries. The hostilities have continued sporadically. Hostilities and tensions may occur in the future and on a wider scale. These hostilities and tensions could lead to political or economic instability in India and harm our business operations, our future financial performance and the price of our shares and our ADSs.

**If wage costs or inflation rise in India, it may adversely affect our competitive advantages over higher cost countries and our profits may decline.**

Wage costs in India have historically been significantly lower than wage costs in developed countries and have been one of our competitive strengths. However, wage increases in India may increase our costs, reduce our profit margins and adversely affect our business and results of operations.

Due to various macro-economic factors, the rate of inflation has recently been highly volatile in India. According to the economic report released by the Department of Economic Affairs, Ministry of Finance in India, the annual inflation rate in India, as measured by the benchmark wholesale price index, Base 2004-05=100 was 6.9% for the year ended March 31, 2012 (as compared to 9.7% for the year ended March 31, 2011). This trend may not continue and the rate of inflation may rise substantially. We may not be able to pass these inflationary costs on to our customers by increasing the price we charge for our products. If this occurs, our profits may decline.

**Stringent labor laws may adversely affect our ability to have flexible human resource policies; labor union problems could negatively affect our production capacity and overall profitability.**

Labor laws in India are more stringent than in other parts of the world. These laws may restrict our ability to have human resource policies that would allow us to react swiftly to the needs of our business. Approximately 7% of our employees belong to a number of different labor unions. If we experience problems with our labor unions, our production capacity and overall profitability could be negatively affected.

**OTHER RISKS RELATING TO OUR ADSs  
THAT ARE NOT SPECIFIC TO OUR COMPANY OR INDUSTRY**

**Indian law imposes certain restrictions that limit a holder's ability to transfer the equity shares obtained upon conversion of ADSs and repatriate the proceeds of such transfer, which may cause our ADSs to trade at a premium or discount to the market price of our equity shares.**

Under certain circumstances, the Reserve Bank of India must approve the sale of equity shares underlying ADSs by a non-resident of India to a resident of India. The Reserve Bank of India has given general permission to effect sales of existing shares or convertible debentures of an Indian company by a resident to a non-resident, subject to certain conditions, including the price at which the shares may be sold. Additionally, except under certain limited circumstances, if an investor seeks to convert the Indian rupee proceeds from a sale of equity shares in India into foreign currency and then repatriate that foreign currency from India, he or she will have to obtain an additional approval from the Reserve Bank of India for each such transaction. Required approval from the Reserve Bank of India or any other government agency may not be obtained on terms favorable to a non-resident investor or at all.



**There are limits and conditions to the deposit of shares into the ADS facility.**

Indian legal restrictions may limit the supply of our ADSs. The only way to add to the supply of our ADSs will be through a primary issuance because the depository is not permitted to accept deposits of our outstanding shares and issue ADSs representing those shares. However, an investor in our ADSs who surrenders an ADS and withdraws our shares will be permitted to redeposit those shares in the depository facility in exchange for our ADSs. In addition, an investor who has purchased our shares in the Indian market will be able to deposit them in the ADS program, but only in a number that does not exceed the number of underlying shares that have been withdrawn from and not re-deposited into the depository facility. Moreover, there are restrictions on foreign institutional ownership of our equity shares as opposed to our ADSs.

**Financial instability in other countries, particularly emerging market countries in Asia, could affect our business and the price and liquidity of our shares and our ADSs.**

The Indian markets and the Indian economy are influenced by economic and market conditions in other countries, particularly emerging market countries in Asia. Although economic conditions are different in each country, investors' reactions to developments in one country can have adverse effects on the securities of companies in other countries, including India. Any worldwide financial instability or any loss of investor confidence in the financial systems of Asian or other emerging markets could increase volatility in Indian financial markets or adversely affect the Indian economy in general. Either of these results could harm our business, our future financial performance and the price of our equity shares and ADSs.

**If U.S. investors in our ADSs are unable to exercise preemptive rights available to our non-U.S. shareholders due to the registration requirements of U.S. securities laws, the investment of such U.S. investors in our ADSs may be diluted.**

A company incorporated in India must offer its holders of shares preemptive rights to subscribe and pay for a proportionate number of shares to maintain their existing ownership percentages prior to the issuance of any shares, unless these rights have been waived by at least 75% of the company's shareholders present and voting at a shareholders' general meeting. U.S. investors in our ADSs may be unable to exercise preemptive rights for the shares underlying our ADSs unless a registration statement under the Securities Act of 1933 is effective with respect to the rights or an exemption from the registration requirements of the Securities Act is available. Our decision to file a registration statement will depend on the costs and potential liabilities associated with a registration statement as well as the perceived benefits of enabling U.S. investors in our ADSs to exercise their preemptive rights and any other factors we consider appropriate at the time. We might choose not to file a registration statement under these circumstances. If we issue any of these securities in the future, such securities may be issued to the depository, which may sell them in the securities markets in India for the benefit of the investors in our ADSs. There can be no assurances as to the value, if any, the depository would receive upon the sale of these securities. To the extent that U.S. investors in our ADSs are unable to exercise preemptive rights, their proportional interests in us would be reduced.

**Our equity shares and our ADSs may be subject to market price volatility, and the market price of our equity shares and ADSs may decline disproportionately in response to adverse developments that are unrelated to our operating performance.**

Market prices for the securities of Indian pharmaceutical companies, including our own, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as the following can have an adverse effect on the market price of our ADSs and equity shares:

- general market conditions,
- speculative trading in our shares and ADSs, and
- developments relating to our peer companies in the pharmaceutical industry.

**There may be less company information available in Indian securities markets than securities markets in developed countries.**

There is a difference between the level of regulation and monitoring of the Indian securities markets over the activities of investors, brokers and other participants, as compared to the level of regulation and monitoring of markets in the United States and other developed economies. The Securities and Exchange Board of India is responsible for improving disclosure and other regulatory standards for the Indian securities markets. The Securities and Exchange Board of India has issued regulations and guidelines on disclosure requirements, insider trading and other matters. There may, however, be less publicly available information about Indian companies than is regularly made available by public companies in developed countries, which could affect the market for our equity shares and ADSs.

**Indian stock exchange closures, broker defaults, settlement delays, and Indian Government regulations on stock market operations could affect the market price and liquidity of our equity shares.**

The Indian securities markets are smaller than the securities markets in the United States and Europe and have experienced volatility from time to time. The regulation and monitoring of the Indian securities market and the activities of investors, brokers and other participants differ, in some cases significantly, from those in the United States and some European countries. Indian stock exchanges have at times experienced problems, including temporary exchange closures, broker defaults and settlement delays and if similar problems were to recur, they could affect the market price and liquidity of the securities of Indian companies, including our shares. Furthermore, any change in Indian Government regulations of stock markets could affect the market price and liquidity of our equity shares and ADSs.

#### **ITEM 4. INFORMATION ON THE COMPANY**

##### **4.A. History and development of the company**

Dr. Reddy's Laboratories Limited was incorporated in India under the Companies Act, 1956, by its promoter and our current Chairman, Dr. K. Anji Reddy, as a Private Limited Company on February 24, 1984. We were converted to a Public Limited Company on December 6, 1985 and listed on the Indian Stock Exchanges in August 1986 and on the New York Stock Exchange on April 11, 2001. We are registered with the Registrar of Companies, Andhra Pradesh, Hyderabad, India as Company No. 4507 (Company Identification No. U85195AP1984 PLC 004507). Our registered office is situated at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500 034, India and the telephone number of our registered office is +91-40-49002900. The name and address of our registered agent in the United States is Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Boulevard (Bldg II), Bridgewater, New Jersey 08807.

##### **Key business developments:**

On April 1, 2011 we launched Peg-grafeel™, our brand of pegylated filgrastim (pegfilgrastim). Peg-grafeel™ has been approved in India to reduce the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes). Pegfilgrastim is a pegylated long-lasting variant of filgrastim. One injection of pegfilgrastim can replace up to 14 injections of filgrastim, which must be administered daily. It can be administered once per chemotherapy cycle, providing convenience to the patient while eliminating many of the additional costs of treatment. Peg-grafeel™ is manufactured using our 'PEGtech' brand of activated methyl ether polyethylene glycol alcohols ("mPEGs") which are synthesized at our facilities located in Mexico and the United Kingdom.

On April 12, 2011, we launched over-the-counter ("OTC") fexofenadine hydrochloride tablets, a bioequivalent version of Sanofi-Aventis' Allegra® tablets, which received OTC sales approval from the United States Food and Drug Administration (the "U.S. FDA") on January 24, 2011. The U.S. FDA approved our Abbreviated New Drug Application ("ANDA") for fexofenadine hydrochloride tablets on April 12, 2011. According to IMS Health, sales of branded and generic fexofenadine hydrochloride prescription products in the United States were approximately U.S.\$452 million for the twelve months ended December 31, 2010.