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

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 many of the international markets into which we sell our products, including the United States, 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-similars 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. More recently, a number of Indian generic pharmaceutical companies were issued import alerts and warning letters by the U.S. FDA. A significant proportion of our manufacturing base of active pharmaceutical ingredients and formulations plants servicing the United States and other markets of our Global Generics business is based out of India. There has been an increasing trend by the U.S. FDA and governmental regulators in other developed countries towards Indian manufacturing site audits. While our quality practices and quality management systems are conducted in a manner designed to satisfy these types of audits, we cannot guarantee that our efforts will prevent adverse outcomes such as audit observations, corrective action requests, warning letters or import bans.

For example, in November 2015, we received a warning letter from the U.S. FDA relating to cGMP deviations at three of our manufacturing facilities - two API manufacturing sites and one formulations injectable manufacturing site in India. This had an adverse impact on new product approvals from these sites, and we have taken steps to minimize the impact from these sites through site transfers of certain key products. We continue to develop and implement our corrective action plans relating to the warning letter. Unless and until these issues are resolved to the U.S. FDA's satisfaction, the U.S. FDA may withhold approval of our new products and new drug applications, refuse admission of products manufactured at the facilities noted in the warning letter into the United States, and/or take additional regulatory or legal action against us. Any such further action could have a material and negative impact on our ongoing business and operations.

Furthermore, we deal with numerous third party manufacturers and despite our strict oversight, any lapse in their quality practices and quality management systems could lead to similarly adverse outcomes in the event of an audit.

If we or our third party suppliers fail to comply fully with applicable regulations or to take corrective actions that are mandated, then there could be a government-enforced shutdown of our production facilities or an import ban, 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. For example, the U.S. FDA imposed an import ban on our manufacturing facility at Cuernavaca, Mexico from June 2011 through July 2012.

Further, while physicians may prescribe products for uses that are not described in the product's labeling and that differ from those approved by the U.S. FDA or other similar regulatory authorities (an "off label" use), we are permitted to market our products only for the indications for which they have been approved. The U.S. FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses, and significant liability can be imposed on manufacturers found to be engaged in off-label marketing violations, including fines in the tens or hundreds of millions of dollars, as well as criminal sanctions. If some of our products are prescribed off label, regulatory authorities such as the U.S. FDA could take enforcement actions if they conclude that we or our distributors have engaged in off label marketing.

An increasing portion of our portfolio is "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.

The U.S. FDA issued final guidance in April 2015 on implementing an abbreviated biosimilar approval pathway. In March 2015, the U.S. FDA approved the first biosimilar product submitted under the abbreviated biosimilar pathway. While the U.S. FDA has issued guidelines, these guidelines contain features that could significantly prolong the biosimilar development process and significant ambiguity and questions remain, including, for example, questions regarding standards and criteria for biosimilars and interchangeables. In addition, due to the recent submissions and approvals of abbreviated biosimilar applications, a number of legal challenges construing the requirements of the abbreviated biosimilar pathway are under review. For example, in July 2015, the U.S. Court of Appeals for the Federal Circuit held that biosimilar applicants were not required to provide copies of the biosimilar application or manufacturing information but needed to provide 180-day commercial marketing notice to the reference sponsor. Although we do not have any existing biosimilar product directly impacted by this decision and other ongoing legal challenges, there remains some uncertainty regarding the abbreviated biosimilar approval pathway.

We operate in a highly competitive and rapidly consolidating industry which may adversely affect our revenues and profits.

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 marketing and selling 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 better 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 receive approvals and enter the market for a given product. 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.

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 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 enter 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. 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.

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 depends, 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. Our products continue to be subject to increasing price and reimbursement pressure that can limit the revenues we earn from our products in many countries due to, among other things:

- The existence of government-imposed price controls and mandatory discounts and rebates;
- removal of drugs from government reimbursement schemes (for example products determined to be less cost-effective than alternatives);
- increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;
- increase in cost containment policies related to health expenses in a context of economic slowdown;
- more demanding evaluation criteria applied by Health Technology Assessment (“HTA”) agencies when considering whether to cover new drugs at a certain price level; and
- more governments using international reference pricing to set the price of drugs based on international comparisons.

We expect these efforts to continue 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.

India

Under the present drug policy of the Government of India, certain drugs have been specified under the Drugs (Prices Control) Order, 2013 (the "DPCO") as subject to price control. The Government of India established the National Pharmaceutical Pricing Authority, 2012 ("NPPA"), to control pharmaceutical prices. Under the DPCO, the NPPA has the authority to fix the maximum selling price for specified products. As a result, hundreds of drugs on India's National List of Essential Medicines were identified and subjected to price controls in India. On May 15, 2013, the Department of Pharmaceuticals of the Government of India released Drugs (Price Control) Order, 2013 governing the price control mechanism for 348 drugs listed in the National List of Essential Medicines.

Recently, there has been a series of proposals and announcements by the Government of India regarding price controls. First, in December 2015 a proposal was issued to list certain additional drugs on the National List of Essential Medicines. That was followed with an announcement on March 3, 2016 of a reduction in the maximum prices of various drugs, as a result of negative inflation as measured by India's Wholesale Price Index. Further, on March 10, 2016, the Department of Pharmaceuticals notified the Drugs (Prices Control) Amendment Order, 2016 ("DPCAO 2016"), which amended the Drugs (Price Control) Order, 2013 and revised the National List of Essential Medicines. Under the DPCAO 2016, a total of 106 medicines were added to and 70 medicines were deleted from the National List of Essential Medicines, which now contains 376 drugs. The NPPA was in the process of notifying / re-notifying the prices for scheduled drugs as of March 31, 2016. The individual drug price notifications for majority of the products have been released by the NPPA. Based on these notifications, we believe that we could be adversely impacted by approximately 3% to 5% of our annual revenues from sales of all of our products in India.

Additionally, on March 12, 2016, the Department of Health and Family Welfare under the ministry of Health and Family Welfare of the Government of India banned 344 fixed dose combination drugs (i.e., two or more active drugs combined in a fixed ratio into a single dosage). A number of pharmaceutical companies, including us, have filed a writ petition before the Delhi High Court challenging the ban. The Delhi High Court granted an interim stay on the ban notification. In the event that this notification comes into effect, it could adversely impact our revenues by approximately 0.7% on an annual basis. Further, it could adversely impact the Indian pharmaceutical industry by approximately 3.1% on an annual basis (as per AWACS, a provider of market research to the Indian Pharmaceutical Industry).

The NPPA has since notified changes to pricing of different products multiple times, which have impacted certain of our oncology and chronic condition products.

Such ongoing changes can disrupt the Indian branded pharmaceutical market and negatively impact the revenues and profitability of our Indian business and our company.

United States

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.

Patient Protection and Affordable Care Act

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. The PPACA imposes additional rebates, discounts and fees, mandates certain reporting and contains various other requirements that could adversely affect our business, as more particularly described under "Patient Protection and Affordable Care Act" in our Global Generics segment's discussion of U.S. Government regulations below in Item 4.B. 'Business overview'.

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 the PPACA that prohibit the use of preexisting condition exclusions, eliminate lifetime and annual dollar limits on benefits, restrict contract rescissions, and provide patient protections.

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 the PPACA and related legislation. CMS accepted comments on this proposed rule through April 2, 2012.

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.

On February 1, 2016, the CMS published a Final Regulation in the Federal Register to implement changes to and clarify ambiguities in the Medicaid Drug Rebate Program that were enacted by the PPACA. With some exceptions, the Final Regulation will be applied prospectively effective April 1, 2016. The key provisions covered under the Final Regulation included, without limitation, the following: (i) the adoption of a final definition of "retail community pharmacy" ("RCP"), (ii) the adoption of a rule permitting inhalation, infusion, instilled, implanted, or injectable drugs ("5i drugs") to be deemed not to be "generally dispensed" through a RCP, and thus excluded from the calculation of their AMP, if 70% or more of its sales were to entities other than RCPs or wholesalers for drugs distributed to RCPs (the prior threshold was 90%), (iii) the inclusion of authorized generics in calculations of AMP and best price, (iv) narrowing the regulatory definition for "best price", (v) requiring additional Medicaid rebate payments for generic drugs, effective as of April 1, 2017, and (vi) clarification of the definition of "bona fide service fees" based on a four part test.

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.

Germany

In Germany, 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, in 2007, 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.

European Union

The European Union enacted the European Falsified Medicines Directive (Directive 2011/62/EU) to reform the rules for importing into the European Union active substances for medicinal products for human use. As of January 2, 2013, all imported active substances must have been manufactured in compliance with standards of good manufacturing practices ("GMP") at least equivalent to the GMP of the European Union. The manufacturing standards in the European Union for active substances are those of the "International Conference for Harmonisation" – ICH Q7. The provisions of the Directive are intended to reduce the risk of counterfeit medicines entering the supply chain.

Russia

During the fiscal year ended March 31, 2012, Russia introduced Federal Law # 323, titled "On the Foundations of Healthcare for Russian Citizens". This 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 include 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.

In March 2015, Russia enacted amendments to Article 61 of the Federal Law ‘On Circulation of Medicines’, which amendments create new rules for the registration, manufacture and quality control of medicines, including new rules for the calculation and registration of the maximum retail prices of vital and essential medicines established by the list of “Essential and Vital Drugs” (also known as the “ZhNVLS”).

The Eurasian Economic Union (“EEU”), whose member states are Russia, Belarus, Kazakhstan, Armenia, and Kyrgyzstan, officially started functioning on January 1, 2015. Among other things, the member states of the EEU signed an international agreement establishing common principles and rules of functioning of the market for medicines within the EEU, which agreement was originally expected to be made effective from January 1, 2016. For these purposes, the member states are working on the necessary regulatory framework and EEU plans for its member states to sign 25 acts governing various stages of drugs circulation. According to the agreement, the market authorization for a particular medicine received in one EEU member state will be valid throughout the whole EEU territory. This agreement, together with Russia’s “Priority Action Plan for sustainable economic and social stability development in 2015,” is expected to have a number of impacts on pharmaceutical pricing and import substitution preferences in Russia.

Other

Governments throughout the world heavily regulate the marketing of pharmaceutical 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. In certain countries certain prescribed marketing codes or guidelines are required to be followed by the pharmaceutical companies. Although our company policies prohibit our employees and third party distributors from violating such regulations, we may not be able to completely 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.

We have operations in certain countries susceptible to political and economic instability that could lead to disruption or other adverse impacts upon such operations.

We expect to derive an increasing portion of our sales from 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 and economic instability. For example, as a result of severe political instability and ongoing conflict in Ukraine, the United States and the European Union have imposed sanctions on certain individuals and companies in Ukraine and Russia, including sanctions targeted at the Crimea region of Ukraine which was annexed by Russia. Political instability in the region has combined with low worldwide oil prices that significantly devalued the Russian rouble and may continue to have a negative impact on the Russian economy. In addition, the Ukrainian hryvnia also experienced significant devaluation in 2014. Some of these are new markets that we have recently entered, and we may decide to enter other new markets in the future and thus may face additional risks arising out of political and 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.

Significant portions of our manufacturing 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.

From time to time we enter new markets, and face risks arising out of our limited knowledge of the market and the customs, laws and regulatory systems that may apply.

From time to time we enter new markets in which we have limited knowledge of the market and the customs, laws, regulatory, political and social systems that may apply. Our success in these new markets is dependent upon the acceptability of our product and brand, the ease of doing business in such market and various other social and economic factors that may be

specific to such market. Further, limitations by the local authorities of repatriation of generated funds may pose a risk to our success in these new markets. Our sales and profit margins may be adversely affected if we fail to provide competitive options in the market or our brands fail to gain acceptability in the market.

Class action lawsuits could expose us to significant liabilities, result in negative publicity, harm our reputation and have a material adverse effect on the price of our ADSs.

Shareholders of a public company sometimes bring securities class action lawsuits against the company following periods of instability in the market price of that company's securities. As a public company grows in size, the risk of such litigations may increase. If we were to be sued in any such class action suit, irrespective of the merits of the underlying case, it could have adverse effects on us, including among other things: (a) a diversion of management's time and attention and other resources from our business and operations, which could harm our results of operations; (b) negative publicity, which could harm our reputation and restrict our ability to raise capital in the future; (c) requiring us to incur significant expenses to defend the suit; and (d) if a claim against us is successful, we may be required to pay significant damages and, in certain circumstances, to indemnify our directors and officers if they are named as defendants in the class action suit. Any of the foregoing could, individually or in the aggregate, have a material adverse effect on our financial condition and results of operations and/or the price of our ADSs.

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 such products declines in the future, our business, financial position and results of operations could be materially adversely affected.

The use of tender systems and other forms of price control could reduce prices for our products or reduce our market opportunities.

A number of markets in which we operate have implemented or may implement tender systems in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender.

For example, this has resulted in more than 90% of generic products currently sold in German retail outlets being supplied through contracts procured in competitive bidding tenders, thereby causing significant pressure on product margins.

Certain other countries may consider the implementation of a tender system or other forms of price controls. Even if a tender system is ultimately not implemented, the anticipation of such could result in price reductions. Failing to win tenders, or the implementation of similar systems or other forms of price controls in other markets leading to further price declines, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

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 depends, 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 may be breached and we may 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. Therefore, despite all of our information security systems and practices, we may still not be able to ensure 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, sales of our generic products may be adversely impacted.

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;
- introducing “next-generation” products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the generic or the reference product for which we seek regulatory approval;
- obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations or by other methods;
- 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;
- 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, leading to a material adverse effect on our results of operations, financial condition and cash flows.

If sales of authorized generic products are restricted, our sales of certain authorized 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 have prohibited 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, or we could be subject to substantial liabilities that could adversely affect our profits. Further, our patent settlement agreements with the innovators may face government scrutiny, exposing us to significant damages.

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 or NDA. 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.

Further, we have been involved in various litigations involving challenges to the validity or enforceability of registered patents and therefore settling said patent litigations has been and is likely to continue to be an important part of our business. Parties to such settlement agreements in the U.S., including us, are required by law to file them with the Federal Trade Commission (“FTC”) and the Antitrust Division of the Department of Justice for review. The FTC has publicly stated that, in its view, some of the brand-generic settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies that have entered into such agreements. For example, in May 2015, Teva Pharmaceutical Industries agreed to a $1.2 billion settlement with the FTC to resolves anti-competition charges over sales of provigil, a sleep-disorder prescription drug. 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.

Such settlement agreements may further expose us to claims by purchasers of the products for unlawfully inhibiting competition.

Similarly, the European Commission has placed European operations of several brand and generic companies, under intense scrutiny in connection with its inquiry into possible anticompetitive conditions in the European pharmaceutical sector. 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.

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.

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 have a material adverse effect on our results of operations, financial condition and cash flows.

Any failure to comply with the complex reporting and payment obligations under the Medicare and Medicaid programs or other laws regulating marketing practices may result in litigation or sanctions and adversely impact our business.

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 a 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 in the calculation outcomes. In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to a drug's average wholesale price ("AWP") and wholesale acquisition cost ("WAC"), and in some cases have filed lawsuits in which they have alleged that reporting of inflated AWPs or WACs has led to excessive payments by Medicare and/or Medicaid for prescription drugs. In addition, we are notified from time to time of governmental investigations regarding marketing practices or pricing issues. In the United States, we are currently responding to federal investigations into our marketing practices with regard to some of our products, which could result in civil litigation brought on behalf of the federal government.

Responding to such queries and any resulting investigations or lawsuits is costly and unpredictable, and involves a significant diversion of management's attention. Such allegations could, if proven or settled, result in significant monetary penalties and possible exclusion from Medicare, Medicaid and other programs. 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.

If any of the above queries and/or investigations were to result in a lawsuit that was determined adversely to us or in a large cash settlement, it could require us to pay significant amounts and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

Research and development efforts invested in our differentiated formulations pipeline may not achieve expected results.

In our Proprietary Products segment, our business model focuses on building a pipeline in the therapeutic areas of neurology and dermatology. We must invest increasingly significant resources to develop differentiated products, both through our own efforts and through collaborations, in-licensing and acquisition of products from or with third parties. The development of differentiated products involves processes and expertise different from those used in the development of generic drugs, which increases the risks of failure. 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 registration; 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 amount of capital required to be invested in augmenting our differentiated products pipeline, in some cases 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. Accordingly, our investment in research and development of innovative products can involve significant costs with no assurances of future revenues or profits.

Our Proprietary Products segment, particularly our Specialty businesses in the United States, faces intense competition from companies that are more entrenched than we are or have greater resources than ours.

Our risk profile for our Proprietary Products segment is lower than the comparable risk profile of companies working with completely novel entities. Nevertheless, the exposure that the businesses in this segment face is higher than that of the Generics business due to several factors outlined below.

Market penetration requires successful commercial positioning in relation not only to past therapies but also new competitors. All of the therapeutic areas in which we compete have many active competitors, each vying for market share in similar indications with products that may have some similar attributes. As such, success in our Proprietary Products segment requires the ability to strategically differentiate our offerings from those of our competitors, which often requires time and investment in additional clinical studies, and brings with it the typical uncertainty of outcome that faces many clinical studies. An additional emerging challenge is access to physicians, who can explicitly refuse to see our sales representatives, and new approaches need to be found to provide them with the information required in order to make informed and appropriate prescription decisions. While the impact of these challenges is currently limited, they could potentially become significant in the future.

Even if we are able to successfully differentiate our products, adequate reimbursement from third party payors for our products is necessary. Typically, a managed care plan relies on a committee made up of physicians and others to decide which drugs will appear on its formulary. Without a reasonable position on the formulary of managed care plans, patients will not be

able to obtain access to our products. Further, even after we contract for access on managed care formularies, we often have to provide additional point-of-sale discounts to patients in order to make their out-of-pocket payments affordable. All of these are necessary in this business segment, as all managed care plans attempt to aggressively direct their patients towards generic medicines.

Additionally, because the Specialty business of our Proprietary Products segment works primary with reformulated drugs, another risk is that the patents that protect the product are easier to engineer around than traditional composition of matter patents. While every attempt is made to create a robust intellectual property ring fence around these assets, the products in our U.S. Specialty business portfolio may enjoy lesser exclusivity periods than traditional innovative products.

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 significantly.

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.

Under the current regulatory scheme in the United States, branded drug manufacturers can independently update product labeling through the “changes being effected” (“CBE”) supplement process, but a generic manufacturer is only permitted to use the CBE process to update its label if the branded drug manufacturer changes its label first. This can prevent generic manufacturers from complying with state law warning requirements and, as a result, state product liability suits based on failure-to-warn and design defect claims against generics manufacturers have generally been determined to be preempted by Federal law.

Following the United States Supreme Court’s June 2013 ruling in *Mutual Pharmaceutical Co. v. Bartlett* upholding such preemption and immunity of generic manufacturers, the U.S. FDA proposed a new rule in November 2013 that would allow generic manufacturers to independently update product labeling through the CBE supplement process. If the U.S. FDA’s proposed new rule is adopted, it may eliminate this preemption and increase our potential exposure to lawsuits relating to product safety, side effects and warnings on labels. This new potential exposure to lawsuits may also increase the risk 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.

Additionally, the proposed rule is likely to increase management and operating costs as a result of the need to set up database and software systems to monitor and track changes made, revisit internal processes regarding product label changes by regulatory teams, enable signal detection by pharmacovigilance and make changes in packaging and logistics involving our supply chain teams. Any failure to do this adequately can lead to an increase in our potential exposure to product liability claims and litigation. The U.S. FDA has announced that it will issue a final rule in April 2017.

The risk of exposure to lawsuits is likely to increase as we develop our own new patented products, or limited competition/complex products, such as injectables or biosimilars, 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.

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.

In recent years, significant questions have arisen regarding the safety, efficacy and potential for misuse of certain over-the-counter medicine products. Litigation, particularly in the United States, sometimes gives rise to these questions. 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. 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, and if such review resulted in the U.S. FDA or another regulator charging us with violations applicable to such product, it could have a significant adverse effect on our sales of such over-the-counter products and, thus, our overall profitability.

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.

In addition, if we make one or more significant acquisitions in which the consideration includes equity shares or other securities, our equity shares may be significantly diluted and may result in a reduction 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. Also, an increasing proportion of our alliances begin with research and development. Our results of operations may suffer if existing joint venture or collaboration partners withdraw, or if these products are not timely developed, approved or successfully commercialized. We cannot guarantee the successful outcome of such efforts, nor that they will result in any intellectual property rights or products that inure to our benefit.

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, joint ventures 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 joint ventures 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 joint ventures 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 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. 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.

If any of the foregoing delays or prevents us from timely delivery of 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.

A significant portion of our revenues are in currencies other than the Indian rupee, especially the U.S. dollar, the Euro, the Russian rouble, Venezuelan bolivar 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, such as the devaluation of the Venezuelan bolivar that occurred in March 2016, as described below.

In February, 2016, the Venezuelan government announced changes to its foreign currency exchange mechanisms, including the devaluation of its official exchange rate. The following changes became effective as of March 10, 2016:

- The CENCOEX preferential rate was replaced with a new “DIPRO” rate. The DIPRO rate is only available for purchases and sales of essential items such as food and medicine. Further, the preferential exchange rate was devalued from 6.3 VEF per U.S.$1.00 to 10 VEF per U.S.$1.00;
- The SICAD exchange rate mechanism, which last auctioned U.S. Dollars for approximately 13 VEF per U.S.$1.00, was eliminated; and
- The SIMADI exchange rate mechanism was replaced with a new “DICOM” rate, which governs all transactions not subject to the DIPRO exchange rate and will fluctuate according to market supply and demand. As of March 31, 2016, the DICOM exchange rate was 272.5 VEF per U.S.$1.00.

We have not yet received approvals from the Venezuelan government to repatriate any amount at preferential rates beyond the U.S.$4 million already approved and received during the year ended March 31, 2016. We believe that in the interim, it is appropriate to use the DICOM rate (i.e., 272.5 VEF per U.S.$1.00) instead of the preferential rate of VEF 10 per U.S.$1.00 for translating the monetary assets and liabilities of our Venezuelan subsidiary as at March 31, 2016. Accordingly, we recorded foreign exchange loss of Rs.4,621 million in the consolidated income statement during the year ended March 31, 2016. Notwithstanding the ongoing uncertainty, we continue to actively engage with the Venezuelan Government and seek approval to repatriate funds at preferential rates so that we may continue to provide affordable medicine to fulfill the needs of people of their country.

Further, we may also be exposed to credit risks in some of the emerging markets from our customers on account of adverse economic conditions.

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.

In the recent past and particularly since March 2013, the Indian rupee exchange rates as compared to the U.S. dollar have been highly volatile. In the year ended March 31, 2016, the Indian rupee depreciated by approximately 7% against the U.S. dollar. Such depreciation of the Indian rupee against the U.S. dollar has had positive benefits to our financial results. However, the Russian rouble and Euro depreciated by approximately 27% and 7%, respectively, against the Indian rupee during the year ended March 31, 2016. Such depreciation of foreign currencies has caused, and further depreciation in the future will cause, our foreign currency revenues as measured in Indian rupees to decrease, and thus adversely 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 concentrations of sales to certain customers that increases our credit risks. Consolidation among distributors and pharmaceutical companies could increase this risk, and also adversely impact our business prospects.

In the United States, similar to other pharmaceutical companies, we sell our products through wholesale distributors and large retail chains in addition to hospitals, pharmacies and other groups. During the year ended March 31, 2016, our ten largest customers accounted for approximately 85% of our North America Global Generics segment's revenues. We are exposed to a concentration of credit risk in respect of these customers such that if one or more are affected by financial difficulty, it could materially and adversely affect our financial results. If the recent trend of consolidation among distributors continues, this risk may increase.

Furthermore, the recent trend of consolidation among distributors and pharmaceutical companies, both innovator and generic companies, could have an adverse impact on our business prospects as well as our customers' choices and preferences. There has been increased concern by pharmaceutical companies and their investors and other stakeholders over geographic and customer concentration risks, as well as the implementation of counter-measures and risk mitigation strategies. Some of our key risk mitigation strategies, such as key account management and locking up customer relationships, are likely to be at risk from such consolidations. If our response to these changes is not adequate and timely, our growth prospects and business can be adversely impacted.

Counterfeit versions of our products could harm our patients and reputation.

Our industry has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the API or no API at all. However, to distributors and patients, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. In addition, there could be thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels. Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our equity shares and ADSs to decline.

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. In addition, our businesses and operating models increasingly depend on outsourcing and collaboration, which requires exchanging data and information. The size and complexity and interconnectivity 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 result in reputational damage and could otherwise have a material adverse effect on our business, financial condition and results of operations. Further, increasing use of information technology ("IT") systems in manufacturing processes would require us to manage issues arising out of human error and/or sabotage.

In our pursuit of operational excellence, several change management initiatives across our organization are currently in progress, including but not limited to information technology automation in the areas of manufacturing, research and development, supply chain and shared services. We have outsourced our IT hardware and applications in order to improve IT capability and performance. Any failure by such outsourced service providers to deliver timely and quality services and to

co-operate with one another could create disruption, which could materially adversely affect our business or results of operations. Further, any failure by us to effectively manage such change initiatives or implement adequate controls in automation, security or availability of information technology systems could have a material adverse effects on our business.

Increased outsourcing or use of cloud services for conducting our business requires highly secure controls to ensure adequate security of information, considering potential for sabotage as well as availability. Data integrity, confidentiality and data privacy requirements are increasingly concerning regulators, and are incorporated into legal contracts. While we have invested heavily in the protection of data and information technology to reduce these risks, there can be no assurance that our efforts or those of our third-party service providers would be sufficient to protect against data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a security breach. We currently do not have any insurance that could mitigate the impact from all such risks.

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.

Compliance with new and changing corporate governance and public disclosure requirements adds uncertainty to our compliance policies and increases our costs of compliance.

Changing laws, regulations and standards relating to accounting, corporate governance and public disclosure, including the Sarbanes Oxley Act of 2002, new SEC regulations, New York Stock Exchange rules, provisions of India’s Companies Act 2013, Securities and Exchange Board of India rules and Indian stock market listing regulations, create uncertainty for our company. These new or changed laws, regulations and standards may lack specificity and are subject to varying interpretations. Their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs of compliance as a result of ongoing revisions to such governance standards.

In particular, continuing compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal control over financial reporting requires the commitment of significant financial and managerial resources and our independent auditor’s independent assessment of the internal control over financial reporting. Further, India’s Companies Act 2013 requires companies listed in India to be compliant with provisions concerning “Internal Financial Controls”.

In connection with this Annual Report on Form 20-F for the year ended March 31, 2016, our management conducted an assessment of the effectiveness of our internal controls over financial reporting as of March 31, 2016 based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the “COSO Framework”). Based on this assessment, our management has concluded that our internal controls over financial reporting were effective as of March 31, 2016. As we continue to undertake management assessments of our internal control over financial reporting in connection with annual reports on Form 20-F for future years, any deficiencies uncovered by these assessments or any inability of our auditors to issue an unqualified opinion could harm our reputation and result in a loss of investor confidence in the reliability of our financial statements, which could cause the price of our equity shares and ADSs to decline.

We are committed to maintaining high standards of corporate governance and public disclosure, and our efforts to comply with evolving laws, regulations and standards in this regard have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, the new laws, regulations and standards regarding corporate governance may make it more difficult for us to obtain director and officer liability insurance. Further, our board members, chief executive

officer and chief financial officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may face difficulties attracting and retaining qualified board members and executive officers, which could harm our business. If we fail to comply with new or changed laws or regulations and standards differ, our business and reputation may be harmed.

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.

We operate in certain jurisdictions that experience 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. In many less-developed markets, we work with 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 violating these anti-bribery laws, any lapses in complying with such anti-bribery laws by these third parties may adversely impact us. 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.

Compliance with the U.S. Foreign Corrupt Practices Act and other anti-bribery laws has been subject to increasing focus and activity by regulatory authorities in recent years. 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.

We need to constantly review and update our compliance program to keep it current and active. If we fail to do so, our vulnerabilities may increase and our controls may be found to be inadequate.

Actions by our employees, or third-party intermediaries acting on our behalf, in violation of such laws, whether carried out in the United States or elsewhere, may expose us to liability for violations of such anti-bribery laws and accordingly may have a material adverse effect on our reputation and our business, financial condition or results of operations.

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 and biosimilars, 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.

Our research and development efforts are increasingly dependent on collaborating with third party partners and contract research organizations which have the capability to handle complex technologies and products. Lack of effective project management at our end, or any failure to manage collaboration arrangements among multiple partners, may pose significant risks to product development, to our ability to obtain requisite regulatory approvals in a timely manner, and to our ability to successfully and profitably produce and market such products. Additionally, if we fail to adequately protect critical proprietary or confidential information or associated intellectual property rights or fail to manage third party partners and contract research organizations that our business depends on, it might have a material adverse impact on our product development execution.

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. 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), timing of our retailers' promotional programs and successful development and commercialization of limited competition and complex products. 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.

Impairment charges or write downs in our books could have a significant adverse effect on our results of operations and financial results.

A substantial portion of the value of our assets pertains to various intangible assets and goodwill. The proportion of the intangible assets and goodwill to our total assets could increase significantly as we pursue various growth strategies. The value of these intangible assets and goodwill could be substantially impaired upon indications of impairment, with adverse effects on our financial condition and the value of our assets. For example, our financial performance for the years ended March 31, 2009 and 2010 was significantly impacted as a result of the impairments pertaining to our Germany operations.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with IFRS. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions or changes in accounting standards could lead to a restatement or revision to previously issued financial statements.

The consolidated financial statements included in the periodic reports we file with the SEC are prepared in accordance with IFRS. The preparation of financial statements in accordance with IFRS involves making estimates, judgments and assumptions in areas such as valuation of inventories, sales returns, rebates and chargebacks provisions, determination of useful life of property, plant and equipment and intangible assets, assets and obligations relating to employee benefits, business combinations and contingencies. Estimates, judgments and assumptions are inherently subject to change in the future and any necessary revisions to prior estimates, judgments or assumptions could lead to a restatement. Furthermore, although we have recorded reserves for litigation related contingencies based on estimates of probable future costs, such litigation related contingencies could result in substantial further costs. Also, any new or revised accounting standards may require adjustments to previously issued financial statements. Any such changes could result in corresponding changes to the amounts of liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

There are risks associated with executing on our strategy.

There are risks associated with executing the strategies we adopt to achieve our core purpose as discussed in Item 4.B. below. Significant execution risks associated with our strategies include, but are not limited to:

- developing and executing our complex product development, manufacturing and marketing strategies for North America and other key markets;
- executing on our strategies for increasing our customer share and for key account management in our Active Pharmaceutical Ingredients ("API") and Custom Pharmaceutical Services ("CPS") businesses; and
- executing our execution excellence and change management initiatives to ensure process safety, product quality and availability.

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

Currently, we are entitled to various tax benefits and exemptions under Indian tax laws, such as tax benefits on research and development spending and exemptions applicable to income derived from manufacturing facilities located in certain tax exempted zones. Any changes in these laws or their application may increase our tax liability and thus adversely affect our financial results.

The Union Budget, 2016 has proposed that the weighted deduction on research and development activities be reduced in a phased manner from 200% to 150% commencing April 1, 2017 and from 150% to 100% commencing April 1, 2020. Further, Special Economic Zone ("SEZ") units commencing manufacture or production of article and things after April 1, 2020 will not be eligible for SEZ tax deductions.

India's Finance Act, 2015 amended the test of residence for foreign companies. While a non-resident company is generally taxed only on its Indian sourced income, a resident company is taxed on its global income. Under the amended rule, a company not formed under the laws of India would be considered a resident in India if its place of effective management in the previous year was in India. The term "place of effective management" (or "PoEM") has been defined to mean a place where key management and commercial decisions that are necessary for the conduct of the business of an entity as a whole are in substance made. It is expected that final rules providing guidance on the interpretation and application of PoEM will be issued during the year ended March 31, 2017.

In India's Finance Act, 2012, the Government of India introduced a levy of service tax based on a negative list of services. Consequently, all services have become taxable, except notified exempted services. The Finance Act, 2015 increased the rate of service tax from 12.36% (inclusive of surcharge and cess) to a consolidated rate of 14% effective as of June 1, 2015. Furthermore, effective November 2015, the service tax of 14% was increased by an additional 0.5% cess called the "Swatch Bharat Cess" to a consolidated rate of 14.50%. Effective June 1, 2016, the Finance Act 2016 further increased the service tax rate to 15% through introduction of another 0.5% cess called the "Krishi Kalyan Cess".

Further, the Union Budget, 2015 proposed to implement Goods and Service Tax ("GST") from April 1, 2016. GST will put in place a state-of-the-art indirect tax system which will integrate State economies and boost overall growth. It is proposed to subsume other taxes (such as central excise duty, service tax, octroi, value added tax, sales tax, and entry tax) into GST, thus avoiding the multiple layers of taxation that currently exist in India. A Constitution amendment bill approving the GST was approved by India's lower house of the Parliament (i.e. Lok Sabha) on May 6, 2015. This Constitution amendment bill is currently pending in the Upper house of the Parliament (i.e. Rajya Sabha), but it is expected that a number of issues (such as the elimination of a controversial proposed 1% additional tax and the introduction of a cap on the maximum GST rate) will need to be resolved before this Constitution amendment bill is likely to be finalized and approved.

Under the Finance Act, 2013, the effective rate of dividend distribution tax ("DDT") was 16.995% inclusive of surcharge and cess. The Finance Act (No 2) 2014 made an amendment in section 115-O, which requires grossing up of the dividend amount distributed for computing DDT. Pursuant to the amendment, effective October 1, 2014, the effective rate of DDT increased from 16.995% to 19.994% inclusive of surcharge and cess, and as a result, dividend amounts receivable by our shareholders after taxes are reduced. Furthermore, as a result of the increase in rate of surcharge in the Finance Act, 2015, effective April 1, 2015, the effective rate of DDT increased from 19.994% to 20.3576%. If the effective rate of dividend distribution tax increases in the future, the dividend amount receivable by our shareholders after taxes may decrease further.

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. Further, the base erosion and profit shifting ("BEPS") project undertaken by the Organization for Economic Cooperation and Development ("OECD") contemplates changes to numerous international tax principles, as well as national tax incentives. It is hard to predict how the principles and recommendations developed by the OECD in the BEPS project will translate into specific national laws adversely impacting our tax liabilities, and therefore we cannot predict at this stage the magnitude of the effect of such rules on our financial results.

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, reduced funding for national social security systems or shifting concentrations of payors and their preferences, may force our competitors and us to reduce prices. The growth of our business may be negatively affected by high unemployment levels and increases in co-pays, which may lead some patients to delay treatments, skip doses or use less effective treatments to reduce their costs. 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. We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies.

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.

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, India, Venezuela and Russia) is affected by such acts, our business and results of operations may be adversely affected as a consequence.

In the last decade, Asia experienced outbreaks of avian influenza and Severe Acute Respiratory Syndrome, or "SARS". In addition, in 2009 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. In May 2015, the Pan American Health Organization issued an alert regarding the first confirmed Zika virus infection in Brazil, and since then it has spread across the Americas. In the United States, there have been reports of local mosquito-borne transmission of the Zika virus in Puerto Rico, the U.S. Virgin Islands, and American Samoa, and there have been reports of cases in the continental United States in returning travelers. 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 25.58% of our issued shares as at March 31, 2016. 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, 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. As a result, the value of the equity shares and/or ADSs of our minority shareholders may be adversely affected or our minority shareholders might be deprived of a potential opportunity to sell their equity shares and/or 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, 2016 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.

We may be subjected to additional compliance and litigation risks as a result of introduction of the Companies Act, 2013 in India and the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

As a company that is incorporated in India, we are governed by the rules and regulations covered under the Indian Companies Act, 1956. Significant amendments to the Companies Act were adopted in 2013 and 2014 and a majority of the provisions of the new Act (called the "Companies Act, 2013") were implemented beginning in April, 2014. Some of the significant changes were in the areas of board and governance processes, boardroom responsibilities, disclosures, compulsory corporate social responsibility, audit matters, initiation of class action suits by shareholders or depositors, fraud reporting and whistle-blower mechanisms.

In addition, on September 2, 2015, the Securities and Exchange Board of India ("SEBI") issued the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 (the "Listing Regulations") that must be followed by all listed Indian public companies effective December 1, 2015. These Listing Regulations were intended to consolidate and streamline the provisions of the existing listing agreements for different segments of the capital markets (e.g., equity securities, debt securities, Indian depository receipts, etc.). The Listing Regulations have thus been structured to provide ease of reference by consolidating into one single document across various types of securities listed on the stock exchanges. Key features of the Listing Regulations include:

- A framework has been prescribed for disclosure of material events and information by listed entities to the Indian stock exchanges. Certain events mentioned in the regulations are deemed material and disclosure is mandatory. Certain events are to be disclosed based on application of the guidelines for materiality as prescribed. The Board of Directors is required to frame a policy for determination of materiality and disclose the same on the website of the company.

- Entities will be required to frame policies on preservation of documents, determination of material subsidiaries, risk management, code of conduct, remuneration of directors, key managerial personnel and other employees, board diversity, materiality of related party transactions and dealing with related party transactions and criteria for evaluation of directors.
- Existing listed entities are required to sign the shortened version of the listing agreement with stock exchanges within six months of the issuance of the Listing Regulations.

However, certain provisions of the Companies Act, 2013 and the new Listing Regulations provisions are subject to varying interpretations and their application in practice may evolve over time as additional guidance is provided by regulatory and governing bodies. This may result in delays or continuing uncertainty regarding compliance matters and higher costs of compliance as a result of ongoing revisions.

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 and more recently in February 2013, although none of our operations were impacted by these terrorist acts.

During the last several years, the state of Telangana, where our headquarters is located, experienced political disruption relating to a movement to bifurcate a part of the then existing undivided state of Andhra Pradesh into a new separate state of "Telangana". In February 2014, the Indian Parliament approved such bifurcation and announced creation of a new state of "Telangana" with effect from June 2, 2014.

Due to civil disturbances and "Bandhs" (i.e., political protests in the form of worker strikes), several productive days were lost from forced or precautionary closures of our production units and offices during the agitation movement. We experienced such issues in 2009 and 2013 in Andhra Pradesh (now Telangana). If there are any such strikes, political protests or civil unrest in the future, 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.

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 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 -0.85% for the year ended March 31, 2016 (as compared to -2.33% for the year ended March 31, 2015). This trend may continue to fluctuate and/or 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 5% 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

The market price of our ADSs may be volatile, and the value of your investment could materially decline.

Investors who hold our ADSs may not be able to sell their ADSs at or above the price at which they purchased such ADSs. The price of our ADSs fluctuate from time to time, and we cannot predict the price of our ADSs at any given time. The risk factors described herein could cause the price of our ADSs to fluctuate materially. In addition, the stock market in general, including the market for generic and specialty pharmaceutical companies, has experienced price and volume fluctuations. These broad market and industry factors may materially harm the market price of our ADSs, regardless of our operating performance. In addition, the price of our ADSs may be affected by the valuations and recommendations of the analysts who cover us, and if our results do not meet the analysts' forecasts and expectations, the price of our ADSs could decline as a result of analysts lowering their valuations and recommendations or otherwise.

Negative media coverage and public scrutiny may adversely affect the prices of our equity shares and ADSs.

Media coverage, including social media coverage such as blogs, of our company has increased dramatically over the past several years. Any negative media coverage, regardless of the accuracy of such reporting, may have an adverse impact on our reputation and investor confidence, resulting in a decline in the share price of our equity shares and our ADSs.

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 must 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 depositary 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 depositary 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 depositary facility. Moreover, there are restrictions on foreign institutional ownership of our equity shares as opposed to our ADSs.

The persistently weak global economic and financial environment in many other countries, particularly emerging market countries in Asia, and increasing political and social instability could have a material adverse effect on our business and the price and liquidity of our shares and our ADSs.

Many of the world's largest economies and financial institutions continue to be impacted by a weak ongoing global economic and financial environment, with some continuing to face financial difficulty, liquidity problems and limited availability of credit. We continue to see weak economic growth or a slowing of economic growth rates in certain emerging growth markets, such as China, Russia, Brazil and India. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. In addition, these issues may be further impacted by the unsettled political conditions currently existing in the United States and Europe, as well as the difficult conditions existing in parts of the Middle East and places such as Ukraine, as well as the ongoing refugee crisis, anti-immigrant activities, social unrest and fears of terrorism that have followed in many countries. Such uncertain times may have a material adverse effect on business and financial performance and, if circumstances worsen, our ability to raise capital at reasonable rates. For example, financial weakness in certain countries has increased pressures on those countries, and on payors in those countries, to force healthcare companies to decrease the prices at which we may sell them our products.

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 our 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 depositary, 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 depositary 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.

Sale of our equity shares may adversely affect the prices of our equity shares and ADSs.

The Government of India has recently issued a notice of the implementation of the Depository Receipts Scheme, 2014, which permits liberalized rules for sponsored and unsponsored secondary market issue of depository receipts, subject to the existing sectorial cap on foreign investment. Once the regulations are fully implemented, an Indian company's equity shares can be freely issued to a depository for the purpose of issuing depository receipts through any mode permissible for the issue of such securities to other investors. This would enable us to more readily issue shares to the depositary for our ADSs and conduct U.S. securities issuances of our ADSs, which would impact the share price and available float in Indian stock exchanges as well as the price and availability of our ADSs on the NYSE.

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 former Chairman, the late 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, Hyderabad, Telangana, India as Company No. 4507 (Company Identification No. L85195TG1984PLC004507). Our registered office is situated at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 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., 107 College Road East, Princeton, New Jersey 08540.

Key business developments:

Receipt of warning letter from the U.S. FDA

We received a warning letter dated November 5, 2015 from the U.S. FDA relating to cGMP deviations at our API manufacturing facilities at Srikakulam, Andhra Pradesh and Miryalaguda, Telangana, as well as violations at our oncology formulation manufacturing facility at Duvvada, Visakhapatnam, Andhra Pradesh previously raised in Form 483 observations following inspections of these sites by the U.S. FDA in November 2014, January 2015 and February-March 2015, respectively.

This has had an adverse impact on new product approvals from these sites, and we have taken steps to minimize the impact from these sites through site transfers of certain key products. We continue to develop and implement our corrective action plans relating to the warning letter.

The warning letter does not restrict production or shipment of our products from these facilities. However, unless and until we are able to correct outstanding issues to the U.S. FDA's satisfaction, the U.S. FDA may withhold approval of our new products and new drug applications, refuse admission of products manufactured at the facilities noted in the warning letter into the United States, and/or take additional regulatory or legal action against us. Any such further action could have a material and negative impact on our ongoing business and operations.

We submitted our response to the warning letter on December 7, 2015. Further, we provided updates on the progress of our corrective actions to the U.S. FDA in January 2016, March 2016 and May 2016.

We believe that we can resolve the issues raised by the U.S. FDA satisfactorily in a timely manner. We take the matters identified by U.S. FDA in the warning letter seriously, and will continue to work diligently to address the observations identified in the warning letter, and are concurrently continuing to refine and implement our corrective action plans relating to the warning letter.

Venezuela operations

Refer to Note 41 to our consolidated financial statements.