

### **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**

##### **Failure of our research and development efforts may restrict introduction of new products, which is critical to our business.**

Our future results of operations depend, to a significant degree, upon our ability to successfully 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. All of our products must meet and continue to comply with regulatory and safety standards and receive regulatory approvals; we may be forced to withdraw a product from the market if health or safety concerns arise with respect to such product. The development and commercialization process, particularly with respect to proprietary products, is both time consuming and costly and involves a high degree of business risk. Our products currently under development, if and when fully developed and tested, may not perform as we expect, 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.

To develop our product pipeline, we commit substantial efforts, funds and other resources to research and development, both through our own dedicated resources and our collaborations with third parties. Our ongoing investments in new product launches and research and development for future products could result in higher costs without a proportionate increase in revenues. Our overall profitability depends on our ability to continue developing commercially successful products, and to introduce them on a timely basis in relation to competitor product introductions.

Our dependence on research and development makes it highly important that we recruit and retain high quality researchers and development specialists. Should we fail in our efforts, this could adversely affect our ability to continue developing commercially successful products and, thus, our overall profitability.

**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, 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 a license to market the product will be granted. Each authority may impose its own requirements and/or delay or refuse to grant approval, even when a product has already been approved in another country. In the United States, as well as many of the international markets into which we sell our products, the approval process for a new product is complex, lengthy and expensive. The time taken to obtain approval varies by country but generally takes from six months to several years from the date of application. This registration 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.

Also, governmental authorities, including the U.S. Food and Drug Administration (“U.S. FDA”), heavily regulate the manufacture of our products. If we or our third party suppliers fail to comply fully with such regulations, then there could be a government-enforced shutdown of our production facilities, which in turn could lead to product shortages. Failure to comply fully with such regulations could also lead to a delay in the approval of our new products.

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. As a result, there is increased risk of our inadvertent non-compliance with such regulations, which

could lead to government-enforced shutdowns and other sanctions, as well as the withholding or delay of regulatory approvals for new products.

**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. From time to time, the pharmaceutical industry has experienced difficulty in obtaining desired amounts of product liability insurance coverage. Although we have obtained product liability coverage with respect to products that we manufacture, if any product liability claim sustained against us were to be not covered by insurance or were to exceed the policy limits, it could harm our business and financial condition. This risk is likely to increase as we develop our own new-patented products in addition to making generic versions of drugs that have been in the market for some time.

In addition, product liability coverage for pharmaceutical companies is becoming more expensive. As a result, we may not be able to obtain the type and amount of coverage we desire at an acceptable price. Furthermore, the severity and timing of future claims are unpredictable. Our customers may also bring lawsuits against us for alleged product defects. 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.

**If we cannot respond adequately to the increased competition we expect to face in the future, we will lose market share and our profits will go down.**

Our products face intense competition from products commercialized or under development by competitors in all our business segments based in India and overseas. Many of our competitors have greater financial resources and marketing capabilities than we do. Some of our competitors, especially multinational pharmaceutical companies, have greater experience than we do in clinical testing and human clinical trials of pharmaceutical products and in obtaining regulatory approvals. Our competitors may succeed in developing technologies and products that are more effective, more popular or cheaper than any we may develop or license. These developments could render our technologies and products obsolete or uncompetitive, which would harm our business and financial results. We believe some of our competitors have broader product ranges, stronger sales forces and better segment positioning than us, which enables them to compete effectively.

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. Selling prices of generic drugs typically decline, sometimes dramatically, as additional companies receive approvals for a given product and competition intensifies. 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.

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

We are constantly striving to build efficiency in our internal processes and cost structures and to build decisive competitive advantages to face increasing competition on product price and market share. However, these advantages and the long term beneficial impact from such initiatives may not sustain in future.

**If we cannot maintain our position in the Indian pharmaceutical industry in the future, we may not be able to attract co-development, outsourcing or licensing partners and may lose market share.**

In order to attract multinational corporations into co-development and licensing arrangements, it is necessary for us to maintain the position of a leading pharmaceutical company in India. Multinational corporations have been increasing their outsourcing of both active pharmaceutical ingredients and generic formulations to highly regarded companies that can produce high quality products at

low cost that conform to standards set in developed markets. If we cannot maintain our current position in the market, we may not be able to attract outsourcing or licensing partners and may lose market share.

In India and our key “rest of the world” markets (which are product detailing driven, as opposed to generics regulated markets which are distribution driven), we follow a business model that is largely dependent upon our products being prescribed by medical practitioners. Our competitors may engage in business practices or models that are competitive and/or contrary to our model that can impact our market share.

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

Our success will depend in part on the extent to which government and health administration authorities, private health insurers and other third-party payors will pay for our products. Increasing expenditures for health care has been the subject of considerable public attention in almost every jurisdiction where we conduct business. Both private and governmental entities are seeking ways to reduce or contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products. In many countries in which we currently operate, including India, pharmaceutical prices are subject to regulation. The existence of price controls can limit the revenues we earn from our products. In the United States, numerous proposals that would affect changes in the United States health care system have been introduced or proposed in Congress and in some state legislatures, including the enactment in December 2003 of expanded Medicare coverage for drugs, which became effective in January 2006. The Obama administration has also indicated that it intends to propose legislation aimed at changing the U.S. healthcare system. While we cannot predict whether legislative or regulatory proposals will be adopted or what effect those proposals might have on our business, the announcement and/or adoption of such proposals could increase our costs and reduce our profit margins.

In Germany, an important market for us, the government has introduced several healthcare reforms in order to control healthcare spending and promote the prescribing of generic drugs. As a result, the prices of generic pharmaceutical products in Germany have declined, impacting our revenues, and may further decline in the future. Furthermore, the shift to a tender (i.e., competitive bidding) based supply model in Germany may further reduce prices for our products and may impact 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.

In addition, governments throughout the world heavily regulate the marketing of our products. Most countries also place restrictions on the manner and scope of permissible marketing to physicians, pharmacies and other health care professionals. 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 fail to comply fully with such regulations, then civil or criminal actions could be brought against us.

**If a regulatory agency amends or withdraws existing approvals to market our products, this may cause our revenues to decline.**

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

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

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

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

expect to continue to file, patent applications seeking to protect our newly developed technologies and products in various countries, including the United States. Any existing or future patents issued to or licensed by us may not provide us with any competitive advantages for our products or may even be challenged, invalidated or circumvented by competitors. In addition, such patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation that we seek to protect, in part by confidentiality agreements with licensees, suppliers, employees and consultants. It is possible that these agreements will be breached and we will not have adequate remedies for any such breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors or we may not be able to maintain the confidentiality of information relating to such products.

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

The policy of the U.S. FDA regarding the award of 180 days of market exclusivity to generic manufacturers who challenge patents relating to specific products continues to be the subject of extensive litigation in the United States. During this 180-day market exclusivity period, nobody other than the generic manufacturer who won exclusivity relating to the specific product can market that product. The U.S. FDA's current interpretation of the Hatch-Waxman Act of 1984 is to award 180 days of exclusivity to the first generic manufacturer who files a Paragraph IV certification under the Hatch-Waxman Act challenging the patent of the branded product, regardless of whether that generic manufacturer was sued for patent infringement.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "Medicare Prescription Drug Act") amended the Hatch-Waxman Act and provides that the 180-day market exclusivity period is triggered by the commercial marketing of the product, as opposed to the old rule under which the exclusivity period was triggered by a final, non-appealable court decision. However, the Medicare Prescription Drug Act also contains forfeiture provisions, which, if met, will deprive the first Paragraph IV filer of exclusivity. As a result, under certain circumstances, we may not be able to exploit our 180-day exclusivity period since it may be forfeited prior to our being able to market the product.

In addition, legal and administrative disputes with respect to triggering dates and shared exclusivities may also prevent us from fully utilizing the exclusivity periods.

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

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

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

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

At times we seek approval to market generic products before the expiration of patents for those products, based upon our belief that such patents are invalid, unenforceable, or would not be infringed by our products. As a result, we are involved in patent litigation, the outcome of which could materially adversely affect our business. Based upon a complex analysis of a variety of legal and commercial factors, we may elect to market a generic product even though litigation is still pending. This could be before any court decision is rendered or while an appeal of a lower court decision is pending. To the extent we elect to proceed in this manner, if

the final court decision is adverse to us, we could be required to cease the sale of the infringing products and face substantial liability for patent infringement. These damages may be significant as they may be measured by a royalty on our sales or by the profits lost by the patent owner and not by the profits we earned. Because of the discount pricing typically involved with generic pharmaceutical products, patented brand products generally realize a significantly higher profit margin than generic pharmaceutical products. In the case of a willful infringer, the definition of which is unclear, these damages may even be trebled.

In April 2006, we launched, and continue to sell fexofenadine, the generic version of Allegra®, despite the fact that litigation with the company that holds the patents for and sells this branded product is still ongoing. This is the only product that we have launched in the United States prior to the resolution of outstanding patent litigation. In the European Union, we also have generic launches that involve ongoing patent litigation, the outcome of which could adversely affect our business or profitability. During the year ended March 31, 2009, we incurred damages of approximately Rs.916 million as a result of the German Federal Court of Justice upholding the validity of an olanzapine patent held by Eli Lilly.

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 example, in the case of our brand 'Oxycodon beta' in Germany, our supplier, Cimex Pharma AG, required us to enter into a cost sharing agreement under which we will pay up to 20% of the losses resulting from any innovator damage claims.

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

**If we do not maintain and increase our arrangements for overseas distribution of our products, our revenues and net income could decrease.**

As of March 31, 2009, our products are marketed in more than 100 countries. Our products are marketed in most of these countries through our subsidiaries as well as joint ventures. Since we do not have the resources to market and distribute our products ourselves in all our export markets, we also market and distribute our products through third parties by way of marketing and agency arrangements. These arrangements may be terminated by either party providing the other with notice of termination or when the contract regarding the arrangement expires. We may not be able to successfully negotiate these third party arrangements or find suitable joint venture partners in the future. Any of these arrangements may not be available on commercially reasonable terms. Additionally, our marketing partners may make important marketing and other commercialization decisions with respect to products we develop without our input. As a result, many of the variables that may affect our revenues and net income are not exclusively within our control when we enter into arrangements like these.

**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 in which we have production facilities, we are subject to significant environmental laws and regulations which govern the discharge, emission, storage, handling and disposal of a variety of substances that may be used in or result from our operations. If any of our plants or the operations of such plants are shut down, 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.

**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.

**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 recently. For example, Mumbai, India's commercial capital, was the target of serial railway bombings in July 2006 as well as the recent "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. In May 2008, the city of Jaipur in the state of Rajasthan, India was subjected to a series of coordinated bombings. If the economy of our major markets is affected by such acts, our business and results of operations may be adversely affected as a consequence.

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

**If we have difficulty in identifying acquisition candidates or consummating acquisitions, 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 or at all. 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 acquisition financing on terms satisfactory to us or may be unable to obtain necessary regulatory approvals, including the approval of antitrust regulatory bodies. The inability to identify suitable acquisition targets or investments or the inability to complete such transactions and the management and financial resources required to pursue such transactions may affect our competitiveness and our growth prospects.

**If we acquire other companies, our business may be harmed by difficulties in integration and employee retention, unidentified liabilities of the acquired companies, or obligations incurred in connection with acquisition financings.**

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.
- Integration of acquisitions may divert management's attention away from our primary product offerings, resulting in the loss of key customers and/or personnel, and may expose us to unanticipated liabilities.
- 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.
- Our acquisition strategy may require us to obtain additional debt or equity financing, resulting in additional leverage, or increased debt obligations as compared to equity, and dilution of ownership.



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

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

Our full time directors and members of their immediate families, in the aggregate, beneficially owned 26.4% of our issued shares as at March 31, 2009. As a result, these people, acting in concert, are likely to have the ability to exercise significant control over most matters requiring approval by our shareholders, including the election and removal of directors and significant corporate transactions. This significant control by these directors and their family members could delay, defer or prevent a change in control of us, impede a merger, consolidation, takeover or other business combination involving us, or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, even if that was in our best interest. As a result, the value of your ADSSs may be adversely affected or you might be deprived of a potential opportunity to sell your ADSSs at a premium.

**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 like sodium azide, acrolein and acetyl chloride. If improperly handled or subjected to the wrong conditions, these materials could hurt our employees and other persons, cause damage to our properties and harm the environment. This, in turn, could subject us to significant litigation, which could lower our profits in the event we were found liable.

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

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

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. In addition, this could result in a conflict between the API needs of our Global Generics segment and the needs of customers of our Pharmaceutical Services and Active Ingredients segment, some of whom are also our competitors in the Global Generics segment. In either case, we could potentially lose business from adversely affected customers and we could be subjected to lawsuits.

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, which may adversely affect our business or results of operations.

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

Currently, we operate our business in certain countries through subsidiaries and equity investees or through supply and marketing arrangements with our alliance partners. In those countries where we have limited experience in operating subsidiaries and in reviewing equity investees, we are subject to additional risks related to complying with a wide variety of national and local laws, including restrictions on the import and export of certain intermediates, drugs, technologies and 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 or with international operations generally. We may also face difficulties integrating new facilities in different

countries into our existing operations, as well as integrating employees that we hire in different countries into our existing corporate culture. If we do not effectively manage our operations in these subsidiaries and review equity investees effectively, or if we fail to manage our alliances, we may lose money in these countries and it may adversely affect our business and results of operations.

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

Our principal subsidiaries are located in the United States, United Kingdom, Germany, Switzerland, Mexico and Russia and each has significant local operations. A significant portion of our revenues are in currencies other than the Indian rupee, especially the U.S. dollar, euro, rouble and 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 rupees may decrease.

We have entered into borrowing arrangements in connection with our acquisition of betapharm. In the future, we may enter into additional borrowing arrangements in connection with acquisitions or for general working capital purposes. In the event interest rates increase, our costs of borrowing will increase and our results of operations may be adversely affected.

**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 which has had, or planned departure which 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 operate in a highly competitive and rapidly consolidating industry.**

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

**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 through our acquisitions of companies and brands. This growth has significantly increased demands on our processes, systems and people. We expect to make 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 are critical to our business, and competition for these people can be intense. Furthermore, to facilitate our growth, we are carrying out reorganizations to improve our focus on delivery, to build decisive competitive advantages or/and to build sustainable cost structures. 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 may result in volatility in the price of our equity shares and our ADSs. Our quarterly revenues, operating results and cash flows may fluctuate as a result of a variety of factors, including but not limited to:

- changes in demand for our products;



- the impact of seasons (weather severity, length and timing) on the price and availability of raw materials which we depend on;
- the 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;
- changes in our pricing policies or those of our competitors;
- the magnitude and timing of our research and development investments;
- changes in the level of inventories maintained by our customers;
- the geographical mix of our sales and currency exchange rate fluctuations;
- adverse market events leading to impairment of any of our assets; and
- timing of our retailers' promotional programs.

Due to all of the foregoing factors, our revenues, operating results and cash flows are difficult to predict and may not meet the expectations of market analysts and investors. In such an event, the trading price of our shares and ADSs may be materially adversely affected.

**Significant disruptions of information technology systems 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. Any significant breakdown or interruption of these systems, whether due to computer viruses or other causes, may result in the loss of key information and/or disruption of production and business processes, which could materially and adversely affect our business.

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

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

**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 which incorporate indemnification provisions. Our indemnification obligations under such agreements may be unlimited in duration and amount. We maintain insurance coverage which we believe will effectively mitigate our obligations under certain of these indemnification provisions. 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.**

The global economy is currently undergoing a period of unprecedented volatility, and the future economic environment may continue to be less favorable than that of recent years. Reduced consumer spending may force our competitors and us to reduce prices. We have exposure to many different industries and counterparties, including our partners under our alliance, research and promotional services agreements, suppliers of raw materials, drug wholesalers and other customers, who may be unstable or may become unstable in the current economic environment.

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

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

The U.S. Foreign Corrupt practices Act 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. Given the high level of complexity of these laws, however, there is a risk that some provisions may be inadvertently breached, for example through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements or otherwise. Any violation of these laws or allegations of such violations, whether or not merited, could have a material adverse effect on our reputation and could cause the trading price of our ordinary shares and ADSs' to decline.

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

#### **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 significant part of our total revenues for the year ended March 31, 2009 were derived from sales in India. As a result, the following additional risk factors apply.

**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 economy is rising while that of the industrial, manufacturing and agricultural sector is declining. It is difficult to gauge the impact of these fundamental economic changes on our business.

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

India has experienced communal disturbances, terrorist attacks and riots during recent years. For example, Mumbai, India's commercial capital, was the target of serial railway bombings in July 2006 as well as the recent "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. In May 2008, the city of Jaipur in the state of Rajasthan, India was subjected to a series of co-ordinated bombings. If such disturbances continue or are exacerbated, our operational, sales and marketing activities may be adversely affected. Additionally, India has from time to time experienced hostilities with neighboring countries. The hostilities have continued sporadically. The hostilities between India and Pakistan are particularly threatening, because both India and Pakistan are nuclear powers. Hostilities and tensions may occur in the future and on a wider scale. These hostilities and tensions could lead to political or economic instability in India and harm our business operations, our future financial performance and the price of our shares and our ADSs.

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

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

Due to various macro-economic factors, the inflation level in the recent period has significantly decreased 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 1993-94=100 was 0.26% for the week ended March 28, 2009 (as compared to 7.75% for the week ended March 29, 2008), which is one of the lowest in recent years. This trend may not continue and

the rate of inflation may further rise. We may not be able to pass these costs on to our customers by increasing the price we charge for our products. If this occurs, our profits may decline.

**In the event that a natural disaster should occur in India, including drought, floods and earthquakes, it could adversely affect our production operations and cause our revenues to decline.**

Our main facilities are situated around Hyderabad, India. This region has experienced earthquakes, floods and droughts in the past and has experienced droughts in recent years. In the event of a drought so serious that the drinking water in the region is limited, the government could cut the supply of water to all industries, including our facilities. This would adversely affect our production operations and reduce our revenues. 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.

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

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

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

Under certain circumstances, the Reserve Bank of India must approve the sale of equity shares underlying ADSs by a non-resident of India to a resident of India. The Reserve Bank of India has given general permission to effect sales of existing shares or convertible debentures of an Indian company by a resident to a non-resident, subject to certain conditions, including the price at which the shares may be sold. Additionally, except under certain limited circumstances, if an investor seeks to convert the 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 shares as opposed to our ADSs.

**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.

**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 shares.

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

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

**If you are not able to exercise preemptive rights available to other shareholders, your investment in our securities 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 75.0% of the company's shareholders present and voting at a shareholders' general meeting. U.S. investors in our ADSs may be unable to exercise preemptive rights for the shares underlying our ADSs unless a registration statement under the Securities Act of 1933 is effective with respect to the rights or an exemption from the registration requirements of the Securities Act is available. Our decision to file a registration statement will depend on the costs and potential liabilities associated with a registration statement as well as the perceived benefits of enabling U.S. investors in our ADSs to exercise their preemptive rights and any other factors we consider appropriate at the time. We might choose not to file a registration statement under these circumstances. If we issue any of these securities in the future, such securities may be issued to the depository, which may sell them in the securities markets in India for the benefit of the investors in our ADSs. We cannot assure you as to the value, if any, the depository would receive upon the sale of these securities. To the extent that you are unable to exercise preemptive rights, your proportional interests in us would be reduced.

**If there is a change in tax regulations, it may increase our tax liabilities and thus adversely affect our financial results.**

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

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

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

Dr. Reddy's Laboratories Limited was incorporated in India under the Companies Act, 1956, by its promoter and our current Chairman, Dr. K. Anji Reddy as a Private Limited Company on February 24, 1984. We were converted to a Public Limited Company on December 6, 1985 and listed on the Indian Stock Exchanges in August 1986 and on the New York Stock Exchange on April 11, 2001. We are registered with the Registrar of Companies, Andhra Pradesh, Hyderabad, India as Company No. 4507 (Company Identification No. U85195AP1984PTC004507). Our registered office is situated at 7-1-27, Ameerpet, Hyderabad – 500 016, Andhra Pradesh, India and the telephone number of our registered office is +91-40-23731946. The name and address of our registered agent in the United States is Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Boulevard (Bldg II), Bridgewater, New Jersey 08807.