

DR REDDYS LABORATORIES LTD

Form 20-F

September 22, 2010

**Table of Contents**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 20-F**

o **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
OR**

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**For the Fiscal Year Ended March 31, 2010**

**OR**

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**OR**

o **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**Date of event requiring this shell company report \_\_\_\_\_**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number: 1-15182**

**DR. REDDY S LABORATORIES LIMITED**

(Exact name of Registrant as specified in its charter)

**Not Applicable**  
(Translation of Registrant's name  
into English)

**ANDHRA PRADESH, INDIA**  
(Jurisdiction of incorporation or  
organization)

**7-1-27, Ameerpet  
Hyderabad, Andhra Pradesh 500 016, India  
+91-40-23731946**

(Address of principal executive offices)

Umang Vohra, *Chief Financial Officer*, +91-40-2373 1946, umangvohra@drreddys.com

7-1-27, Ameerpet, Hyderabad, Andhra Pradesh, India

(Name, telephone, e-mail and/or facsimile number and address of company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

**Title of Each Class  
American depository shares, each  
representing one equity share**

**Name of Each Exchange on which Registered  
New York Stock Exchange**

**Equity Shares\***

**\* Not for  
trading, but  
only in**

**connection with the registration of American depositary shares, pursuant to the requirements of the Securities and Exchange Commission.**

Securities registered or to be registered pursuant to Section 12(g) of the Act. None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

**168,845,385 Equity Shares**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes  No

Note: Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP  International Financial Reporting Standards as issued by the International Accounting Standards Board  Other

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934).

Yes  No



**Table of Contents**

**Currency of Presentation and Certain Defined Terms**

In this annual report on Form 20-F, references to \$ or U.S.\$ or dollars or U.S. dollars are to the legal currency of United States and references to Rs. or rupees or Indian rupees are to the legal currency of India. Our financial statements are presented in Indian rupees and translated into U.S. dollars and are prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or

IASB. References to Indian GAAP are to Indian Generally Accepted Accounting Principles and references to U.S. GAAP are to United States Generally Accepted Accounting Principles. References to a particular fiscal year are to our fiscal year ended March 31 of such year. References to our ADSs are to our American Depositary Shares.

References to U.S. or United States are to the United States of America, its territories and its possessions. References to India are to the Republic of India. References to EU are to the European Union. All references to we, us, our

Dr. Reddy's or the Company shall mean Dr. Reddy's Laboratories Limited and its subsidiaries. Dr. Reddy's is a registered trademark of Dr. Reddy's Laboratories Limited in India. Other trademarks or trade names used in this annual report on Form 20-F are trademarks registered in the name of Dr. Reddy's Laboratories Limited or are pending before the respective trademark registries.

Except as otherwise stated in this report, all translations from Indian rupees to U.S. dollars are based on the noon buying rate in the City of New York on March 31, 2010 for cable transfers in Indian rupees as certified for customs purposes by the Federal Reserve Bank of New York, which was Rs.44.95 per U.S.\$1.00. No representation is made that the Indian rupee amounts have been, could have been or could be converted into U.S. dollars at such a rate or any other rate. As of September 17, 2010 that rate was Rs.45.88 per U.S.\$1.00.

Any discrepancies in any table between totals and sums of the amounts listed are due to rounding.

Information contained in our website, www.drreddys.com, is not part of this Annual Report and no portion of such information is incorporated herein.

**Forward-Looking and Cautionary Statement**

IN ADDITION TO HISTORICAL INFORMATION, THIS ANNUAL REPORT CONTAINS CERTAIN FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933, AS AMENDED AND SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (THE EXCHANGE ACT). THE FORWARD-LOOKING STATEMENTS CONTAINED HEREIN ARE SUBJECT TO CERTAIN RISKS AND UNCERTAINTIES THAT COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE REFLECTED IN THE FORWARD-LOOKING STATEMENTS. FACTORS THAT MIGHT CAUSE SUCH A DIFFERENCE INCLUDE, BUT ARE NOT LIMITED TO, THOSE DISCUSSED IN THE SECTIONS ENTITLED RISK FACTORS AND OPERATING AND FINANCIAL REVIEW AND PROSPECTS AND ELSEWHERE IN THIS REPORT. READERS ARE CAUTIONED NOT TO PLACE UNDUE RELIANCE ON THESE FORWARD-LOOKING STATEMENTS, WHICH REFLECT MANAGEMENT'S ANALYSIS ONLY AS OF THE DATE HEREOF. IN ADDITION, READERS SHOULD CAREFULLY REVIEW THE OTHER INFORMATION IN THIS ANNUAL REPORT AND IN OUR PERIODIC REPORTS AND OTHER DOCUMENTS FILED AND/OR FURNISHED WITH THE SECURITIES AND EXCHANGE COMMISSION (SEC) FROM TIME TO TIME.

## TABLE OF CONTENTS

### PART I

<u>ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS</u>	4
<u>ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE</u>	4
<u>ITEM 3. KEY INFORMATION</u>	4
<u>ITEM 4. INFORMATION ON THE COMPANY</u>	20
<u>ITEM 4A. UNRESOLVED STAFF COMMENTS</u>	52
<u>ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u>	53
<u>ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</u>	83
<u>ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</u>	98
<u>ITEM 8. FINANCIAL INFORMATION</u>	101
<u>ITEM 9. THE OFFER AND LISTING</u>	107
<u>ITEM 10. ADDITIONAL INFORMATION</u>	108
<u>ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	118
<u>ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES</u>	119

### PART II

<u>ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES</u>	122
<u>ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS</u>	122
<u>ITEM 15. CONTROLS AND PROCEDURES</u>	122
<u>ITEM 16. [RESERVED]</u>	125
<u>ITEM 16.A. AUDIT COMMITTEE FINANCIAL EXPERT</u>	125
<u>ITEM 16.B. CODE OF ETHICS</u>	125
<u>ITEM 16.C. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	125
<u>ITEM 16.D. EXEMPTION FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES</u>	125

<u>ITEM 16.E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS</u>	125
<u>ITEM 16.F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT</u>	125
<u>ITEM 16.G. CORPORATE GOVERNANCE</u>	126
<u>PART III</u>	
<u>ITEM 17. FINANCIAL STATEMENTS</u>	128
<u>ITEM 18. FINANCIAL STATEMENTS</u>	128
<u>ITEM 19. EXHIBITS</u>	129
<u>SIGNATURES</u>	130
<u>Exhibit 1.4</u>	
<u>Exhibit 8</u>	
<u>Exhibit 23.1</u>	
<u>Exhibit 99.1</u>	
<u>Exhibit 99.2</u>	
<u>Exhibit 99.3</u>	
<u>Exhibit 99.4</u>	

**Table of Contents****PART I****ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS**

Not applicable.

**ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

Not applicable.

**ITEM 3. KEY INFORMATION****3.A. Selected financial data**

You should read the selected consolidated financial data below in conjunction with our consolidated financial statements and the related notes, as well as the section titled Operating and Financial Review and Prospects, all of which are included elsewhere in this Annual Report on Form 20-F. The selected consolidated statements of income for the three years ended March 31, 2010, 2009 and 2008 and the selected consolidated statement of financial position data as of March 31, 2010 and 2009 have been prepared and presented in accordance with IFRS as issued by the IASB, and have been derived from our audited consolidated financial statements and related notes included elsewhere herein. The selected consolidated financial data below has been presented for the three most recent fiscal years. Historical results are not necessarily indicative of future results.

Selected IFRS financial data for the years ended March 31, 2007 and 2006 have not been included in this Annual Report on Form 20-F because IFRS financial statements for such periods have not previously been prepared and could not be without unreasonable effort and expense. We changed our basis of accounting to IFRS during the year ended March 31, 2009 and, in connection therewith, our consolidated financial statements for the year ended March 31, 2008 were restated to conform with IFRS. Prior to adoption of IFRS, we prepared financial statements in accordance with accounting principles generally accepted in the United States of America for purposes of our SEC reporting.

**Income Statement Data**

	<b>For the Year Ended March 31,</b>			
	<b>2010</b>	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(Rs. in millions, U.S.\$ in millions except share and per share data)</b>			
	<i>Convenience translation into U.S.\$</i>			
Revenues	U.S.\$ 1,563	Rs. 70,277	Rs. 69,441	Rs. 50,006
Cost of revenues	755	33,937	32,941	24,598
<b>Gross profit</b>	<b>808</b>	<b>36,340</b>	<b>36,500</b>	<b>25,408</b>
Selling, general and administrative expenses	501	22,505	21,020	16,835
Research and development expenses	84	3,793	4,037	3,533
Impairment loss on other intangible assets	77	3,456	3,167	3,011
Impairment loss on goodwill	115	5,147	10,856	90
Other (income)/expense, net	(13)	(569)	254	(402)
<b>Results from operating activities</b>	<b>45</b>	<b>2,008</b>	<b>(2,834)</b>	<b>2,341</b>
Finance (expense)/income, net		(3)	(1,186)	521
Share of profit of equity accounted investees, net of income tax	1	48	24	2
<b>Profit/(loss) before income tax</b>	<b>46</b>	<b>2,053</b>	<b>(3,996)</b>	<b>2,864</b>
Income tax (expense)/benefit	(22)	(985)	(1,172)	972



<b>Profit/(loss) for the year</b>	<b>U.S.\$</b>	<b>24</b>	<b>Rs.</b>	<b>1,068</b>	<b>Rs.</b>	<b>(5,168)</b>	<b>Rs.</b>	<b>3,836</b>
<b>Earnings/(loss) per share</b>								
Basic	U.S.\$	0.14	Rs.	6.33	Rs.	(30.69)	Rs.	22.88
Diluted	U.S.\$	0.14	Rs.	6.30	Rs.	(30.69)	Rs.	22.80
<b>Weighted average number of equity shares used in computing earnings/(loss) per equity share*</b>								
Basic		168,706,977		168,706,977		168,349,139		168,075,840
Diluted		169,615,943		169,615,943		168,349,139		168,690,774
Cash dividend per equity share (Rs.)**				6.25		3.75		3.75

\* Each ADR represents one equity share.

\*\* Excludes corporate dividend tax

**Table of Contents****Statement of financial position Data**

	As of March 31,			
	2010	2010	2009	
	(Rs. in millions, U.S.\$ in millions)			
	Convenience translation into U.S.\$			
Cash and cash equivalents	U.S.\$ 146	Rs. 6,584	Rs. 5,596	
Total assets	1,787	80,330	83,792	
Total long term debt, excluding current portion	120	5,385	10,132	
Total equity	U.S.\$ 955	Rs. 42,915	Rs. 42,045	

**Convenience translation**

For the convenience of the reader, our consolidated financial statements as of March 31, 2010 have been translated into U.S. dollars at the noon buying rate in New York City on March 31, 2010 for cable transfers in Indian rupees, as certified for customs purposes by the Federal Reserve Bank of New York, of U.S.\$1.00 = Rs.44.95. No representation is made that the Indian rupee amounts have been, could have been or could be converted into U.S. dollars at such a rate or any other rate.

**Exchange Rates**

The following table sets forth, for the fiscal years indicated, information concerning the number of Indian rupees for which one U.S. dollar could be exchanged based on the noon buying rate in the City of New York on business days during the period for cable transfers in Indian rupees as certified for customs purposes by the Federal Reserve Bank of New York. The column titled *Average* in the table below is the average of the daily noon buying rate on the last business day of each month during the year.

Year Ended	Period End	Average	High	Low
March 31, 2008	40.02	40.00	43.05	38.48
2009	50.87	46.32	51.96	39.73
2010	44.95	47.36	50.48	44.94

The following table sets forth the high and low exchange rates for the previous six months and is based on the noon buying rates in the City of New York on business days of each month during such period for cable transfers in Indian rupees as certified for customs purposes by the Federal Reserve Bank of New York.

Month	High	Low
October 2009	47.72	46.00
November 2009	47.37	46.06
December 2009	46.85	46.00
January 2010	46.40	45.35
February 2010	46.79	45.97
March 2010	46.01	44.94

## **Table of Contents**

On September 17, 2010, the noon buying rate in the City of New York was Rs.45.88 per U.S. dollar.

### **3.B. *Capitalization and indebtedness***

Not applicable.

### **3.C. *Reasons for the offer and use of proceeds***

Not applicable.

### **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 either directly or in partnership with contract research organizations. 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, development specialists and other science and technology experts. 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.



**Table of Contents**

Also, governmental authorities, including the U.S. Food and Drug Administration ( U.S. FDA ), heavily regulate the manufacturing 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 due to absence of adequate precedents or for other reasons. 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.

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

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

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

For example, in recent years Russia and other countries of the former Soviet Union were adversely affected by the global economic crisis and began to experience economic instability characterized by, among other things, liquidity issues and local currency devaluations against the U.S. dollar. We instituted strict credit controls and receivables monitoring mechanisms to mitigate our collection risks and, as a result, we managed to avoid any write-offs. However, in future periods we may be unable to successfully mitigate these or other risks of political, legal and economic instability, and our international operations could be adversely affected.

**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 and the clinical trials that we conduct, 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.

**Table of Contents**

**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.

**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.



## **Table of Contents**

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

The PPACA imposes on pharmaceutical manufacturers a variety of additional rebates, discounts and fees. Among other things, the PPACA includes annual, non-deductible fees that go into effect in 2011 for entities that manufacture or import certain prescription drugs and biologics. This fee will be calculated based upon each organization's percentage share of total branded prescription drug sales to U.S. government programs (such as Medicare, Medicaid and Veterans Affairs and Public Health Service discount programs), and authorized generic products are treated as branded products. In addition, the PPACA changes the computations used to determine Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program by redefining the average manufacturer's price ( AMP ), effective October 1, 2010, and by using 23.1% instead of 15% of AMP for most branded drugs and 13% instead of 11% of AMP for generic drugs, effective January 1, 2010. The PPACA also increases the number of healthcare entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

The PPACA has pro-generic provisions that could increase competition in the generic pharmaceutical industry and therefore adversely impact our selling prices or costs and reduce our profit margins. Among other things, the PPACA creates an abbreviated pathway to U.S. FDA approval of biosimilar biological products and allows the first interchangeable bio-similar biological product 18 months of exclusivity, which could increase competition for our bio-generics business. Conversely, the PPACA has some anti-generic provisions that could adversely affect our bio-generics business, including provisions granting the innovator of a biological drug product 12 years of exclusive use before generic drugs can be approved based on being biosimilar.

The PPACA makes several important changes to the federal anti-kickback statute, false claims laws, and health care fraud statutes that may make it easier for the government or whistleblowers to pursue such fraud and abuse violations. In addition, the PPACA increases penalties for fraud and abuse violations. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and our financial results. To further facilitate the government's efforts to coordinate and develop comparative clinical effectiveness research, the PPACA establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in such research. The manner in which the comparative research results would be used by third-party payors is uncertain.

The impact of the PPACA will be seen as it is implemented, by promulgation of regulations and other administrative and judicial actions. We are in the process of evaluating the impact of the PPACA and how it may affect our financial condition, results of operations and cash flows.

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.

**Table of Contents**

**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, the generic manufacturer who won exclusivity relating to the specific product usually is the only company marketing 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.



**Table of Contents**

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

There has been substantial patent related litigation in the pharmaceutical industry concerning the manufacture, use and sale of various products. In the normal course of business, we are regularly subject to lawsuits and the ultimate outcome of litigation could adversely affect our results of operations, financial condition and cash flow. Regardless of regulatory approval, lawsuits are periodically commenced against us with respect to alleged patent infringements by us, such suits often being triggered by our filing of an application for governmental approval, such as an abbreviated 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<sup>®</sup>, 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. In Canada, we continue to sell olanzapine tablets (the generic version of Eli Lilly's Zyprexa<sup>®</sup> tablets) through a partnership with Pharmascience, Inc., despite the fact that Pharmascience has agreed to pay damages if Eli Lilly is successful in its olanzapine patent litigation against Novopharm, and our partnership arrangement with Pharmascience would require us to share a portion of any such damages obligation realized by Pharmascience.

Furthermore, there may be risks involved in entering into in-licensing arrangements for products, which are often conditioned upon the licensee's sharing in the patent-related risks. For 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, 2010, our products were marketed in numerous countries. In large overseas markets, our products are usually marketed through our subsidiaries or 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.

**Table of Contents**

**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, 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.

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

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

**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. 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.

**Table of Contents**

**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 a 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 ADSs may be harmed.**

Our full time directors and members of their immediate families, in the aggregate, beneficially owned 25.8% of our issued shares as at March 31, 2010. 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 ADSs may be adversely affected or you might be deprived of a potential opportunity to sell your ADSs 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.

**Table of Contents**

**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. 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.

**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