

DR REDDYS LABORATORIES LTD

Form 20-F

June 26, 2014

[Table of Contents](#)

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 20-F**

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

**OR**

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

**For the Fiscal Year Ended March 31, 2014**

**OR**

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

**OR**

**.. 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)

**TELANGANA, INDIA**

(Jurisdiction of incorporation or organization)

**8-2-337, Road No. 3, Banjara Hills**

**Hyderabad, Telangana 500 034, India**

**+91-40-49002900**

(Address of principal executive offices)

**Saumen Chakraborty, Chief Financial Officer, +91-40-49002004, saumenc@drreddys.com**

**8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, 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.**

<b>Title of Each Class</b>	<b>Name of Each Exchange on which Registered</b>
<b>American depositary shares, each</b>	<b>New York Stock Exchange</b>
<b>representing one equity share</b>	
<b>Equity Shares*</b>	

**\* 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.

**170,108,868 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 ☐

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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 or a non-accelerated filer. 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 ☐

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

Other ☐

by the International Accounting Standards Board ☒

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 prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. These standards include International Accounting Standards, or IAS, and their interpretations issued by the International Financial Reporting Interpretations Committee, or IFRIC, or its predecessor, the Standing Interpretations Committee, or SIC. 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. Market share data is based on information provided by IMS Health Inc. and its affiliates (IMS Health), a provider of market research to the pharmaceutical industry, unless otherwise stated.

Our financial statements are presented in Indian rupees and translated into U.S. dollars for the convenience of the reader. Except as otherwise stated in this report, all translations from Indian rupees to U.S. dollars are at the certified foreign exchange rate of U.S.\$1 = Rs.60.00, as published by Federal Reserve Board of Governors on March 31, 2014. 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.

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](http://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**

**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>	25
<u>ITEM 4A. UNRESOLVED STAFF COMMENTS</u>	57
<u>ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u>	57
<u>ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</u>	92
<u>ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</u>	106
<u>ITEM 8. FINANCIAL INFORMATION</u>	108
<u>ITEM 9. THE OFFER AND LISTING</u>	115
<u>ITEM 10. ADDITIONAL INFORMATION</u>	116
<u>ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	127
<u>ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES</u>	129

**PART II**

<u>ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES</u>	131
<u>ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS</u>	131
<u>ITEM 15. CONTROLS AND PROCEDURES</u>	132
<u>ITEM 16. [RESERVED]</u>	134
<u>ITEM 16.A. AUDIT COMMITTEE FINANCIAL EXPERT</u>	134
<u>ITEM 16.B. CODE OF ETHICS</u>	134
<u>ITEM 16.C. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	134
<u>ITEM 16.D. EXEMPTION FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES</u>	134
<u>ITEM 16.E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS</u>	134
<u>ITEM 16.F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT</u>	134
<u>ITEM 16.G. CORPORATE GOVERNANCE</u>	135
<u>ITEM 16.H. MINE SAFETY DISCLOSURE</u>	137

**PART III**

<u>ITEM 17. FINANCIAL STATEMENTS</u>	137
--------------------------------------	-----

<u>ITEM 18. FINANCIAL STATEMENTS</u>	137
<u>ITEM 19. EXHIBITS</u>	138
<u>SIGNATURES</u>	139



**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 income statement data for the years ended March 31, 2014, 2013, 2012, 2011 and 2010 and the selected consolidated statement of financial position data as of March 31, 2014, 2013, 2012, 2011 and 2010 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 five most recent fiscal years. Historical results are not necessarily indicative of future results.

**Income Statement Data**

	<b>For the Year Ended March 31,</b>					
	<b>2014</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
	<b>(Rs. in millions, U.S.\$ in millions, both except share and per share data)</b>					
	<i>Convenience translation into U.S.\$</i>					
Revenues	U.S.\$ 2,203	Rs. 132,170	Rs. 116,266	Rs. 96,737	Rs. 74,693	Rs. 70,277
Cost of revenues	939	56,369	55,687	43,432	34,430	33,937
<b>Gross profit</b>	<b>1,263</b>	<b>75,801</b>	<b>60,579</b>	<b>53,305</b>	<b>40,263</b>	<b>36,340</b>
Selling, general and administrative expenses	647	38,783	34,272	29,907	23,689	31,108
Research and development expenses	207	12,402	7,674	5,911	5,060	3,793
Other (income)/expense, net	(24)	(1,416)	(2,479)	(765)	(1,115)	(569)
<b>Results from operating activities</b>	<b>434</b>	<b>26,032</b>	<b>21,112</b>	<b>18,252</b>	<b>12,629</b>	<b>2,008</b>

Finance (expense)/income, net	7	400	460	160	(189)	(3)
Share of profit of equity accounted investees, net of income tax	3	174	104	54	3	48
<b>Profit/(loss) before income tax</b>	<b>443</b>	<b>26,606</b>	<b>21,676</b>	<b>18,466</b>	<b>12,443</b>	<b>2,053</b>
Income tax expense	(85)	(5,094)	(4,900)	(4,204)	(1,403)	(985)
<b>Profit/(loss) for the year</b>	<b>359</b>	<b>21,512</b>	<b>16,776</b>	<b>14,262</b>	<b>11,040</b>	<b>1,068</b>
<b>Attributable to:</b>						
Equity holders of the Company	359	21,515	16,777	14,262	11,040	1,068
Non-controlling interests	0	(3)	(1)			
<b>Profit/(loss) for the year</b>	<b>U.S.\$ 359</b>	<b>Rs. 21,512</b>	<b>Rs. 16,776</b>	<b>Rs. 14,262</b>	<b>Rs. 11,040</b>	<b>Rs. 1,068</b>
<b>Earnings/(loss) per share</b>						
Basic	U.S.\$ 2.11	Rs. 126.52	Rs. 98.82	Rs. 84.16	Rs. 65.28	Rs. 6.33
Diluted	U.S.\$ 2.10	Rs. 126.04	Rs. 98.44	Rs. 83.81	Rs. 64.95	Rs. 6.30
<b>Weighted average number of equity shares used in computing earnings/(loss) per equity share*</b>						
Basic		170,044,518	169,777,458	169,469,888	169,128,649	168,706,977
Diluted		170,695,017	170,432,680	170,177,944	169,965,282	169,615,943
<b>Cash dividend per equity share**</b>	<b>U.S.\$ 0.25</b>	<b>Rs. 15</b>	<b>Rs. 13.75</b>	<b>Rs. 11.25</b>	<b>Rs. 11.25</b>	<b>Rs. 6.25</b>

\* Each ADR represents one equity share.

\*\* Excludes corporate dividend tax.

**Table of Contents****Statement of Financial Position Data**

As of March 31,												
2014				2013		2012		2011		2010		
				Restated*		Restated*		Restated*				
				(Rs. in millions, U.S.\$ in millions)								
Convenience translation into U.S.\$												
Cash and cash equivalents	U.S.\$	141	Rs.	8,451	Rs.	5,136	Rs.	7,379	Rs.	5,729	Rs.	6,584
Other investments		418		25,083		17,172		10,773		33		3,600
Total assets		2,837		170,223		142,369		119,477		95,005		80,330
Total long term debt, excluding current portion		346		20,740		12,625		16,335		5,271		5,385
Total equity	U.S.\$	1,513	Rs.	90,801	Rs.	72,805	Rs.	57,287	Rs.	45,803	Rs.	42,915
Number of shares outstanding				170,108,868		169,836,475		169,560,346		169,252,732		168,845,385

**March 31,**

2010	44.95	47.36	50.48	44.94
2011	44.54	45.49	47.49	43.90
2012	50.89	48.01	53.71	44.00
2013	54.52	54.48	57.13	50.64
2014	60.00	60.35	68.80	53.65

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.

<b>Month</b>	<b>High</b>	<b>Low</b>
October 2013	62.46	61.07
November 2013	63.73	61.74
December 2013	62.38	60.87
January 2014	63.09	61.45
February 2014	62.63	61.78
March 2014	62.17	59.89

On June 20, 2014, the noon buying rate in the city of New York was Rs.60.23 per U.S. dollar.

**3.B. Capitalization and indebtedness**

Not applicable.

## **Table of Contents**

### ***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**

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

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

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

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

Our research and development activities are heavily regulated. If we fail to comply fully with applicable regulations, then there could be a delay in the submission or approval of potential new products for marketing approval. In addition, the submission of an application to a regulatory authority does not guarantee that approvals required to market the product will be granted. Each authority may impose its own requirements and/or delay or refuse to grant approval, even when a product has already been approved in another country. In many of the international markets

into which we sell our products, including the United States, the approval process for a new product is complex, lengthy and expensive. The time taken to obtain approval varies by country but generally takes from six months to several years from the date of application. This approval process increases the cost to us of developing new products and increases the risk that we will not be able to successfully sell such new products.

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

Additionally, governmental authorities, including among others the U.S. Food and Drug Administration ( U.S. FDA ) and the U.K. Medicines and Healthcare Products Regulatory Agency ( MHRA ), heavily regulate the manufacturing of our

## **Table of Contents**

products, including manufacturing quality standards. Periodic audits are conducted on our manufacturing sites, and if the regulatory and quality standards and systems are not found adequate, it could result in an audit observation (on Form 483, if from the U.S. FDA), or a subsequent investigative letter which may require further corrective actions. More recently, a number of Indian generic pharmaceutical companies were issued import alerts and warning letters by the U.S. FDA. A significant proportion of our manufacturing base of API and Formulations plants servicing the United States and other markets of our Global Generics business are based out of India. There appears to be an increasing trend by the U.S. FDA and governmental regulators in other developed countries towards manufacturing site audits which are unannounced and conducted with unprecedented rigor and expectations. While our quality practices and quality management systems are conducted in a manner designed to satisfy these types of audits, we cannot guarantee that our efforts will prevent adverse outcomes such as audit observations, corrective action requests, warning letters or import bans. Furthermore, we deal with numerous third party manufacturers and despite our strict oversight, any lapse in their quality practices and quality management systems could lead to such adverse outcomes in the event of an audit.

If we or our third party suppliers fail to comply fully with such regulations or to take corrective actions which are mandated, then there could be a government-enforced shutdown of our production facilities or an import ban, which in turn could lead to product shortages that delay or prevent us from fulfilling our obligations to customers, or we could be subjected to government fines. For example, the U.S. FDA imposed an import ban on our manufacturing facility at Cuernavaca, Mexico from June 2011 through July 2012. Failure to comply fully with such regulations could also lead to a delay in the approval of our new products

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

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

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

Significant delays in the development of pathways for the registration and approval of such bio-similar products, or significant impediments that may be built into such pathways, could diminish the value of the investments we have made and will continue to make in our biotechnology capabilities. For example, in the healthcare reform legislation

adopted in the United States, biosimilar products may not be approved for twelve years following approval of the branded biotechnology product. As a result, filings and launches of biosimilar products may be delayed significantly, adversely affecting our ability to develop a successful biosimilars business. The U.S. FDA is in the process of establishing regulations relating to biosimilars to implement the new healthcare legislation. These regulations, when ultimately adopted, could further complicate the process of bringing biosimilar products to market on a timely basis and could thus adversely affect our ability to develop a successful biosimilars business. While the U.S. FDA has issued guidelines, their guidelines contained features that could significantly prolong the biosimilar development process and failed to address other important concerns.

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

In recent years, significant questions have arisen regarding the safety, efficacy and potential for misuse of certain over-the-counter medicine products. Litigation, particularly in the United States, sometimes gives rise to these questions. As a result, health authorities around the world have begun to re-evaluate some important over-the-counter products, leading to restrictions



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**Table of Contents**

on the sale of some of them and even the banning of certain products. For example, in 2010, the U.S. FDA undertook a review of one cough medicine ingredient to consider whether over-the-counter sales of the ingredient remained appropriate. While the U.S. FDA has not, to date, changed the ingredient's status, further regulatory or legislative action may follow. Additional actions and litigation regarding over-the-counter products are possible in the future. If the U.S. FDA or another regulator were to review one or more of our over-the-counter products for such purposes, and such review results in regulatory charges applicable to such product, it could have a significant adverse effect on our sales of such over-the-counter products and, thus, our overall profitability.

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

We expect to derive an increasing portion of our sales from regions such as Latin America, Russia and other countries of the former Soviet Union, Central Europe, Eastern Europe and South Africa, all of which may be more susceptible to political or economic instability. For example, recent political unrest in Ukraine has resulted in riots, clashes and violence, often leading to safety and security concerns for our colleagues and expatriates working there.

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

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

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

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

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

Following the United States Supreme Court's June 2013 ruling in *Mutual Pharmaceutical Co. v. Bartlett* upholding such preemption and immunity of generic manufacturers, the U.S. FDA proposed a new rule in November 2013 that would allow generic manufacturers to independently update product labeling through the CBE supplement process. If the U.S. FDA's proposed new rule is adopted, it may eliminate this preemption and increase our potential exposure to lawsuits relating to product safety, side effects and warnings on labels. This new potential exposure to lawsuits may also increase the risk that, in the future, we may not be able to obtain the type and amount of coverage we desire at an acceptable price and self-insurance may become the sole commercially reasonable means available for managing the product liability risks of our business.

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

## **Table of Contents**

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

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

Our success depends, in part, on the extent to which government and health administration authorities, private health insurers and other third-party payors will pay for our products. Increasing expenditures for health care has been the subject of considerable public attention in almost every jurisdiction where we conduct business. Both private and governmental entities are seeking ways to reduce or contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products. These pressures are particularly strong given the lingering effects of the recent global economic and financial crisis, including the ongoing debt crisis in certain countries in Europe. In many countries in which we currently operate, including India, pharmaceutical prices are subject to regulation. The existence of government-imposed price controls and mandatory discounts and rebates can limit the revenues we earn from our products.

We expect these efforts to continue as healthcare payors around the globe in particular government-controlled health authorities, insurance companies and managed care organizations step up initiatives to reduce the overall cost of healthcare.

## **India**

India recently enacted the National Pharmaceuticals Pricing Policy, 2012. As a result, hundreds of drugs on India's National List of Essential Medicines were identified and subjected to price controls in India. On May 15, 2013, the Department of Pharmaceuticals released Drugs (Price Control) Order, 2013 governing the price control mechanism for 348 drugs listed in the National List of Essential Medicines. As per this order, the prices of each of the drugs are determined based on the average of all drugs having an Indian market share of more than 1% by value. The individual drug price notifications for a majority of the products have been released by the National Pharmaceutical Pricing Authority. Based on these notifications, we were adversely impacted by approximately 3% (the annualized impact is approximately 4%) of our revenues from sales of all of our formulation products in India during the year ended March 31, 2014.

## **United States**

In the United States, numerous proposals that would affect changes in the health care system have been introduced in Congress and in some state legislatures.

### *Patient Protection and Affordable Care Act*

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA"), were signed into law. The PPACA is one of the most significant healthcare reform measures in the United States in decades, and is expected to significantly impact the U.S. pharmaceutical industry. We may see an increase in revenues by virtue of the PPACA's anticipated extension of health insurance to tens of millions of previously uninsured Americans and the prohibitions on denials of health insurance

coverage due to pre-existing diseases and on lifetime value limits on insurance policy coverage. However, the PPACA imposes additional rebates, discounts and fees, mandates certain reporting and contains various other requirements that could adversely affect our business, including the following:

The PPACA imposes annual, non-deductible fees for entities that manufacture or import certain prescription drugs and biologics. This fee is calculated based upon each manufacturer's percentage share of total branded prescription drug and biologics sales to U.S. government programs (such as Medicare, Medicaid, Veterans Affairs and Public Health Service discount programs), and authorized generic products are generally treated as branded products. The manufacturer must have at least \$5 million in sales of branded prescription drugs or biologics in order to be subject to this fee.

## **Table of Contents**

In August 2013, we received a final invoice from the United States Internal Revenue Service (the "IRS") determining our liability for the manufacturers' fee for calendar year 2013 to be \$12,171, based upon our calendar year 2011 sales of branded and authorized generic prescription drugs and biologics. We expect our sales of brand and authorized generic products during calendar year 2012 to the specified U.S. government programs to be below the threshold limit of \$5 million, and thus we may not be subject to the fee for calendar year 2014, based on our calendar year 2012 sales.

In addition, the PPACA changed the computations used to determine Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program by redefining the average manufacturer's price ("AMP"), effective October 1, 2010, and by using 23.1% instead of 15.1% of AMP for most branded drugs and 13% instead of 11% of AMP for generic drugs, effective January 1, 2010. The PPACA also increased the number of healthcare entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

The PPACA also increased the number of healthcare organizations eligible to participate in the Public Health Service pharmaceutical pricing program, which provides for government controlled prices that result in substantial discounts for participants.

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-similars business. Conversely, the PPACA has some anti-generic provisions that could adversely affect our bio-similars business, including provisions granting the innovator of a biological drug product 12 years of exclusive use before generic drugs can be approved based on being biosimilar.

The PPACA makes several important changes to the federal anti-kickback statute, false claims laws, and health care fraud statutes that may make it easier for the government or whistleblowers to pursue such fraud and abuse violations. In addition, the PPACA increases penalties for fraud and abuse violations. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and our financial results.

To further facilitate the government's efforts to coordinate and develop comparative clinical effectiveness research, the PPACA establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in such research. The manner in which the comparative research results would be used by third-party payors is uncertain.

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

On January 27, 2012, The Centers for Medicare and Medicaid Services ( CMS ) issued its long awaited proposed rule implementing the Medicaid pricing and reimbursement provisions of the PPACA and related legislation. CMS accepted comments on this proposed rule through April 2, 2012, and issuance of the final rule by CMS is pending.

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

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

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**Table of Contents**

**Germany**

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

**European Union**

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

**Russia**

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

one-on-one meetings and communications between healthcare decision makers and medical product representatives, except for participation in clinical trials, pharmacovigilance, group educational events and certain other limited exceptions;

the acceptance by a healthcare decision maker of compensation, gifts or entertainment paid by medical product representatives;

the agreement by a healthcare decision maker to prescribe or recommend drug products or medical equipment; or

the engagement by a healthcare decision maker in a conflict of interest transaction with a medical product representative, unless approved by regulators pursuant to certain specified procedures.

Although certain of the above prohibitions technically restrict only the actions of healthcare decision makers, liability for non-compliance with such restrictions nonetheless extends to both the healthcare decision maker and the medical product representative.

Other

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

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

Our overall profitability depends, among other things, on our ability to continuously and timely introduce new generic as well as proprietary products. Our success depends, in part, on our ability in the future to obtain patents, protect trade secrets,



## **Table of Contents**

intellectual property rights and other proprietary information and operate without infringing on the proprietary rights of others. Our competitors may have filed patent applications, or hold issued patents, relating to products or processes that compete with those we are developing, or their patents may impair our ability to successfully develop and commercialize new products.

Our success with our proprietary products depends, in part, on our ability to protect our current and future innovative products and to defend our intellectual property rights. If we fail to adequately protect our intellectual property, competitors may manufacture and market products similar to ours. We have been issued patents covering our innovative products and processes and have filed, and expect to continue to file, patent applications seeking to protect our newly developed technologies and products in various countries, including the United States. Any existing or future patents issued to or licensed by us may not provide us with any competitive advantages for our products or may even be challenged, invalidated or circumvented by competitors. In addition, such patent rights may not prevent our competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

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

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

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

pursuing new patents for existing products that may be granted just before the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;

selling the brand product as an authorized generic, either by the brand company directly, through an affiliate or by a marketing partner;

using the Citizen Petition process to request amendments to U.S. FDA standards or otherwise delay generic drug approvals;

seeking changes to U.S. Pharmacopeia, an organization that publishes industry recognized compendia of drug standards;

attaching patent extension amendments to non-related federal legislation;

engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing; and

seeking patents on methods of manufacturing certain active pharmaceutical ingredients.

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

**If sales of authorized generic products are restricted, our sales of certain authorized generic products may suffer.**

Recently, some U.S. generic pharmaceutical companies who obtained rights to market and distribute a generic alternative of a brand product (i.e., an authorized generics arrangement) under the brand manufacturer's new drug application (NDA) have experienced challenges to their ability to distribute authorized generics during a competitor's 180-day period of abbreviated new drug application (ANDA) exclusivity under the Hatch-Waxman Act. These challenges have come in the form of Citizen Petitions filed with the U.S. FDA, lawsuits alleging violation of the antitrust and consumer protection laws,

## **Table of Contents**

and seeking legislative intervention. For example, in February 2011, legislation was introduced in both the U.S. Senate and the U.S. House of Representatives that would have prohibited the marketing of authorized generics during the 180-day period of ANDA exclusivity under the Hatch-Waxman Act. If distribution of authorized generic versions of brand products is otherwise restricted or found unlawful, our results of operations, financial condition and cash flows could be materially adversely affected.

### **If we are unable to defend ourselves in patent challenges, we could be subject to injunctions preventing us from selling our products, or we could be subject to substantial liabilities that could adversely affect our profits.**

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

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

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

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

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

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

### **Research and development efforts invested in our innovative pipeline may not achieve expected results.**

In our Proprietary Products segment, our business model focuses on building a pipeline in the therapeutic areas of pain management, neurology, dermatology and infectious diseases. We must invest increasingly significant resources to develop innovative pharmaceuticals, both through our own efforts and through collaborations, in-licensing and acquisition of products from or with third parties. The development of innovative drugs involves processes and expertise different from those used in the development of generic drugs, which increases the risks of failure that we face. For example, the time from discovery to commercial launch of an innovative product can be 15 years or even longer, and involves multiple stages: not only intensive preclinical and clinical testing, but also highly complex, lengthy and expensive approval processes which can vary from country to country. The longer it takes to develop a product, the less time there will be for us to recover our development costs and generate profits.

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

## **Table of Contents**

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

Because of the amounts required to be invested in augmenting our innovative pipeline, in some cases we are reliant on partnerships and joint ventures with third parties, and consequently face the risk that some of these third parties may fail to perform their obligations, or fail to reach the levels of success that we are relying on to meet our revenue and profit goals. There is a trend in the innovative pharmaceutical industry of seeking to outsource drug development by acquiring companies with promising drug candidates, and we face substantial competition from historically innovative companies for such acquisition targets. Accordingly, our investment in research and development of innovative products can involve significant costs with no assurances of future revenues or profits.

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

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

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

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

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

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

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

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

## **Table of Contents**

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

Our competitors, which include major multinational corporations, are consolidating, and the strength of the combined companies could affect our competitive position in all of our business areas. Furthermore, if one of our competitors or their customers acquires any of our customers or suppliers, we may lose business from the customer or lose a supplier of a critical raw material. In addition, our increased focus on innovative and specialty pharmaceuticals requires much greater use of a direct sales force than does our core generic business. Our ability to realize significant revenues from direct marketing and sales activities depends on our ability to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. We may also need to enter into co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or sufficiently well-aligned to achieve maximum penetration in the market. Any failure to attract or retain qualified sales personnel or to enter into third-party arrangements on favorable terms could prevent us from successfully maintaining current sales levels or commercializing new innovative and specialty products.

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

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

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

We may fail to successfully integrate our acquisitions in accordance with our business strategy.

The initial rationale for the acquisition may not remain viable due to a variety of factors, including unforeseen regulatory changes and market dynamics after the acquisition, and this may result in a significant delay and/or reduction in the profitability of the acquisition.

We may not be able to retain the skilled employees and experienced management that may be necessary to operate the businesses we acquire. If we cannot retain such personnel, we may not be

able to locate or hire new skilled employees and experienced management to replace them.

We may purchase a company that has contingent liabilities that include, among others, known or unknown patent or product liability claims or environmental liability claims.

We may purchase companies located in jurisdictions where we do not have operations and as a result we may not be able to anticipate local regulations and the impact such regulations have on our business.

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



## **Table of Contents**

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

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

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

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

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

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

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

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

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

A significant portion of our revenues are in currencies other than the Indian rupee, especially the U.S. dollar, the Euro, the Russian rouble and the U.K. pound sterling, while a significant portion of our costs are in Indian rupees. As a result, if the value of the Indian rupee appreciates relative to these other currencies, our revenues measured in Indian rupees may decrease and our financial performance may be adversely impacted. This also exposes us to additional risks in the event of devaluations, hyperinflation or restrictions on the conversion of foreign currencies, such as the devaluation of the Venezuelan bolívar that occurred in February 2013.

## **Table of Contents**

We use derivative financial instruments to manage some of our net exposure to currency exchange rate fluctuations in the major foreign currencies in which we operate. We do not use derivative financial instruments or other hedging techniques to cover all of our potential exposure. Therefore, we are subjected to exchange rate fluctuations that could significantly affect our financial results.

In the recent past and particularly since March 2013, the Indian rupee exchange rates as compared to the U.S. dollar have been highly volatile. In the fiscal year ended March 31, 2014, the Indian rupee has depreciated by more than 10% against the U.S. dollar. Such depreciation of the Indian rupee against the U.S. dollar has had significant positive benefits to our financial results. However, if the Indian rupee appreciates against the U.S. dollar, such appreciation will cause our U.S. dollar revenues as measured in Indian rupees to decrease, and thus adversely affect our financial results.

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

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

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

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

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

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

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

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

## **Table of Contents**

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

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

### **We have concentrations of sales to certain customers that increases our credit risks. Consolidation among distributors and pharmaceutical companies could increase this risk, and also adversely impact our business prospects.**

In the United States, similar to other pharmaceutical companies, we sell our products through wholesale distributors and large retail chains in addition to hospitals, pharmacies and other groups. During the year ended March 31, 2014, our ten largest customers accounted for approximately 78% of our Global Generics segment's revenues from the United States. We are exposed to a concentration of credit risk in respect of these customers such that if one or more are affected by financial difficulty, it could materially and adversely affect our financial results. If the recent trend of consolidation among distributors continues, this risk may increase.

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

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

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

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

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

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

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

## **Table of Contents**

In our pursuit of operational excellence, several change management initiatives across our organization are currently underway, including but not limited to information technology automation in the areas of manufacturing, research and development, supply chain and shared services. Any failure to effectively manage such change initiatives or implement adequate controls in automation, security or availability of information technology systems can have material adverse effects on our business.

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

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

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

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

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

### **There are risks associated with executing on our strategy.**

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

developing and executing our complex product development, manufacturing and marketing strategies, given our limited experience, for North America and other developed markets;

executing on our strategies for increasing our customer share and for key account management in our Active Pharmaceutical Ingredients ( API ) and Custom Pharmaceutical Services ( CPS ) businesses; and

executing our execution excellence and change management initiatives to ensure process safety, product quality and availability.

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

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



## **Table of Contents**

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

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

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

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

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

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

In particular, continuing compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal control over financial reporting requires the commitment of significant financial and managerial resources and our independent auditor's independent assessment of the internal control over financial reporting.

In connection with this Annual Report on Form 20-F for the year ended March 31, 2014, our management assessed our internal controls over financial reporting, and determined that our internal controls were effective as of March 31, 2014. As we continue to undertake management assessments of our internal control over financial reporting in connection with annual reports on Form 20-F for future years, any deficiencies uncovered by these assessments or any inability of our auditors to issue an unqualified opinion could harm our reputation and result in a loss of investor confidence in the reliability of our financial statements, which could cause the price of our equity shares and ADSs to decline.

Companies are being encouraged to implement the new internal control framework ( COSO 2013 ) issued by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ) as early as possible. The new COSO

2013 framework relies heavily on entity level controls and operational risks, in addition to controls over financial reporting. Our current management assurance systems are geared to respond to the earlier COSO framework, and we are currently in the process of assessing the changes required to transition to the COSO 2013 framework and preparing a suitable migration plan.

We are committed to maintaining high standards of corporate governance and public disclosure, and our efforts to comply with evolving laws, regulations and standards in this regard have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, the new laws, regulations and standards regarding corporate governance may make it more difficult for us to obtain director and officer liability insurance. Further, our board members, chief executive officer and chief financial officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may face difficulties attracting and retaining qualified board members and executive officers, which could harm our business. If we fail to comply with new or changed laws or regulations and standards differ, our business and reputation may be harmed.

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**Table of Contents**

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

In recent years, the global economy has experienced volatility and an unfavorable economic environment, and these trends may continue in the future. Reduced consumer spending, reduced funding for national social security systems or shifting concentrations of payors and their preferences, may force our competitors and us to reduce prices. The growth of our business may be negatively affected by high unemployment levels and increases in co-pays, which may lead some patients to delay treatments, skip doses or use less effective treatments to reduce their costs. We have exposure to many different industries and counterparties, including our partners under our alliance, research and promotional services agreements, suppliers of raw materials, drug wholesalers and other customers, who may be unstable or may become unstable in the current economic environment. We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies. This risk is accentuated by the current worldwide financial crisis.

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

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

The U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business. These laws may require not only accurate books and records, but also sufficient controls, policies and processes to ensure business is conducted without the influence of bribery and corruption. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties including fines, criminal prosecution and potential debarment from public procurement contracts. Failure to comply may also result in reputational damages.

We operate in certain jurisdictions that experience governmental corruption to some degree or are found to be low on the Transparency International Corruption Perceptions Index and, in some circumstances, anti-bribery laws may conflict with some local customs and practices. In addition, in many less-developed markets, we work with third-party distributors and other agents for the marketing and distribution of our products. Although our policies prohibit these third parties from making improper payments or otherwise violating these anti-bribery laws, any lapses in complying with such anti-bribery laws by these third parties may adversely impact us. Business activities in many of these markets have historically been more susceptible to corruption. If our efforts to screen third-party agents and detect cases of potential misconduct fail, we could be held responsible for the noncompliance of these third parties under applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act.

Compliance with the U.S. Foreign Corrupt Practices Act and other anti-bribery laws has been subject to increasing focus and activity by regulatory authorities in recent years. Actions by our employees, or third-party intermediaries acting on our behalf, in violation of such laws, whether carried out in the United States or elsewhere, may expose us to liability for violations of such anti-bribery laws and accordingly may have a material adverse effect on our reputation and our business, financial condition or results of operations.

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

If flooding, droughts, earthquakes, volcanic eruptions or other natural disasters were to directly damage, destroy or disrupt our manufacturing facilities, it could disrupt our operations, delay new production and shipments of existing

inventory or result in costly repairs, replacements or other costs, all of which would negatively impact our business. A significant portion of our manufacturing facilities are situated around Hyderabad, India, a region that has experienced earthquakes, floods and droughts in the past.

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

## **Table of Contents**

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

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

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

In the last decade, Asia experienced outbreaks of avian influenza and Severe Acute Respiratory Syndrome, or SARS. In addition, in 2009 a rising death toll in Mexico from a new strain of Swine Flu led the World Health Organization to declare a public health emergency of international concern. If the economy of our key markets is affected by such outbreaks or other epidemics, our business and results of operations may be adversely affected as a consequence.

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

Our full time directors and members of their immediate families, in the aggregate, beneficially owned 25.52% of our issued shares as at March 31, 2014. As a result, these people, acting in concert, are likely to have the ability to exercise significant control over most matters requiring approval by our shareholders, including the election and removal of directors and significant corporate transactions. This significant control by these directors and their family members could delay, defer or prevent a change in control, impede a merger, consolidation, takeover or other business combination involving us, or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. As a result, the value of the equity shares and/or ADSs of our minority shareholders may be adversely affected or our minority shareholders might be deprived of a potential opportunity to sell their equity shares and/or ADSs at a premium.

## **RISKS RELATING TO INVESTMENTS IN INDIAN COMPANIES**

We are an Indian company. Our headquarters are located in India, a substantial part of our operations are conducted in India and a significant part of our infrastructure and other assets are located in India. In addition, a substantial portion of our total revenues for the year ended March 31, 2014 continued to be derived from sales in India. As a result, the following additional risk factors apply that are not specific to our company or industry.

### **We may be subjected to additional compliance and litigation risks as a result of introduction of the new Companies Act, 2013 in India and changes to the SEBI Equity Listing Agreement.**

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

In addition, the Securities and Exchange Board of India ( SEBI ) recently revised certain requirements of the Equity Listing Agreement pertaining to corporate governance matters that must be followed by listed Indian public companies effective as of October 1, 2014. Some of these changes are intended to align the Equity Listing Agreement with the requirements of the Companies Act, 2013, while others include: new requirements as to parent company shareholder approval for a sale or lease of equity or assets reflecting 20% or more of the value of a subsidiary or a disinvestment in a subsidiary; risk management committee requirements for certain large companies; requirements that plans be in place for orderly succession for appointments to the board and senior management; shareholder approval requirements for certain transactions with related parties; and increased definitions of the rights and roles of shareholders.

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

## **Table of Contents**

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

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

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

India has experienced communal disturbances, terrorist attacks and riots during recent years. For example, Mumbai, India's commercial capital, was the target of serial railway bombings in July 2006 as well as the 26/11 attacks on November 26, 2008. Hyderabad, the city in which we are headquartered, was also subjected to terrorist acts in May and August 2007 and more recently in February 2013, although none of our operations were impacted by these terrorist acts.

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

Due to civil disturbances and Bandhs (i.e., political protests in the form of worker strikes), several productive days were lost from forced or precautionary closures of our production units and offices during the agitation movement. If there are any such strikes, political protests or civil unrest in the future, our business and results of operations may be adversely affected as a consequence.

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

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

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

Due to various macro-economic factors, the rate of inflation has recently been highly volatile in India. According to the economic report released by the Department of Economic Affairs, Ministry of Finance in India, the annual inflation rate in India, as measured by the benchmark wholesale price index, Base 2004-05=100 was 5.93% for the year ended March 31, 2014 (as compared to 7.35% for the year ended March 31, 2013). This trend may not continue and the rate of inflation may rise substantially. We may not be able to pass these inflationary costs on to our customers by increasing the price we charge for our products. If this occurs, our profits may decline.

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

Labor laws in India are more stringent than in other parts of the world. These laws may restrict our ability to have human resource policies that would allow us to react swiftly to the needs of our business. Approximately 6% 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.



**Table of Contents**

**OTHER RISKS RELATING TO OUR ADSS**

**THAT ARE NOT SPECIFIC TO OUR COMPANY OR INDUSTRY**

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

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

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

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

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

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

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

A company incorporated in India must offer its holders of shares preemptive rights to subscribe and pay for a proportionate number of shares to maintain their existing ownership percentages prior to the issuance of any shares, unless these rights have been waived by at least 75% of our shareholders present and voting at a shareholders' general meeting. U.S. investors in our ADSs may be unable to exercise preemptive rights for the shares underlying our ADSs unless a registration statement under the Securities Act of 1933 is effective with respect to the rights or an exemption

from the registration requirements of the Securities Act is available. Our decision to file a registration statement will depend on the costs and potential liabilities associated with a registration statement as well as the perceived benefits of enabling U.S. investors in our ADSs to exercise their preemptive rights and any other factors we consider appropriate at the time. We might choose not to file a registration statement under these circumstances. If we issue any of these securities in the future, such securities may be issued to the depositary, which may sell them in the securities markets in India for the benefit of the investors in our ADSs. There can be no assurances as to the value, if any, the depositary would receive upon the sale of these securities. To the extent that U.S. investors in our ADSs are unable to exercise preemptive rights, their proportional interests in us would be reduced.

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

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

general market conditions,

## **Table of Contents**

speculative trading in our shares and ADSs, and

developments relating to our peer companies in the pharmaceutical industry.

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

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

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

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

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

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

Dr. Reddy's Laboratories Limited was incorporated in India under the Companies Act, 1956, by its promoter and our former Chairman, the late Dr. K. Anji Reddy, as a Private Limited Company on February 24, 1984. We were converted to a Public Limited Company on December 6, 1985 and listed on the Indian Stock Exchanges in August 1986 and on the New York Stock Exchange on April 11, 2001. We are registered with the Registrar of Companies, Hyderabad, Telangana, India as Company No. 4507 (Company Identification No. L85195TG1984PLC004507). Our registered office is situated at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India and the telephone number of our registered office is +91-40-49002900. The name and address of our registered agent in the United States is Dr. Reddy's Laboratories, Inc., 107 College Road East, Princeton, New Jersey 08540.

### **Key business developments:**

#### ***Product launches***

In April 2013, we launched zoledronic acid injection (5 mg/100 mL), a bioequivalent generic version of Reclast®, in the United States. The Reclast® brand had U.S. sales of approximately \$355 million for the twelve months ended February 28, 2013, according to IMS Health. Reclast® is used to prevent skeletal fractures in patients with cancers such as multiple myeloma and prostate cancer, as well as for treating osteoporosis. It can also be used to treat

hypercalcemia of malignancy and can be helpful for treating pain from bone metastases.

In June 2013, we launched lamotrigine extended release tablets (25 mg, 50 mg, 100 mg, 200 mg, and 300 mg), a therapeutic equivalent generic version of Lamictal® XR (lamotrigine), in the United States. The Lamictal® XR brand and generic lamotrigine extended release tablets had combined U.S. sales of approximately \$300 million for the twelve months ended April 30, 2013, according to IMS Health. The Lamictal® XR is an anticonvulsant drug used in the treatment of epilepsy and bipolar disorders.

## **Table of Contents**

In July 2013, we launched decitabine injection (50 mg), a therapeutic equivalent generic version of Dacogen® (decitabine for injection), in the United States. The Dacogen® brand had U.S. sales of approximately \$260 million for the twelve months ended March 31, 2013, according to IMS Health. Dacogen® for the treatment of myelodysplastic syndromes, a class of conditions where certain blood cells are dysfunctional, and for acute myeloid leukemia (AML).

In July 2013, we launched donepezil hydrochloride tablets (23 mg), a therapeutic equivalent generic version of Aricept® (23 mg), in the United States. The Aricept® brand had U.S. sales of approximately \$93 million for the twelve months ended May 31 2013, according to IMS Health. Aricept® is used in the palliative treatment of Alzheimer's disease.

In August 2013, we launched divalproex sodium extended release tablets (250 mg and 500 mg), a therapeutic equivalent generic version of Depakote® ER, in the United States. The Depakote® ER brand had U.S. sales of approximately \$194 million for the twelve months ended June 30, 2013, according to IMS Health. Depakote® ER is used as an anticonvulsant and mood-stabilizing drug, primarily in the treatment of epilepsy, bipolar disorder and prevention of migraine headaches.

In September 2013, we launched azacitidine injection (100 mg/vial), a therapeutic equivalent generic version of Vidaza®, in the United States. The Vidaza® brand had U.S. sales of approximately \$378 million for the twelve months ended July 31, 2013, according to IMS Health. Vidaza® is mainly used in the treatment of myelodysplastic syndrome (MDS).

In February 2014, we launched Sumatriptan Injection USP, Autoinjector System 6 mg/0.5 mL, for subcutaneous use, a therapeutic equivalent generic version of IMITREX STATdose Pen® (sumatriptan succinate) 6 mg/0.5 mL, in the United States. The IMITREX STATdose Pen® brand and generic sumatriptan succinate product combined had U.S. sales of approximately \$169 million for the twelve months ended December 31, 2013, according to IMS Health. IMITREX STATdose Pen® (sumatriptan succinate) is mainly used in the treatment of migraine headaches.

In March 2014, we launched moxifloxacin hydrochloride tablets (400 mg), a therapeutic equivalent generic version of Avelox®, in the United States. The Avelox® brand had U.S. sales of approximately \$195 million for the twelve months ended December 31, 2013, according to IMS Health. Avelox® is mainly used for the treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, community acquired pneumonia, complicated and uncomplicated skin and skin structure infections, and complicated intra-abdominal infections.

In March 2014, we launched amlodipine besylate and atorvastatin calcium tablets (2.5/10 mg, 2.5/20 mg, 2.5/40 mg, 5/10 mg, 5/20 mg, 5/40 mg, 5/80 mg, 10/10 mg, 10/20 mg, 10/40 mg and 10/80 mg), a therapeutic equivalent generic version of CADUET®, in the United States. The CADUET® brand and generic amlodipine besylate and atorvastatin calcium tablets had combined U.S. sales of approximately \$163 million for the twelve months ended January 31, 2014, according to IMS Health. CADUET® is used for the treatment of hypercholesterolemia and hypertension.

In April 2014, we launched eszopiclone tablets (1 mg, 2 mg and 3 mg), a therapeutic equivalent generic version of LUNESTA® tablets C-IV, in the United States. The LUNESTA® tablets C-IV brand and generic eszopiclone tablets had U.S. sales of approximately \$887 Million for the twelve months ended January 2014 according to IMS Health. LUNESTA® is used for the treatment of insomnia.

In April 2014, we launched fenofibrate capsules (USP 43 mg and 130 mg), a therapeutic equivalent generic version of ANTARA® (fenofibrate) capsules in the United States. The ANTARA® capsules brand and generic fenofibrate capsules had combined U.S. sales of approximately \$74 million for the twelve months ended February 28, 2014 according to IMS Health. ANTARA® is used for the treatment of hypercholesterolemia or mixed dyslipidemia.

***Other key business developments***

**Termination of Joint Venture with Fujifilm Corporation**

In June 2013, we mutually agreed with Fujifilm Corporation ( Fujifilm ) to terminate the Memorandum of Understanding dated July 28, 2011, which had provided for the parties to enter into an exclusive partnership in the generic drugs business for the Japanese market and to establish a joint venture in Japan.

Based on the Memorandum of Understanding, we had conducted detailed studies with Fujifilm on the establishment of a joint venture for developing and manufacturing generic drugs in Japan. However, as Fujifilm realigns its long-term growth strategy for the pharmaceutical business, both companies mutually agreed to terminate the Memorandum of Understanding.

## **Table of Contents**

The two companies will continue to explore partnership/alliance opportunities in other pharmaceutical businesses such as active pharmaceutical ingredient development and manufacturing, contract research and development and manufacturing, and the development and marketing of super-generics.

## **Senior Level Changes**

In May 2014, our Board of Directors (the Board) decided to separate the role of the Chairman of the Board from those of the Managing Director and the Chief Executive Officer.

Pursuant to this, the Board designated Satish Reddy as Chairman of the Board. He previously held the position of Vice-Chairman, Managing Director and Chief Operating Officer. Simultaneously, G.V. Prasad was designated as the Co-Chairman and Managing Director in addition to his current role as the Chief Executive Officer.

We also announced that Abhijit Mukherjee, President, Global Generics, has been designated as Chief Operating Officer. He will be responsible for our Global Generics and Pharmaceutical Services and Active Ingredients (PSAI) businesses.

## ***Principal capital expenditures***

During the years ended March 31, 2014, 2013 and 2012, we invested Rs.9,996 million, Rs.6,606 million and Rs.6,816 million (net of sales of capital assets), respectively, in capital expenditures for manufacturing, research and development facilities and other assets. We believe that these investments will create the capacity to support our strategic growth agenda. As of March 31, 2014, we also had contractual commitments of Rs.2,920 million for capital expenditures. These commitments included Rs.2,654 million to be spent in India and Rs.266 million in other countries.

## **Table of Contents**

### **4.B. Business overview**

Established in 1984, we are an integrated global pharmaceutical company committed to providing affordable and innovative medicines through our three core business segments:

Global Generics segment, which includes our branded and unbranded prescription and over-the-counter ( OTC ) drug products business as well as our biologics business;

Pharmaceutical Services and Active Ingredients ( PSAI ) segment, which consists of our Active Pharmaceutical Ingredients ( API ) business and Custom Pharmaceutical Services ( CPS ) business; and

Proprietary Products segment, which consists of our Differentiated Formulations business, our New Chemical Entities ( NCEs ) business, and our dermatology focused specialty business operated through Promius Pharma.

We have a strong presence in highly regulated markets such as the United States, the United Kingdom and Germany, as well as other key markets such as India, Russia, Venezuela, Romania, South Africa and certain countries of the former Soviet Union.

## **OUR STRATEGY**

Our core purpose is to provide affordable and innovative medicines to enable people to lead healthier lives. Spiraling health care costs across the world have put many medicines out of the reach of millions of people who desperately need them. As a global pharmaceutical company, we take very seriously our responsibility to help alleviate the burden of disease on individuals and on the world. Our strategy to achieve this core purpose is to combine industry-leading science and technology, product offerings and customer service with execution excellence. The key elements of our strategy include the following:

### **Strengths in Science and Technology**

Our strengths in science and technology range from synthetic organic chemistry, formulation development, biologics development and small molecule based drug discovery. Such expertise enables the creation of unique competitive advantages with an industry-leading intellectual property and technology-leveraged product portfolio.

### **Product Offerings**

Global Generics: Through our branded and unbranded Global Generics segment, we aim to offer affordable alternatives to highly-priced innovator brands, both directly and through key partnerships.

*Branded Generics*: We seek to have a portfolio that is strongly differentiated and offers compelling advantages to doctors and patients. Many of our brands hold significant market shares in the molecule and therapy areas where they are present. We have also entered into strategic partnerships with third parties to sell our products in markets where we have not established our own sales and distribution



operations.

*Unbranded Generics:* We aim to ensure that our development capabilities remain strong and enable us to deliver first to market limited competition products that are technologically challenging.

Our vertical integration and process innovation helps to ensure that quality products are available to the patients in need at all times. Our biologics business focuses on developing and manufacturing bio-similar products. We were the first company to launch a generic version of Rituximab in 2007, and have launched 4 bio-similar products globally.

Pharmaceutical Services and Active Ingredients: Our Pharmaceutical Services and Active Ingredients segment is comprised of our Active Pharmaceutical Ingredients ( API ) business and our Custom Pharmaceutical Services ( CPS ) business. Through our API and CPS businesses, we aim to offer technologically advanced product lines and niche product services through partnerships internally and externally.

Our product offerings in our API business are positioned to offer intellectual property and technology-advantaged products to enable launches ahead of others at competitive prices.

Through our CPS business, we aim to offer niche product service capabilities, technology platforms, and competitive cost structures to innovator companies.

## **Table of Contents**

**Proprietary Products:** Our Proprietary Products business is comprised of our Differentiated Formulations business, our New Chemical Entity ( NCE ) research business and our dermatology focused Specialty business.

*Differentiated Formulations:* Our Differentiated Formulations business focuses on meeting unmet medical needs by investigating new dosage forms and indications for existing medicines as well as new combination products and technologies that improve safety and/or efficacy by improving pharmacokinetics.

*New Chemical Entities (NCEs):* We are also focused in the discovery, development and commercialization of novel small molecule agents in therapeutic areas such as anti-infectives, metabolic disorders, and pain and inflammation.

*Specialty business:* We have a portfolio of in-licensed patented dermatology products and off-patent cardiovascular products. We also have an internal pipeline of dermatology products in various stages of development.

## **Execution Excellence (Building Blocks)**

Execution excellence provides the framework to create sustainable customer value across all of our activities. We have been investing in the following to achieve this:

**Safety.** The concept of safety has been imbued in the operating culture throughout the organization. Specific initiatives are being carried out to increase safety awareness, to achieve a safe working environment, to avoid accidents and injuries, and to minimize the loss of manufacturing time.

**Quality.** We are fully dedicated to quality and have robust quality processes and systems in place at our developmental and manufacturing facilities to ensure that every product is safe and of high quality. In addition, we have integrated Quality by Design to build quality into all processes and use quality tools to minimize process risks.

**Principles of the Theory of Constraints and Lean Manufacturing.** Our supply chain and product development processes are designed on the principles of the Theory of Constraints and lean manufacturing. This results in a flexible supply chain which is able to increase availability of products to the customer with reduced cycle time and waste.

**Leadership Development.** We are focused on developing leaders, as well as enhancing leadership behavior, across our organization.

## **OUR PRINCIPAL AREAS OF OPERATIONS**

The following table shows our revenues and the percentage of total revenues of our business segments for the years ended March 31, 2012, 2013 and 2014, respectively:

Segment	Year Ended March 31,						
	2012		2013		2014		
	(Rs. in millions, U.S.\$ in millions)						
Global Generics	Rs. 70,243	72%	Rs. 82,563	71%	Rs. 105,164	80%	U.S. \$1,753
Pharmaceutical Services and Active Ingredients	23,812	25%	30,702	26%	23,974	18%	400
Proprietary Products	1,078	1%	1,468	1%	1,778	1%	30
Others	1,604	2%	1,533	2%	1,254	1%	21
Total Revenue	Rs. 96,737	100%	Rs. 116,266	100%	Rs. 132,170	100%	U.S. \$2,203

Revenues by geographic market for the years ended March 31, 2012, 2013 and 2014 are discussed in detail in Note 5 to our consolidated financial statements.

**Table of Contents****Global Generics Segment**

The production processes for finished dosages are similar, to a certain extent, regardless of whether the finished dosages are to be marketed to highly regulated or less regulated markets. In many cases, the processes share common and interchangeable facilities and employee bases, and use similar raw materials. However, differences remain between highly regulated and less regulated markets in terms of manufacturing, packaging and labeling requirements and the intensity of regulatory oversight, as well as the complexity of patent regimes. While the degree of regulation in certain markets may impact product development, we are observing increasing convergence of development needs throughout both highly regulated and less regulated markets. As a result, when we begin the development of a product, we may not necessarily target it at a particular market, but will instead target the product towards a cluster of markets that will include both highly regulated and less regulated markets.

Today, we are one of the leading generic pharmaceutical companies in the world. With the integration of all the markets where we are selling generic pharmaceuticals into our Global Generics segment, our front-end business strategies in various markets and our support services in India are increasingly being developed with a view to leverage our global infrastructure.

Our Global Generics segment's revenues were Rs.105,164 million in the year ended March 31, 2014, as compared to Rs.82,563 million in the year ended March 31, 2013. The revenue growth was largely led by this segment's operations in the United States and our Emerging Markets (which is comprised of Russia, other countries of the former Soviet Union, and certain other countries from our Rest of the World markets, primarily South Africa, Venezuela and Australia). The following is a discussion of the key markets in our Global Generics segment.

***India***

Approximately 15% of our Global Generics segment's revenues in the year ended March 31, 2014 were derived from sales in the Indian market. In India, our key therapeutic categories include gastro-intestinal, cardiovascular, pain management and oncology. We are also increasing our presence in the niche areas of dermatology, urology and nephrology.

As of March 31, 2014, we had a total of 277 branded products in India. Our top ten branded products together accounted for 35% of our revenues in India in the year ended March 31, 2014. According to IMS Health, in its moving annual total report for the 12-month period ended March 31, 2014, our secondary sales in India grew by 12.2%. In comparison, the Indian pharmaceutical market experienced growth of 9.9% during such period. IMS Health is a provider of market research to the Indian pharmaceutical industry. Strategic Marketing Solutions and Research Center Private Limited (SMSRC), a prescription market research firm, in its report measuring pharmaceutical prescriptions in India for the period from November 2013 to February 2014, ranked us 11th in terms of the number of prescriptions generated in India during such period.

The following tables summarize the position of our top 10 brands in the Indian market for the years ended March 31, 2012, 2013 and 2014, respectively:

Brand	2012		Year Ended March 31, 2013		2014	
	Revenues (in millions)	% Total <sup>(1)</sup>	Revenues (in millions)	% Total <sup>(1)</sup>	Revenues (in millions)	% Total <sup>(1)</sup>

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Omez	Rs. 1,089	8%	Rs. 1,181	8%	Rs. 1,052	7%
Omez-DSR	468	4%	562	4%	701	4%
Nise	596	5%	647	4%	674	4%
Stamlo	566	4%	634	4%	664	4%
Reditux	472	4%	561	4%	568	4%
Stamlo Beta	358	3%	376	3%	426	3%
Razo	306	2%	346	2%	372	2%
Razo-D	249	2%	309	2%	363	2%
Atocor	317	2%	351	2%	324	2%
Econorm	185	1%	263	2%	311	2%
Others	8,325	64%	9,330	64%	10,258	65%
<b>Total</b>	<b>Rs. 12,931</b>	<b>100%</b>	<b>Rs. 14,560</b>	<b>100%</b>	<b>Rs. 15,713</b>	<b>100%</b>

- (1) Refers to the brand s revenues from sales in India expressed as a percentage of our total revenues from sales in all of our therapeutic categories in India.

## Table of Contents

### Sales, marketing and distribution network

We generate demand for our products through our 4,863 sales representatives (which include representatives engaged by us on a contract basis through a service provider) and front line managers, who frequently visit doctors to detail our related product portfolio. They also visit various pharmacies to ensure that our brands are adequately stocked.

We sell our products primarily through clearing and forwarding agents to approximately 2,500 wholesalers who decide which brands to buy based on demand. The wholesalers pay for our products in an agreed credit period and in turn sell these products to retailers. Our clearing and forwarding agents are responsible for transporting our products to the wholesalers. We pay our clearing and forwarding agents on a commission basis. We have insurance policies that cover our products during shipment and storage at clearing and forwarding locations.

### Competition

We compete with different companies in the Indian formulations market, depending upon therapeutic and product categories and, within each category, upon dosage strengths and drug delivery. On the basis of sales, we were the 16<sup>th</sup> largest pharmaceutical company in India, with a market share of 2.1%, according to IMS Health in its moving annual total report for the 12-month period ended March 31, 2014.

Some of the key observations on the performance of the Indian pharmaceutical market, as published by IMS Health in its moving annual total report for the 12-month period ended March 31, 2014, are as follows:

The Indian pharmaceutical market experienced growth of 9.9% for such period. Growth was impacted by 3% due to price controls for products designated as specified products by the National Pharmaceutical Pricing Authority ( NPPA ) pursuant to the Drugs (Prices Control) Order, 2013 (the DPCO ).

New products launched in the preceding 24 months accounted for 5.7% of total Indian pharmaceutical growth for such period.

The top 300 existing brands grew at a rate of 9.2%, which was 0.7% lower than the Indian pharmaceutical market's overall average, and together they account for 30.8% of the market's total sales.

There was an increasing emergence of bio-similar products to address the needs of patients in the oncology therapeutic area.

Our principal competitors in the Indian market include Cipla Limited, Ranbaxy Laboratories Limited, GlaxoSmithKline Pharmaceuticals Limited, Cadila Healthcare Limited, Sun Pharmaceutical Industries Limited, Alkem Limited, Mankind Pharma Limited, Pfizer Limited, Abbott India, Lupin Limited, Aristo Pharma Limited, Intas Pharma, Sanofi India Limited and Emcure Pharmaceuticals Limited.

### Government regulations

The manufacturing and marketing of drugs, drug products and cosmetics in India is governed by many statutes, regulations and guidelines, including but not limited to the following:

The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945;

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954;

The Narcotic Drugs and Psychotropic Substances Act, 1985;

The Drugs (Price Control) Order, 1995 and 2013, read in conjunction with the Essential Commodities Act, 1955;

The Medicinal and Toilet Preparations (Excise Duties) Act, 1955; and

The National Pharmaceuticals Pricing Policy, 2012.

These statutes, regulations and guidelines govern the testing, manufacturing, packaging, labeling, storing, record-keeping, safety, approval, advertising, promotion, sale and distribution of pharmaceutical products.

Pursuant to the amendments in May 2005 to Schedule Y of the Drugs and Cosmetics Act, 1940, manufacturers of finished dosages are required to submit additional technical data to the Drugs Controller General of India in order to obtain a no-objection certificate for conducting clinical trials as well as to manufacture new drugs for marketing.

## **Table of Contents**

An approval is required from the Ministry of Health before a generic equivalent of an existing or referenced brand drug can be marketed. When processing a generics application, the Ministry of Health usually waives the requirement of conducting complete clinical studies, although it generally requires bio-availability and/or bio-equivalence studies.

Bio-availability indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce a therapeutic effect. Bio-equivalence compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of the active drug substance in the body are equivalent for the generic drug with the previously approved drug. A generic application may be submitted for a drug on the basis that it is the equivalent of a previously approved drug. Before approving our generic products, the Ministry of Health also requires that our procedures and operations conform to current Good Manufacturing Practice ( cGMP ) regulations, relating to good manufacturing practices as defined by various countries. We must follow the cGMP regulations at all times during the manufacture of our products. We continue to spend significant time, money and effort in the areas of production and quality testing to help ensure full compliance with cGMP regulations.

The timing of final Ministry of Health approval of a generic application depends on various factors, including patent expiration dates, sufficiency of data and regulatory approvals.

On March 22, 2005, the Government of India passed the Patents (Amendment) Bill, 2005 (the 2005 Amendment ), introducing a product patent regime for food, chemicals and pharmaceuticals in India. The 2005 Amendment specifically provides that new medicines (patentability of which is not specifically excluded) for which a patent has been applied for in India on or after January 1, 1995 and for which a patent is granted cannot be manufactured or sold in India by anyone other than the patent holder and its assignees and licensees. This has resulted in a reduction of new product introductions in India for all Indian pharmaceutical companies engaged in the development and marketing of generic finished dosages and APIs. Processes for the manufacture of APIs and formulations were patentable in India even prior to the 2005 Amendment, so no additional impact results from patenting of such processes.

Under the present drug policy of the Government of India, certain drugs have been specified under the Drugs (Prices Control) Order, 2013 (the DPCO ) as subject to price control. The Government of India established the National Pharmaceutical Pricing Authority ( NPPA ) to control pharmaceutical prices. Under the DPCO, the NPPA has the authority to fix the maximum selling price for specified products.

During the year ended March 31, 2013, the Department of Pharmaceuticals under the ministry of Chemicals and Fertilizers of the Government of India proposed the National Pharmaceuticals Pricing Policy, 2012, a revised national Pharmaceutical Pricing policy to apply price controls to 348 drugs listed in National List of Essential Medicines. Some of our formulation products are subject to these price controls.

On May 15, 2013, the Department of Pharmaceuticals released Drugs (Price Control) Order, 2013 governing the price control mechanism for 348 drugs listed in the National List of Essential Medicines. As per this order, the prices of each of the drugs are determined based on the simple average of all drugs having market share of more than 1% by value. The individual drug price notifications for a majority of the products have been released by the NPPA. Based on these notifications, we were adversely impacted by approximately 3% (the annualized impact is approximately 4%) of our annual revenues from sales of all of our formulation products in India during the year ended March 31, 2014.

## ***Russia and other Countries of the former Soviet Union***

### ***Russia***



Russia accounted for 16% of our Global Generics segment's revenues in the year ended March 31, 2014. IMS Health ranked us 18th in sales in Russia with a market share of 1.80% as of March 31, 2014 in its moving annual total report for the 12-months ended March 31, 2014. According to IMS Health, as per its moving annual total report for the 12 months ended March 31, 2014, our sales value and volume growths for the year ended March 31, 2014 were 7.7% and 4.1%, respectively, as compared to the Russian pharmaceutical market value growth and volume decrease of 1.9% and 5.0%, respectively. We were the top ranked Indian pharmaceutical company in Russia for such period.

**Table of Contents**

The following table provides a summary of the revenues of our top 10 brands in the Russian market for the years ended March 31, 2012, 2013 and 2014 respectively:

Brands	Year Ended March 31,					
	2012		2013		2014	
	Revenues (in millions)	% Total <sup>(1)</sup>	Revenues (in millions)	% Total <sup>(1)</sup>	Revenues (in millions)	% Total <sup>(1)</sup>
Nise	Rs. 3,122	28%	Rs. 3,661	26%	Rs. 4,689	29%
Omez	1,864	17%	2,104	15%	2,432	15%
Ketorol	1,563	14%	1,752	12%	1,967	12%
Cetrine	748	7%	1,107	8%	1,253	8%
Ciprolet	833	8%	992	7%	980	6%
Senade	687	6%	964	7%	967	6%
Sirdalud		0%	439	3%	540	3%
Ibucilin	182	2%	302	2%	515	3%
Novigan	103	2%	291	2%	486	3%
Bion	260	1%	301	2%	472	3%
Others	1,694	15%	2,135	15%	2,032	12%
<b>Total</b>	<b>Rs. 11,056</b>	<b>100%</b>	<b>Rs. 14,048</b>	<b>100%</b>	<b>Rs. 16,333</b>	<b>100%</b>

(1) Refers to the brand's revenues from sales in Russia expressed as a percentage of our total revenues from all sales in Russia.

Our top four brands, Nise, Omez, Ketorol and Cetrine, accounted for 63% of our Global Generics segment's revenues in Russia in the year ended March 31, 2014. Omez (an anti-ulcerant product), Nise and Ketorol (both pain management products) and Cetrine (a respiratory product) were ranked as the 49th, 15th, 90th and 139th best-selling formulation brands, respectively, in the Russian market as of March 31, 2014 by IMS Health in its moving annual total retail segment report for the 12 months ended March 31, 2014.

Our strategy in Russia is to focus on the gastro-intestinal, pain management, anti-infectives, respiratory, oncology and cardiovascular therapeutic areas. Our focus is on building leading brands in these therapeutic areas in prescription, over-the-counter and hospital sales. Nise, Omez, Ketorol, Cetrine and Ciprolet continue to be brand leaders in their respective categories, as reported by IMS Health in its moving annual total report for the 12-months ended March 31, 2014.

Novigan, a pain management product, and Ibucilin, a cold and flu product, were switched from prescription to over-the-counter during the years ended March 31, 2013 and 2014, respectively. Revenues from these products grew by 54% and 58%, respectively, as reported by IMS Health in its moving annual total report for the 12-months ended March 31, 2014.

Growth during the year ended March 31, 2014 was driven by increased marketing initiatives for prescription products, launches of new products and scaling up of media and pharmacy chain activities for over-the-counter medicines.

*Other Countries of the former Soviet Union*

We operate in other countries of the former Soviet Union, including Ukraine, Kazakhstan, Belarus and Uzbekistan. For the year ended March 31, 2014, revenues from these countries accounted for approximately 3% of our total Global Generics segment's revenues.

Sales, marketing and distribution network

Our marketing and promotion efforts in our Russian prescription division is driven by a team of 275 medical representatives and 44 managers to detail our products to doctors in 67 cities in Russia.

Our Russian OTC division has 181 medical representatives and is focused on establishing a network of relationships with key pharmacy chains and individual pharmacies. Our Russian hospital division has 38 hospital specialists and 17 key account managers, and is focused on expanding our presence in hospitals and institutes.

In Russia, we generally extend credit only to customers after they have established a satisfactory history of payment with us. The credit ratings of these customers are based on turnover, payment record and the number of the customers branches or pharmacies, and are reviewed on a periodic basis. We review the credit terms offered to our key customers on a periodic basis and modify them to take into account the macro-economic scenario in Russia.

## **Table of Contents**

Our principal competitors in the Russian market include Berlin Chemi AG, Gedeon Richter Limited, Krka d.d., Teva Pharmaceutical Industries Ltd., Lek-Sandoz Pharmaceuticals (an affiliate of Novartis Pharma A.G.), Ranbaxy Laboratories Limited, Nycomed International Management GmbH and Zentiva N.V. (an affiliate of Sanofi-Aventis S.A.).

### **Healthcare reforms and reference pricing**

The Russian government's prioritization plan for the pharmaceutical market is making a transition from a largely out-of-pocket market to the western European model of centralized reimbursements. In January 2005, Russia's federal drug supply system (the Dopolnitelnoye lekarstvennoye obespechenoye, or DLO) was introduced with the objective of subsidizing medicine expenditures for sectors of the population with low income or certain categories of illnesses. The initial budget provided approximately 10% of the population with state-funded benefits for medicine expenditures. In late 2007, the Russian government decentralized the DLO and split it into two components. The first component, known as the 7 nosologies program, remains centralized and covers expensive treatments for patients with certain severe chronic diseases. The second component, known as the ONLS program, involves regional purchasing and covers the medicines reimbursed for patients who are designated members of vulnerable groups, such as children, pregnant women, veterans and the elderly.

In order to promote local industry, in October 2009 the Russian government announced the Strategy of Pharmaceutical Industry Development in the Russian Federation for the period up to the year 2020 (or the Pharma 2020 plan), which aims to develop the research, development and manufacturing of pharmaceutical products by Russia's domestic pharmaceutical industry. The goal of the Pharma 2020 plan is to reduce Russia's reliance on imported pharmaceutical products and increase Russia's self-sufficiency in that regard. In March 2011, the Russian government announced the approval of 120 billion rubles (\$4 billion) in financing for the Pharma 2020 plan.

During the year ended March 31, 2010, the Russian government announced a reference pricing regime, pursuant to which a price freeze on certain drugs categorized as "essential" was implemented effective as of April 2010. Pharmaceutical companies have had to register maximum import prices for approximately 5,000 drugs on a list of Essential and Vital Drugs (also known as the ZhNVLS). During the year ended March 31, 2011, the Russian government announced price re-registration in local currency (Russian roubles) for drugs categorized as "essential" and the new registered prices were effective as of December 10, 2010. Also, effective as of September 1, 2010, the price controls on certain drugs categorized as "non-essential" were removed by the Russian Ministry of Health.

For the past several years, the Russian Ministry of Industry and Trade has enacted and renewed short term government regulations under which local manufacturers (i.e., in Russia, Belarus and Kazakhstan) get a 15% price preference over non-local manufacturers in procurement tenders by the state.

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

one-on-one meetings and communications between healthcare professionals and medical product representatives, except for participation in clinical trials, pharmacovigilance, group educational events and certain other limited exceptions approved by Russia's Healthcare Organization Administration;

the acceptance by a healthcare professional of compensation, gifts or entertainment paid by medical product representatives;

the agreement by a healthcare professional to prescribe or recommend a drug product or medical equipment; or

the engagement by a healthcare decision maker in a conflict of interest transaction with a medical product representative, unless approved by regulators pursuant to certain specified procedures.

## **Table of Contents**

At the end of 2013, the State Duma (i.e., the lower chamber of the Russian parliament) adopted a series of amendments to various healthcare related laws. Among other things, the Law On Medicines was amended to add regulations restricting interactions between medical product representatives with medical professionals in connection with events sponsored by medical product companies. Under these regulations, in the event that medical product companies wish to sponsor certain scientific, medical education or similar events, they are required to disclose the date, place and time of the event and the plans, programs and agendas for discussion. Disclosure is to be made by publishing appropriate information on their official websites not later than two months before the indicated events, and the same information shall also be sent to Russia's Federal Healthcare Service (Roszdravnadzor).

Although certain of the above prohibitions technically restrict only the actions of healthcare professionals, liability for non-compliance with such restrictions nonetheless extends to both the healthcare professional and the medical product representative. Except providing information on conflicts of interest, no other liability has been currently prescribed for medical product companies. The methodology to define a conflict of interest has not yet been clarified.

On July 2, 2013, the Ministry of Health of the Government of Russia published an order on its website that binds physicians to prescribe medicinal products by International Nonproprietary Name (i.e. active substance) or by combination list (which combines different International Nonproprietary Names in one treatment group).

### ***North America (the United States and Canada)***

During the year ended March 31, 2014, North America (the United States and Canada) accounted for 53% of our total Global Generics segment sales. In the United States, we sell generic drugs that are the chemical and therapeutic equivalents of reference branded drugs, typically sold under their generic chemical names at prices below those of their brand drug equivalents. Generic drugs are finished pharmaceutical products ready for consumption by the patient. These drugs are required to meet the U.S. FDA standards that are similar to those applicable to their brand-name equivalents and must receive regulatory approval prior to their sale.

Generic drugs may be manufactured and marketed only if relevant patents on their brand name equivalents and any additional government-mandated market exclusivity periods have expired, been challenged and invalidated, or otherwise validly circumvented.

Generic pharmaceutical sales have increased significantly in recent years, partly due to an increased awareness and acceptance among consumers, physicians and pharmacists that generic drugs are the equivalent of brand name drugs. Among the factors contributing to this increased awareness are the passage of legislation permitting or encouraging substitution and the publication by regulatory authorities of lists of equivalent drugs, which provide physicians and pharmacists with generic drug alternatives. In addition, various government agencies and many private managed care or insurance programs encourage the substitution of generic drugs for brand-name pharmaceuticals as a cost-savings measure in the purchase of, or reimbursement for, prescription drugs. We believe that these factors should lead to continued expansion of the generic pharmaceuticals market as a whole. We intend to capitalize on the opportunities resulting from this expansion of the market by leveraging our product development capabilities, manufacturing capacities inspected by various international regulatory agencies and access to our own APIs, which offer significant supply chain efficiencies.

In April 2008, we acquired BASF's pharmaceutical contract manufacturing business and related facility in Shreveport, Louisiana, U.S.A. The acquisition included the relevant business, customer contracts, certain supplier contracts, related Abbreviated New Drug Applications (ANDAs) and New Drug Applications (NDAs), trademarks, as well as the manufacturing facility and assets owned by BASF in Shreveport, Louisiana. The facility is designed to manufacture solid, semi-solid and liquid dosage forms.

In March 2011, we acquired from GlaxoSmithKline plc and Glaxo Group Limited (collectively, GSK ) a penicillin-based antibiotics manufacturing site in Bristol, Tennessee, U.S.A., the product rights for GSK's *Augmentin*® and *Amoxil*® brands of oral penicillin-based antibiotics in the United States (GSK retained the existing rights for these brands outside the United States), certain raw materials and finished goods inventory associated with Augmentin®, and rights to receive certain transitional services from GSK. The acquisition enabled us to enter the U.S. oral antibiotics market with a comprehensive product filing and a dedicated manufacturing site.

Through the coordinated efforts of our teams in the United States and India, we constantly seek to expand our pipeline of generic products. During the year ended March 31, 2014, we filed 12 ANDAs and one NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act in the United States, including 10 Paragraph IV filings. During the year ended March 31, 2014, the U.S. FDA granted us 13 final ANDA approvals. As of March 31, 2014, we had filed a cumulative total

## **Table of Contents**

of 209 ANDAs in the United States, out of which 62 ANDAs were pending approval at the U.S. FDA, including 11 tentative approvals. As of March 31, 2014, we had also filed two NDAs under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act in the United States, one of which is tentatively approved and awaits final approval. During the year ended March 31, 2014, we have filed two new Investigational New Drugs ( INDs ) our proposed biosimilars to rituximab and PEG-GCSF. We have also received permissions from the U.S. FDA to conduct Phase I trials for both of these IND filings.

Our Canada business generated revenues of Rs.676 million during the year ended March 31, 2014. This business includes revenues from certain profit sharing arrangements with distributors to market certain of our generic products.

## **Sales, Marketing and Distribution Network**

Dr. Reddy s Laboratories, Inc., our wholly-owned subsidiary in New Jersey, United States, is primarily engaged in the marketing of our generic products in the United States. In early 2003, we commenced sales of generic products under our own label. We have our own sales and marketing team to market these generic products. Our key account representatives for generic products call on purchasing agents for chain drug stores, drug wholesalers, health maintenance organizations, hospital group purchasing organizations (GPOs), specialty distributors and pharmacy buying groups.

In the year ended March 31, 2008, we entered the over-the-counter ( OTC ) products market in the United States by launching a new division that markets and distributes store brand OTC products. This division has successfully launched 9 products since our entry into this market. OTC products include store brand generic equivalents of products that originally have prescription drug status and are switched to OTC drug status by the innovator upon U.S. FDA approval (sometimes called Rx-to-OTC switch products). For the year ended March 31, 2014, our OTC division generated Rs.8,056 million in revenues.

In the year ended March 31, 2014, we started supplying products for private label customers for prescription products.

## **Competition**

Revenues and gross profit derived from the sales of generic pharmaceutical products are affected by certain regulatory and competitive factors. As patents and regulatory exclusivity for brand name products expire, the first manufacturer to receive regulatory approval for generic equivalents of such products is generally able to achieve significant market penetration. As competing manufacturers receive regulatory approvals on similar products, market share, revenues and gross profit typically decline, in some cases significantly. Accordingly, the level of market share, revenues and gross profit attributable to a particular generic product is normally depended upon the number of competitors and the timing of that product s regulatory approval and launch, in relation to competing approvals and launches. Consequently, we must continue to develop and introduce new products in a timely and cost-effective manner to maintain our revenues and gross margins. In addition, the other competitive factors critical to this business include price, product quality, consistent and reliable product supplies, customer service and reputation. Our major competitors in the United States include Teva Pharmaceutical Industries Limited, Mylan Inc., Actavis Inc., Sandoz, a division of Novartis Pharma A.G., Par Pharmaceuticals, Sun Pharmaceuticals Limited and Lupin Limited.

Recent consolidation of customer purchasing power via alliances and joint ventures (such as the Walgreens Boots Alliance Development, the CVS and Cardinal Health Joint Venture, and the Rite Aid McKesson expanded distribution agreement) has served to intensify the competition and drive down prices. Consolidation of manufacturers will also continue, and at the same time, new manufacturers continue to enter the generic market in the United States, which may further lower our pricing power and adversely affect our revenues in that market.



Brand name manufacturers have devised numerous strategies to delay competition from lower cost generic versions of their products. One of these strategies is to change the dosage form or dosing regimen of the brand product prior to generic introduction, which may reduce the demand for the original dosage form as sought by a generic ANDA dossier applicant or create regulatory delays, sometimes significant, while the generic applicant, to the extent possible, amends its ANDA dossier to match the changes in the brand product. In many of these instances, the changes to the brand product may be protected by patent or data exclusivities, further delaying generic introduction. Another strategy is the launch by the innovator or its licensee of an authorized generic during the 180-day generic exclusivity period, resulting in two generic products competing in the market rather than just the product that obtained the generic exclusivity. This may result in reduced revenues for the generic company which has been awarded the generic exclusivity period.

## Table of Contents

The U.S. market for OTC pharmaceutical products is highly competitive. Competition is based on a variety of factors, including price, quality and assortment of products, customer service, marketing support and availability of and approvals for new products. Our competition in store brand products in the United States consists of several publicly traded and privately owned companies, including large brand-name pharmaceutical companies. The competition is highly fragmented in terms of both geographic market coverage and product categories, such that a competitor generally does not compete across all product lines. In the store brand market, we compete directly with other companies that sell store brand OTC products. Some of our primary OTC competitors in the United States include Perrigo Company and PL Developments. In addition, since our products are generic equivalents of innovator brands, we also compete against large brand-name pharmaceutical companies. The competitive landscape and market dynamics of the OTC market are rapidly evolving. Large brand-name pharmaceutical companies have begun to more aggressively pursue Rx-to-OTC switches in new categories, which could present opportunities for us and other companies that sell store brand products. On the other hand, pricing pressures and the threat of new entrants are likely events which may unfold in the future.

## Government regulations

### *U.S. REGULATORY ENVIRONMENT*

All pharmaceutical manufacturers that sell products in the United States are subject to extensive regulation by the U.S. federal government, principally pursuant to the Federal Food, Drug and Cosmetic Act, the Hatch-Waxman Act, the Generic Drug Enforcement Act and other federal government statutes and regulations. These regulations govern or influence the testing, manufacturing, packaging, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of products.

Our facilities and products are periodically inspected by the U.S. FDA, which has extensive enforcement powers over the activities of pharmaceutical manufacturers. Non-compliance with applicable requirements can result in fines, criminal penalties, civil injunction against shipment of products, recall and seizure of products, total or partial suspension of production, sale or import of products, refusal of the U.S. government to enter into supply contracts or to approve new drug applications and criminal prosecution. The U.S. FDA also has the authority to deny or revoke approvals of drug active pharmaceutical ingredients and dosage forms and the power to halt the operations of non-complying manufacturers. Any failure to comply with applicable U.S. FDA policies and regulations could have a material adverse effect on the operations in our generics business.

U.S. FDA approval of an ANDA is required before a generic equivalent of an existing or referenced brand drug can be marketed. The ANDA approval process is abbreviated because the U.S. FDA waives the requirement of conducting complete clinical studies, although it generally requires bio-availability and/or bio-equivalence studies. An ANDA may be submitted for a drug on the basis that it is the equivalent of a previously approved drug or, in the case of a new dosage form, is suitable for use for the indications specified.

An ANDA applicant in the United States is required to review the patents of the innovator listed in the U.S. FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, and make an appropriate certification. There are several different types of certifications that can be made. A Paragraph IV filing is made when the ANDA applicant believes its product or its manufacture, use or sales thereof does not infringe on the innovator's patents listed in the Orange Book or where the applicant believes that such patents are not valid or enforceable. The first generic company to file a Paragraph IV filing may be eligible to receive a six-month marketing exclusivity period starting from either the first commercial marketing of the drug by any of the first applicants or a decision of a court holding the patent that is the subject of the paragraph IV certification to be invalid or not infringed. A Paragraph III filing is made when the ANDA applicant does not intend to market its

generic product until the patent expiration. A Paragraph II filing is made where the patent has already expired. A Paragraph I filing is made when there are no patents listed in the Orange Book. Another type of certification is made where a patent claims a method of use, and the ANDA applicant's proposed label does not claim that method of use. When an innovator has listed more than one patent in the Orange Book, the ANDA applicant must file separate certifications as to each patent.

Before approving a product, the FDA also requires that our procedures and operations conform to current Good Manufacturing Practice ( cGMP ) regulations, relating to good manufacturing practices as defined in the U.S. Code of Federal Regulations. We must follow cGMP regulations at all times during the manufacture of our products. We continue to spend significant time, money and effort in the areas of production and quality to help ensure full compliance with cGMP regulations.

The timing of final U.S. FDA approval of an ANDA depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the brand-name manufacturer is entitled to one or more statutory exclusivity periods, during which the U.S. FDA may be prohibited from accepting applications for, or approving, generic

## **Table of Contents**

products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, in certain circumstances the U.S. FDA may extend the exclusivity of a product by six months past the date of patent expiration if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the Medicare Act of 2003 ) modified certain provisions of the Hatch-Waxman Act. In particular, significant changes were made to provisions governing 180-day exclusivity and forfeiture thereof. The new statutory provisions governing 180-day exclusivity may or may not apply to an ANDA, depending on whether the first Paragraph IV certification submitted by any applicant for the drug was submitted prior to the enactment of the Medicare Amendments on December 8, 2003.

Where the first Paragraph IV certification was submitted on or after December 8, 2003, the new statutory provisions apply. Under these provisions, 180-day exclusivity is awarded to each ANDA applicant submitting a Paragraph IV certification for the same drug with regard to any patent on the first day that any ANDA applicant submits a Paragraph IV certification for the same drug. The 180-day exclusivity period begins on the date of first commercial marketing of the drug by any of the first applicants or a decision of a court holding the patent that is the subject of the paragraph IV certification to be invalid or not infringed. However, a first applicant may forfeit its exclusivity in a variety of ways, including, but not limited to (a) failure to obtain tentative approval within 30 months after the application is filed or (b) failure to market its drug by the later of two dates calculated as follows: (x) 75 days after approval or 30 months after submission of the ANDA, whichever comes first, or (y) 75 days after each patent for which the first applicant is qualified for 180-day exclusivity is either (1) the subject of a final court decision holding that the patent is invalid, not infringed, or unenforceable or (2) withdrawn from listing with the U.S. FDA (court decisions qualify if either the first applicant or any applicant with a tentative approval is a party; a final court decision is a decision by a court of appeals or a decision by a district court that is not appealed). The foregoing is an abbreviated summary of certain provisions of the Medicare Act of 2003, and accordingly it should be consulted for a complete understanding of both the provisions described above and other important provisions related to 180-day exclusivity and forfeiture thereof.

Where the first Paragraph IV certification was submitted prior to enactment of the Medicare Act of 2003, the statutory provisions governing 180-day exclusivity prior to the Medicare Act of 2003 still apply. The U.S. FDA interprets these statutory provisions to award 180-day exclusivity to each ANDA applicant submitting a Paragraph IV certification for the same drug on the same day with regard to the same patent on the first day that any ANDA applicant submits a Paragraph IV certification for the same drug with regard to the same patent. The 180-day exclusivity period begins on the date of first commercial marketing of the drug by any of the first applicants or on the date of a final court decision holding that the patent is invalid, not infringed, or unenforceable, whichever comes first. A final court decision is a decision by a court of appeals or a decision by a district court that is not appealed.

## *Food and Drug Administration Safety and Innovation Act ( FDASIA ) and Generic Drug User Fee Agreement ( GDUFA )*

In 2012, the United States enacted the Food and Drug Administration Safety and Innovation Act ( FDASIA ), a landmark legislation intended to enhance the safety and security of the U.S. drug supply chain by imposing stricter oversight and by holding all drug manufacturers supplying products to the United States to the same U.S. FDA inspection standards. Specifically, prior to the passage of FDASIA, U.S. law required U.S. based manufacturers to be inspected by the U.S. FDA every two years but remained silent with respect to foreign manufacturers, causing some foreign manufacturers to go as many as nine years without a routine U.S. FDA current Good Manufacturing Practice ( cGMP ) inspection, according to the Government Accountability Office. FDASIA requires foreign manufacturers to have cGMP inspections at least every two years, or more frequently for manufacturers with high risk profiles.

FDASIA also includes the Generic Drug User Fee Agreement ( GDUFA ), a program to provide the U.S. FDA with additional funds through newly imposed user fees on generic and biosimilar products. These new fees are estimated to total approximately \$1.5 billion through 2018, and are intended to fund increases in the U.S. FDA's operations and staffing with a focus on three key aims:

*Safety* To ensure that industry participants, foreign or domestic, are held to consistent quality standards and are inspected with foreign and domestic parity using a risk-based approach.

*Access* To expedite the availability of generic drugs by bringing greater predictability to the review times for ANDAs, amendments and supplements and improving timeliness in the review process. For example, FDASIA is expected to decrease the review time for ANDAs by approximately two-thirds.

*Transparency* To enhance the U.S. FDA's visibility into the complex global supply environment by requiring the identification of facilities involved in the manufacture of drugs and associated active pharmaceutical ingredients, and improve the U.S. FDA's communications and feedback with industry.

## **Table of Contents**

The establishment of dedicated biosimilar fees should also help ensure that the U.S. FDA has appropriate resources for managing the introduction of biosimilar products on the U.S. market. Under GDUFA, 70% of the total fees will be derived from facility fees paid by finished dosage form manufacturers and active pharmaceutical ingredient facilities listed or referenced in a pending or approved generic drug application. The remaining 30% of the total fees will be derived from application fees, including generic drug application fees, prior approval supplement fees and drug master file fees.

### *U.S. FDA Proposed New Labeling Rule*

On November 13, 2013, the U.S. FDA proposed a new labeling rule which the agency believes will speed up the dissemination of new safety information about generic drugs to health professionals and patients by allowing generic drug makers to use the same process as brand drug manufacturers to update safety information in the product labeling. Under the proposal, generic drug manufacturers would be able to independently update product labeling (also called prescribing information or package inserts) with newly-acquired safety information before the U.S. FDA's review of the change, in the same way brand drug manufacturers do today. Generic manufacturers would also be required to inform the brand name manufacturer about the change. The U.S. FDA would then evaluate whether the proposed change is justified and make an approval decision on the generic drug labeling change and the corresponding brand drug labeling change at the same time, so that brand and generic drug products would ultimately have the same U.S. FDA-approved prescribing information.

Currently, generic manufacturers must wait to update product safety information until the corresponding brand name product has received approval to update its safety information. Brand drug manufacturers are allowed to independently update and promptly distribute updated safety information by submitting a change being effected (CBE) supplement to the U.S. FDA. Generic manufacturers must notify the U.S. FDA of new safety information, and wait for the U.S. FDA and the brand manufacturer to determine the updated labeling, which may result in a delay in getting new information to health care professionals and patients.

Under current law, generic and brand drug manufacturers are required to promptly review safety information about their drugs and comply with the U.S. FDA's reporting and recordkeeping requirements. When new information becomes available that causes the product labeling to be inaccurate, all drug manufacturers must take steps to update the labeling.

To enhance transparency while the U.S. FDA is reviewing the change and to make safety-related changes to drug labeling quickly available to health care professionals and the public, the U.S. FDA plans to create a web page where safety-related changes proposed by all drug manufacturers would be posted. Members of the public could subscribe to receive updates.

Comments on the proposed labeling rule were due on March 13, 2014. Various comments and concerns were expressed by various stakeholders on the proposed rule, which is yet to be finalized.

Because the current regulatory scheme only permits a generic manufacturer to use the CBE process to update its label if the branded drug manufacturer changes its label first, this can prevent generic manufacturers from complying with state law warning requirements. As a result, state product liability suits based on failure-to-warn and design defect claims against generics manufacturers have generally been held preempted by Federal law, and in June 2013 the United States Supreme Court upheld such preemption and immunity of generic manufacturers in *Mutual Pharmaceutical Co. v. Bartlett*.

If the U.S. FDA's proposed new rule is adopted, it may eliminate this preemption and increase our potential exposure to lawsuits relating to product safety, side effects and warnings on labels. This new potential exposure to lawsuits may also increase the risk that, in the future, we may not be able to obtain the type and amount of coverage we desire at an acceptable price and self-insurance may become the sole commercially reasonable means available for managing the product liability risks of our business.

*Prescription Drug Marketing Act and Laws Regulating Payments to Healthcare Professionals*

The FDA also enforces the requirements of the Prescription Drug Marketing Act, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians. Sales, marketing and scientific/educational grant programs must comply with the federal anti-kickback statute, the Medicare-Medicaid Anti-Fraud

## **Table of Contents**

and Abuse Act, as amended, the False Claims Act, as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. We are also subject to Section 6002 of the Patient Protection and Affordable Care Act, commonly known as the Physician Payment Sunshine Act which regulates disclosure of payments to certain healthcare professionals and providers.

### *Patient Protection and Affordable Care Act*

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), was 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. Among the provisions of the PPACA that may affect our business include the following:

The PPACA imposes annual, non-deductible fees for entities that manufacture or import certain prescription drugs and biologics. This fee is calculated based upon each manufacturer's percentage share of total branded prescription drug and biologics sales to U.S. government programs (such as Medicare, Medicaid, Veterans Affairs, and Public Health Service discount programs), and authorized generic products are generally treated as branded products. The manufacturer must have at least \$5 million in sales of branded prescription drugs or biologics in order to be subject to this fee.

In August 2013, we received a final invoice from the United States Internal Revenue Service determining our liability for the manufacturer's fee under the PPACA for calendar year 2013 to be \$12,171, based upon our calendar year 2011 sales of branded and authorized generic prescription drugs and biologics. We expect our sales of brand and authorized generic products during calendar year 2012 to the specified government programs to be below the threshold limit of \$5 million, and thus we may not be subject to the fee for calendar year 2014, based on our calendar year 2012 sales.

In addition, the PPACA changed the computations used to determine Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program by redefining the average manufacturer's price (AMP), effective October 1, 2010, and by using 23.1% instead of 15% of AMP for most branded drugs and 13% instead of 11% of AMP for generic drugs, effective January 1, 2010. The PPACA also increased the number of healthcare entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

The PPACA also increased the number of healthcare organizations eligible to participate in the Public Health Service pharmaceutical pricing program, which provides for government controlled prices that result in substantial discounts to participants.

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-similars business. Conversely, the PPACA has some anti-generic provisions that could adversely affect our bio-similars 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 made 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 increased penalties for fraud and abuse violations.

To further facilitate the government's efforts to coordinate and develop comparative clinical effectiveness research, the PPACA established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in such research. The manner in which the comparative research results will be used by third-party payors is uncertain.

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

On January 27, 2012, The Centers for Medicare and Medicaid Services ( CMS ) issued its long awaited proposed rule implementing the Medicaid pricing and reimbursement provisions of the PPACA and related legislation. CMS accepted comments on this proposed rule through April 2, 2012, and we are waiting for CMS to issue a final rule.

## **Table of Contents**

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

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

### *Drug Quality and Security Act*

On November 28, 2013, the Drug Quality and Security Act was signed into law in the United States. The legislation introduces a federal track-and-trace system for medicines with serial numbers added to individual packs and (non-mixed) cases within four years of the legislation's adoption, and electronic tracing of production through the supply chain mandated within 10 years. It also strengthens licensure requirements for wholesale distributors and third-party logistics providers, and requires the U.S. FDA to maintain a database of wholesalers that will be available to the public through its website. The law also boosts oversight of compounding pharmacies that make drugs to order, and increases the powers of the U.S. FDA to oversee large-volume or outsourcing compounders without individual prescriptions.

### *Biologics Pathway*

The Biologics Price Competition and Innovation Act of 2009 created a statutory pathway and abbreviated approval processes for the approval of biosimilar versions of brand-name biological products and a process to resolve patent disputes. While regulations are still being developed by the U.S. FDA, the U.S. FDA issued three substantial draft guidance documents in February 2012 that are intended to provide a roadmap for development of biosimilar products. These draft guidance documents address quality considerations, scientific considerations and questions and answers regarding commonly posed issues.

## **CANADA REGULATORY ENVIRONMENT**

In Canada, we are required to file product dossiers with the Health Canada for permission to market the generic formulation. The regulatory authorities may inspect our manufacturing facility before approval of the dossier.

### ***Europe***

Our sales of generic medicines in Europe for the year ended March 31, 2014 were Rs.6,970 million, which accounted for 7% of our Global Generics segment's sales.

In the European Union (the "EU"), the manufacture and sale of pharmaceutical products is regulated in a manner substantially similar to that in the United States. Legal requirements generally prohibit the handling, manufacture, marketing and importation of any pharmaceutical product unless it is properly registered and manufactured in accordance with applicable law. The registration file relating to any particular product must contain scientific data related to product efficacy and safety, including results of clinical testing and references to medical publications, as well as detailed information regarding production methods and quality control. Regulatory authorities are authorized

to suspend, restrict or cancel the registration of a product if it is found to be harmful or ineffective, or manufactured and marketed other than in accordance with registration conditions.

Sales, Marketing and Distribution Network

*Germany*

In Germany, we sell a broad range of generic pharmaceutical products under the betapharm brand.

Over the last few years, the German pharmaceutical market has significantly changed. The healthcare reform known as the Statutory Health Insurance (SHI) Competition Strengthening Act or Wettbewerbsstärkungsgesetz ( GKV-WSG ) (an act to strengthen the competition in public health insurance), which was effective as of April 1, 2007, has significantly increased the power of insurance companies and statutory health insurance funds ( SHI funds ) to influence dispensing of medicines.

## **Table of Contents**

Pursuant to the GKV-WSG law, those pharmaceutical products covered by rebate contracts with insurance companies and SHI funds have to be prescribed by physicians and dispensed by pharmacies with priority. This has increased the power of insurance companies and SHI funds. As a result, many SHI funds have enacted tender (i.e., competitive bidding) processes to determine which pharmaceutical companies they will enter into rebate contracts with, resulting in the market moving towards a tender based supply model while causing pressure on margins. This has caused a significant shift from the previous prescription based model, where the key driver for generating sales had previously been doctors' prescriptions and pharmacists' influence. In response to these market changes, betapharm underwent a comprehensive restructuring of its sales force, with a reduction of more than 200 employees since we acquired it in March 2006. In addition, we are participating in the tender opportunities by bidding at prices which meet our internal incremental profitability thresholds. In view of this, our success ratio in winning these tender awards has declined and, accordingly, the ratio of our tender based sales to our overall sales has significantly reduced over the past few years.

### *United Kingdom and other Countries within Europe*

We market our generic products in the United Kingdom and other EU countries through our U.K. subsidiary, Dr. Reddy's Laboratories (U.K.) Limited. This subsidiary was formed in the year ended March 31, 2003 after our acquisition of Meridian Healthcare Limited, a United Kingdom based generic pharmaceutical company. We currently market 39 generic products in such countries, representing 80 dosage strengths.

## **Competition**

Our key competitors within the German generics market include the Sandoz group of Novartis Pharma A.G. (including its Hexal, Sandoz and 1A Pharma subsidiaries), the Ratiopharm group of Teva Pharmaceutical Industries Ltd. (including its Ratiopharm, AbZ-Pharma and CT Arzneimittel subsidiaries), Winthrop Arzneimittel GmbH and the Stada group of Stada Arzneimittel AG (including its Stada and Aliud subsidiaries). In the rebate contracts with SHI funds, prices are one of the most important competitive factors.

The United Kingdom is one of the largest markets for generic pharmaceuticals in Europe. It is also one of the most competitive markets, due to its low barriers to entry. Significant vertical integration exists between wholesalers and retailers, ensuring low prices as long as there are several suppliers.

## **Government regulations**

### *European Union Regulatory Environment*

The activities of pharmaceutical companies within the European Union are governed in particular by Directives 2001/83/EC and 2003/94/EC, as amended, and as implemented in national laws within the countries of the European Union. These Directives outline the legislative framework, including the legal basis of marketing authorization procedures, and quality standards including manufacture, patient information and pharmacovigilance activities.

Prior approval of a marketing authorization is required to supply products within the European Union. Such marketing authorizations may be restricted to one member state, cover a selection of member states or can be for the whole of the European Union, depending upon the form of registration procedure selected.

All pharmaceutical companies that manufacture and market human medicinal products in Germany are subject to the applicable rules and regulations executed by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte or BfArM) and the supervisory authorities of the respective federal state in Germany. All pharmaceutical companies in Germany are periodically inspected by the competent supervisory

authority, which has extensive enforcement powers over the activities of pharmaceutical companies. Non-compliance can result in closure of the facility.

Generic or abridged applications omit full non-clinical and clinical data but contain limited non-clinical and clinical data, depending upon the legal basis of the application or to address a specific issue. In the case of a generic medicine application, the applicant is required to demonstrate that its generic product contains the same active pharmaceutical ingredients in the same dosage form for the same indication as the innovator product. Specific data is included in the application to demonstrate that the proposed generic product is interchangeable to the innovator product with respect to quality, safe usage and continued efficacy. European Union laws prevent regulatory authorities from accepting applications for approval of generics that rely on the safety and efficacy data of an innovator of a branded product until the expiration of the innovator's data exclusivity period (usually 8 years from the first marketing authorization in the European Union, depending on the circumstances). The applicant is also required to demonstrate bioequivalence with the EU reference product. Once all these criteria are met, a marketing authorization may be considered for grant.

## **Table of Contents**

Unlike in the United States, there is no equivalent regulatory mechanism within the European Union to incentivize challenge to any patent protection, nor is any period of market exclusivity conferred upon the first generic approval. In situations where the period of data exclusivity given to the innovator of a branded product expires before their patent expires, the launch of our product would then be delayed until patent expiration.

Our U.K. facilities are licensed and periodically inspected by the U.K. Medicines and Healthcare products Regulatory Agencies ( MHRA ) good manufacturing practice Inspectorate, which has extensive enforcement powers over the activities of pharmaceutical manufacturers. Non-compliance can result in product recall, plant closure or other penalties and restrictions. In addition, the U.K. MHRA Inspectorate has approved and periodically inspected our manufacturing facilities based in Hyderabad, Telangana, India for the manufacture of generic medicines for supply to Europe.

In Germany, the government has in recent years enacted a number of laws designed to limit pharmaceutical cost increases, including the GKV-WSG discussed above and the Economic Optimization of Pharmaceutical Care Act (also known as the AVWG ). During the fiscal year ended March 31, 2011, the German government introduced a new law entitled Act on the reorganization of the pharmaceutical market in the public health insurance (or *Arzneimittelmarktneuordnungsgesetz* , commonly referred to as AMNOG ), which affects reimbursement of drugs within Germany's statutory health care system in order to further control the costs of medical care. The key elements of this law are as follows:

Historically, the pharmaceutical companies had been free to set the initial asking price for novel drugs in the German public health system, subject to certain mandatory rebates. Under this new law, a pharmaceutical company determines the price for a new drug or new therapeutic indication for the first year after launch, but must submit to the Joint Federal Committee (the Gemeinsamer Bundesausschuss or G-BA ) a benefit/risk assessment dossier on the drug at or prior to its launch. The G-BA analyzes whether the drug shows an additional clinical benefit in comparison to a corresponding established drug (the appropriate comparator therapy ).

If an additional benefit is established, the pharmaceutical company must negotiate the price of the drug with the Federal Association of the health insurance funds. If no agreement is reached in the negotiation, then the price is determined pursuant to an arbitration procedure. There must be a minimum term of one year.

If no additional benefit is established, the drug is immediately included in a group of drugs with comparable pharmaceutical and therapeutic characteristics, for which maximum reimbursement prices have already been set. If this is not possible due to the drug's novelty, then the pharmaceutical company must negotiate a reimbursement price with the Federal Association of the health insurance funds that may not exceed the costs of the appropriate comparator therapy.

The prices determined pursuant to the above procedures also apply to private insurance agencies, privately insured persons and self-payers, although they may negotiate further discounts.

For drugs developed specifically to treat rare medical conditions that are designated as orphan drugs, the orphan drug will be presumed to have an additional benefit under certain circumstances.

A new regulation for packaging size had to be implemented in 2013. Standard sizes are now based upon the duration of therapies, instead of being based on fixed quantity. Three different types of package sizes are now allowed: N1-packages for treatment periods of 10 days; N2-packages for treatment periods of 30 days; and N3-packages for treatment periods of 100 days.

The law increases the choice to patients by the use of co-payment as an option for patients opting for a non-rebated generic drug.

In Germany, the German Drug Law (Arzneimittelgesetz) ( AMG ), which implements European Union requirements, is the primary regulation applicable to medicinal products. In 2012, the 16<sup>th</sup> Amendment to the AMG and related laws were enacted in order to implement European Directives into national laws. Among other things, the most important changes refer to pharmacovigilance, clinical trials, protection measures against counterfeited medicines and liberalization of German drug advertising law. These transpositions of European Union legislation into national law also took place in the United Kingdom.

The German Social Code's price freeze imposed on reimbursable drugs, which was due to expire at the end of 2013, was amended in 2013 and 2014 to extend the price freeze until December 31, 2017, although the continued price freeze will not apply to medicines subject to internal reference pricing. New European pharmacovigilance legislation (Regulation (EU) No 1235/2010 and Directive 2010/84/EU) was implemented in July 2012. These new requirements are intended to improve patient safety, but will also increase our administrative burdens and therefore our costs. In addition, there are proposals from the European Commission to introduce fees that industry pays for the simplification and maintenance of the European

## **Table of Contents**

pharmacovigilance system as well as fees for the assessment of pharmacovigilance reports, study protocols and referrals. The principle of the proposal has been agreed, but the actual financial proposals are currently in the final stages of discussion and will likely be implemented during the year ending March 31, 2015. This may lead to further increased costs in Europe whenever such proposals are implemented.

### ***Rest of the World markets of our Global Generics segment***

We refer to all markets of our Global Generics segment other than North America, Europe, Russia and other countries of the former Soviet Union and India as our Rest of the World markets. Our significant Rest of the World markets include Venezuela, South Africa and Australia. Our revenues from our Rest of the World markets were Rs.7,359 million in the year ended March 31, 2014, an increase of 33% as compared to the year ended March 31, 2013.

### ***GSK Alliance***

We have entered into a strategic partnership with GlaxoSmithKline plc ( GSK ) to develop and market select products across emerging markets outside India. The products are manufactured by us, and licensed and supplied to GSK in markets such as Latin America, Africa, the Middle East and Asia Pacific, excluding India.

### ***Collaboration agreement with Merck Serono***

During June 30, 2012, we entered into a partnership agreement with Merck Serono, a division of Merck KGaA, Darmstadt, Germany, to co-develop a portfolio of biosimilar compounds in oncology, primarily focused on monoclonal antibodies (MAbs). The partnership covers co-development, manufacturing and commercialization of the compounds included in the agreement. The partnership with Merck Serono expands on our presence in the bio-similar space in select emerging market countries and enables our entry in the bio-similar space into the regulated markets of the United States and Europe.

The agreement is based on full research and development cost sharing. The deal structure calls for Merck Serono and us to co-develop the molecules included in the agreement. We will lead early product development and complete Phase I development. Upon completion of Phase I, Merck Serono will take over manufacturing of the compounds and will lead Phase III development. Merck Serono will undertake commercialization globally, outside the United States, with the exception of select emerging markets that will be co-exclusive or where we maintain exclusive rights. We will receive royalty payments from Merck Serono upon commercialization by them. In the United States, the parties will co-commercialize the products on a profit-sharing basis.

As part of the collaboration arrangement, we are currently conducting early product development, technology transfers and Phase I trials.

### **Global Generics Manufacturing and Raw Materials**

Manufacturing for our Global Generics segment entails converting active pharmaceutical ingredients ( API ) into finished dosages. As of March 31, 2014, we had twelve manufacturing facilities within this segment. Ten of these facilities are located in India and two are located in the United States (Shreveport, Louisiana; and Bristol, Tennessee). We also have one packaging facility in the United Kingdom. Two of the Indian facilities, one each in Hyderabad and Vishakhapatnam, are U.S. FDA compliant. Two of the Indian facilities located in Hyderabad are approved by German drug regulator Bundesinstitut für Arzneimittel und Medizinprodukte (also known as BfARM ) and by the United Kingdom Medicines and Health Care Products Regulatory Agencies ( MHRA ). All the facilities are designed in accordance with and are compliant with current Good Manufacturing Practice ( cGMP ) requirements and are used for



the manufacture of tablets, hard gelatin capsules, injections, liquids and creams for sale in India as well as other markets. The manufacturing site in Vishakhapatnam, India is a state of the art facility for the manufacture of injectable form and solid oral products. The Vishakhapatnam facility has satisfactorily passed inspection by the U.S. FDA, the National Health Surveillance Agency (also known as ANVISA ) of Brazil and the German BfARM. All our sites outside of India are approved by the respective regulatory bodies in the jurisdictions where they are located.

We manufacture most of our finished products at these facilities and also use contract manufacturing arrangements as we determine necessary. For each of our products, we continue to identify, upgrade and develop alternate vendors as part of risk mitigation and continual improvement.

## **Table of Contents**

The ingredients for the manufacture of the finished products are sourced from in-house API manufacturing facilities and from vendors, both local and non-local. Each of these vendors undergo a thorough assessment as part of the vendor qualification process before they qualify as an approved source. We attempt to identify more than one supplier in each drug application or make plans for alternate vendor development from time to time, considering the supplier's history and future product requirements. Arrangements with international raw material suppliers are subject to, among other things, respective country regulations, various import duties and other government clearances.

The prices of our raw materials generally fluctuate in line with commodity cycles. Raw material expense forms the largest portion of our cost of revenues. We evaluate and manage our commodity price risk exposure through our operating procedures and sourcing policies.

The logistics services for storage and distribution in the United States, Germany and Russia are outsourced to a third party service provider.

We manufacture formulations in various dosage forms including tablets, capsules, injections, liquids and creams. These dosage forms are then packaged, quarantined and subject to stringent quality tests, to assure product quality before release into the market. We manufacture our key brands for our Indian markets at our facilities in Baddi, Himachal Pradesh, to take advantage of certain fiscal benefits offered by the Government of India, which includes partial exemption from income taxes for a specified period.

All pharmaceutical manufacturers that sell products in any country are subject to regulations issued by the Ministry of Health (or its equivalent) of the respective country. These regulations govern, or influence the testing, manufacturing, packaging, labeling, storing, record-keeping, safety, approval, advertising, promotion, sale and distribution of products. Our facilities and products are periodically inspected by various regulatory authorities such as the U.S. FDA, the U.K. MHRA, the German BfARM, the South African Medicines Control Council, the Brazilian ANVISA, the Romanian National Medicines Agency, Ukrainian State Pharmacological Center, the local World Health Organization and Drug Control Authority of India, all of which have extensive enforcement powers over the activities of pharmaceutical manufacturers operating within their jurisdiction.

### *Capacity Expansion*

To meet growing demand in regulated markets, we are in the process of obtaining approvals from the U.S. FDA for products to be manufactured from our recently commissioned oral solid dosage form facility in a Special Economic Zone in Devunipalavalasa, Srikakulam, Andhra Pradesh, India. We have also set up a new manufacturing facility in a Special Economic Zone in Duvvada, Visakhapatnam, Andhra Pradesh, India for the manufacture of parenteral (injectable form) products. This will ease the manufacturing pressure and optimize the capacities across our plants. We have also expanded our biosimilars facility in Hyderabad, Telangana, India to meet growing demand in emerging markets.

## **Pharmaceutical Services and Active Ingredients Segment ( PSAI )**

Our Pharmaceutical Services and Active Ingredients ( PSAI ) segment includes active pharmaceutical ingredients and intermediates, also known as active pharmaceutical products or bulk drugs, which are the principal ingredients for finished pharmaceutical products. Active pharmaceutical ingredients and intermediates become finished pharmaceutical products when the dosages are fixed in a form ready for human consumption, such as a tablet, capsule or liquid using additional inactive ingredients. This segment also includes contract research services and the manufacture and sale of active pharmaceutical ingredients and steroids in accordance with specific customer requirements.

Our PSAI segment's revenues for the year ended March 31, 2014 were Rs.23,974 million, a decrease of 22% as compared to the year ended March 31, 2013. Our PSAI segment accounted for 18% of our total revenues for the year ended March 31, 2014.

During the year ended March 31, 2014, we filed 61 Drug Master Files ( DMFs ) worldwide, of which 12 were filed in the United States, 13 were filed in Europe and 36 were filed in other countries. Cumulatively, our total DMFs filed worldwide as of March 31, 2014 were 631, including 196 DMFs filed in the United States.

We produce and market more than 100 different APIs in numerous markets. We export API to developed markets as well as many other key markets, covering more than 80 countries. Our principal overseas markets in this business segment include North America (the United States and Canada) and Europe. Our PSAI segment's API business is operated independently from our Global Generics segment and, in addition to supplying API to our Global Generics segment, our PSAI segment sells API to third parties for use in manufacturing generic products, subject to any patent rights of other third parties. Our PSAI

## **Table of Contents**

segment's API business also manufactures and supplies the API requirements of our pharmaceutical services business. The research and development group within our API business contributes to our business by creating intellectual property (principally with respect to novel and non-infringing manufacturing processes and intermediates), providing research intended to reduce the cost of production of our products and developing new products every year.

The pharmaceutical services (contract research and manufacturing) arm of our PSAI segment was established in 2001 to leverage our strength in process chemistry to serve the niche segment of the pharmaceutical and fine chemicals industry. Over the years, our business strategy in this area has evolved to focus on the marketing of process development and manufacturing services. Our objective is to be the preferred partner for innovator pharmaceutical companies, providing a complete range of services that are necessary to take their innovations to the market speedily and more efficiently. The focus is to leverage our skills in process development, analytical development, formulation development and Current Good Manufacturing Practice ( cGMP ) to serve various needs of innovator pharmaceutical companies. We have positioned our PSAI segment's Custom Pharmaceutical Services business to be the partner of choice for large and emerging innovator companies across the globe, with service offerings spanning the entire value chain of pharmaceutical services.

## **Sales, Marketing and Distribution**

*Developed Markets.* Our principal overseas markets are the United States and Europe. Our sales to these markets were Rs.12,878 million for the year ended March 31, 2014, and accounted for 54% of our PSAI segment's revenues for the year ended March 31, 2014. In the United States and Europe, the patent protection for a large number of high value branded pharmaceutical products expired in the years ended March 31, 2011, 2012 and 2013 and this opened the market to generic products that sourced their API from our PSAI segment. However, during the year ended March 31, 2014, such expirations were much less frequent, which resulted in a decrease in new opportunities in these markets for the customers of our PSAI segment. As a result, we experienced a significant decrease in the revenues of our PSAI segment from these markets. We expect our API division to show growth on account of our investments in newer technologies and platforms in the future. We are also pursuing a partnership model to enable our customers to reach more markets faster and efficiently by leveraging our cost leadership and presence across the globe. We market our products through our subsidiaries in the United States and Europe. These subsidiaries are engaged in all aspects of marketing activity and support our customers' pursuit of regulatory approval for their products, focusing on building long-term relationships with the customers.

*Other Key Markets.* India is an important market with total sales of Rs.3,787 million and it accounted for 16% of the PSAI segment's revenues in the year ended March 31, 2014. In India, we market our API products to Indian and multinational companies, many of whom are also our competitors in our Global Generics segment. The market in India is highly competitive, with severe pricing pressure and competition from lower cost foreign imports in several products.

Our sales to all of the other key markets (excluding India) were Rs.7,309 million for the year ended March 31, 2014 and accounted for 30% of our PSAI segment's revenues for such year. Our other key markets include Brazil, Mexico, South Korea and Japan. While we work through our agents in these markets, our zonal marketing managers also interact directly with our key customers in order to service their requirements. Our focus is on building relationships with top customers in each of these markets and partnering with them in product launches by providing timely technical and analytical support.

For our custom pharmaceutical services line of business, we have focused business development teams dedicated to our key geographies of North America (the United States and Canada), the European Union and Asia Pacific. These teams target large and emerging innovator companies to build long-term business relationships focused on catering to

their outsourcing needs.

PSAI Manufacturing and Raw Materials

The infrastructure for our PSAI segment consists of eight U.S. FDA-inspected plants (six of which are in India, one of which is in Mexico, and one of which is in Mirfield, United Kingdom) and four technology development centers (two of which are in Hyderabad, India, one of which is in Cambridge, United Kingdom and one of which is in Leiden, the Netherlands as a result of our acquisition of Netherlands-based specialty pharmaceutical company OctoPlus N.V.).

*India.* All of the facilities in India are located in the states of Andhra Pradesh and Telangana. We have the flexibility to produce quantities that range from a few kilograms to several metric tons. We have also set up a new manufacturing facility which is part of a Special Economic Zone located in Devunipalavalasa, Srikakulam, Andhra Pradesh, India. The manufacturing process consumes a wide variety of raw materials that we obtain from sources that comply with the requirements of regulatory authorities in the markets to which we supply our products. We procure raw materials on the basis

## **Table of Contents**

of our requirement planning cycles. We utilize a broad base of suppliers in order to minimize risk arising from dependence on a single supplier. We also source several APIs from third party suppliers for resale in some of the key markets in which we make sales. During the year ended March 31, 2014, approximately 10% of our total API revenues resulted from sales of API procured from third-party suppliers. We maintain stringent quality controls when procuring materials from third-party suppliers.

The prices of our raw materials generally fluctuate in line with commodity cycles although the prices of raw materials used in our API business are generally more volatile. Raw material expense forms the largest portion of our cost of revenues. We evaluate and manage our commodity price risk exposure through our operating procedures and sourcing policies.

*Mexico.* Our manufacturing plant in Cuernavaca, Mexico (the Mexico facility ) was acquired from Roche during the year ended March 31, 2006. In addition to manufacturing the active pharmaceutical ingredients naproxen and naproxen sodium and a range of intermediates, the Mexico facility synthesizes steroids for use in pharmaceutical and veterinary products.

For our contract research services, we have well-resourced synthetic organic chemistry laboratories, analytical laboratories and kilo laboratories at our technology development centers at Miyapur and Jeedimetla in Hyderabad, India. Our chemists and engineers understand cGMP manufacturing and regulatory requirements for synthesis, manufacture and formulation of a NCE from the pre-clinical stage to commercialization. To complete the full value chain in development services, we also provide formulation development services. We now have facilities for pre-formulation and formulation development, analytical development, clinical trial supplies, pilot scale and product regulatory support. Larger quantities of APIs are sourced from API plants in India and Mexico.

The Dowpharma Small Molecules business, which we acquired from The Dow Chemical Company in April 2008, continues to offer niche capabilities, such as biocatalysis, chemocatalysis and hydroformulation, to provide cost effective solutions for chiral molecules. The non-exclusive license to Dow's Pfēnex Expression Technology for biocatalysis development, also acquired as part of the acquisition, continues to offer us opportunities to provide technology leveraged manufacturing services to innovators, including major global pharmaceutical companies.

In the year ended March 31, 2013, we acquired Netherlands-based specialty pharmaceutical company OctoPlus N.V. ( OctoPlus ). OctoPlus has developed significant in-house expertise in the development and creation of micro-spheres and liposomes using certain polymer based technologies that enhance and enable controlled-release of the subject API into the human body. OctoPlus is well-known in the market for formulating complex injectables using polylactic-co-glycolic acid ( PLGA ) technology, which requires significant expertise and experience. In addition, it also uses its own patented PolyActive technology in specific project based injectables.

Our contract research and manufacturing business is uniquely positioned in the market where it utilizes assets (both in terms of physical assets and technical know-how) of a vertically integrated pharmaceutical company and combines this with the service model which we built over the last few years.

## **Competition**

The global API market can broadly be divided into regulated and less regulated markets. The less regulated markets offer low entry barriers in terms of regulatory requirements and intellectual property rights. The regulated markets, like the United States and Europe, have high entry barriers in terms of intellectual property rights and regulatory requirements, including facility approvals. As a result, there is a premium for quality and regulatory compliance along with relatively greater stability for both volumes and prices. During the year ended March 31, 2014, the competitive

environment for the API industry continued to change due to increased consolidation in the global generics industry and vertical integration of some key generic pharmaceutical companies. As an API supplier, we compete with a number of manufacturers within and outside India, which vary in size. Our main competitors in this segment are Divis Laboratories Limited, Aurobindo Pharma Limited, Ranbaxy Laboratories Limited, Cipla Limited, Mylan Laboratories Limited, Sun Pharmaceutical Industries Limited and MSN Laboratories Limited, all based or operating in India. In addition, we experience competition from European and Chinese manufacturers, as well as from Teva Pharmaceuticals Industries Limited, based in Israel.

With respect to our custom pharmaceuticals business, we believe that contract manufacturing is a significant opportunity for Indian pharmaceutical companies, based on their strengths of a skilled workforce and a low-cost manufacturing infrastructure. Key competitors in India include Divis Laboratories Limited, Dishman Pharmaceuticals & Chemicals Limited, Jubilant Organosys Limited and Nicholas Piramal India Limited. Key competitors from outside India include Lonza Group, Koninklijke DSM N.V., Albany Molecular Research, Inc., Patheon, Inc. and Cardinal Health, Inc. We distinguish ourselves

## **Table of Contents**

from our key competitors by offering a wider range of cost effective services spanning the entire pharmaceutical value chain. Growth in contract manufacturing is likely to be driven by increasing outsourcing of late-stage and off-patent molecules by large pharmaceutical companies to compete with generics. India is emerging as an alliance and outsourcing destination of choice for global pharmaceutical companies. Companies such as Roche, Bayer, Aventis, Novartis, Eli Lilly, Merck Sereno and GlaxoSmithKline may make India the regional hub for API and supply of bulk drugs.

## **Government regulations**

All pharmaceutical companies that manufacture and market products in India are subject to various national and state laws and regulations, which principally include the Drugs and Cosmetics Act, 1940, the Drugs (Prices Control) Order, 1995, various environmental laws, labor laws and other government statutes and regulations. These regulations govern the testing, manufacturing, packaging, labeling, storing, record-keeping, safety, approval, advertising, promotion, sale and distribution of pharmaceutical products.

In India, manufacturing licenses for drugs and pharmaceuticals are generally issued by state drug authorities. Under the Drugs and Cosmetics Act, 1940, the state drug administration agencies are empowered to issue manufacturing licenses for drugs if they are approved for marketing in India by the Drug Controller General of India ( DCGI ). Prior to granting licenses for any new drugs or combinations of new drugs, the DCGI clearance has to be obtained in accordance with the Drugs and Cosmetics Act, 1940.

We submit a DMF for active pharmaceutical ingredients to be commercialized in the United States. Any drug product for which an ANDA is being filed must have a DMF in place with respect to a particular supplier supplying the underlying API. The manufacturing facilities are inspected by the U.S. FDA to assess compliance with Current Good Manufacturing Practice regulations ( cGMP ). The manufacturing facilities and production procedures utilized at the manufacturing facilities must meet U.S. FDA standards before products may be exported to the United States. Eight of our manufacturing facilities are inspected and approved by the U.S. FDA. For European markets, we submit a European DMF and where applicable, obtain a certificate of suitability from the European Directorate for the Quality of Medicines.

## **Proprietary Products Segment**

Our Proprietary Products segment includes the discovery and development of new chemical entities and differentiated formulations for subsequent commercialization. This segment also includes our dermatology focused specialty business operated through Promius Pharma.

We continue to leverage our semi-virtual research and development model to expand our portfolio of drug discovery, differentiated and specialty formulations programs. We achieve this by efficiently collaborating with different biotechnology companies and service providers, and tapping their expertise in the different areas of our drug development process. We continue to progress towards building a sustainable mix of proprietary, branded research and development portfolio with significantly reduced fixed costs.

## ***Proprietary Products business***

In our Proprietary Products segment, our business model focuses on building a pipeline in the therapeutic areas of neurology, pain management, dermatology and infectious diseases.



Our research and development efforts have a unique medicines-to-molecules approach to product development. In this approach, we leverage in an integrated manner the disciplines of biology, chemistry, drug delivery, clinical development, regulatory and commercial positioning to construct novel differentiated formulations and NCEs.

We follow a hybrid research and development model, both in-house and virtual (i.e., operations are outsourced, subject to our retention of strategic and project management functions), with the following core principles:

develop creative research and development investment models and partnerships to tap external innovation focused on leveraging, rather than replicating, unique core competencies;

select assets based on potential for early risk mitigation, both with respect to product development and commercialization; and

leverage knowledge and presence in emerging markets (especially India) to maximize cost advantage.

**Table of Contents**

Our principal research laboratory is based in Hyderabad, India. As of March 31, 2014, we employed a total of 125 scientists, including 30 scientists who held Ph.D. degrees, across all of this segment's locations. We pursue an integrated research strategy through a mix of translational, formulation and analytical research at our laboratories. Our research strategy focuses on discovery of new molecular targets, designing of screening assays to screen promising molecules and developing novel formulations of currently marketed drugs or combinations thereof to address unmet medical needs.

While we continue to seek licensing and development arrangements with third parties to further develop our product pipeline, we also conduct clinical development of some candidate drugs ourselves, which will enable us to derive higher value for our products. Our goal is to balance internal development of our own product candidates with in-licensing of promising compounds that complement our strengths. We also pursue licensing and joint development of some of our lead compounds with companies looking to implement their own product portfolio.

**Pipeline Status**

As of March 31, 2014, we had 20 active products in our Proprietary Products pipeline, of which 9 were in clinical development stage. Since repositioning our research activities in the years ended March 31, 2009 and 2010, our Proprietary Products segment has focused its efforts towards developing drugs to meet key unmet clinical needs. We have built a pipeline of assets that we expect to produce a steady stream of Investigational New Drugs ( INDs ) in the coming years. The details of clinical development candidates from our Proprietary Products segments as of March 31, 2014 are as follows:

Compound	Therapeutic Area	Status	Remarks
DRL 17822	Metabolic disorders/cardiovascular disorders	Phase II	Targeting dyslipidemia/atherosclerosis
DFP-08	Pain	Phase I	Targeting pain
DFA-02	Anti-infectives	Phase II	Targeting bacterial infections
DFP-02	Migraine	Phase III	Targeting migraine
DFD-01	Psoriasis	Phase III	Targeting psoriasis
DFD-06	Atopic dermatitis/psoriasis	Phase II	Targeting psoriasis, atopic dermatitis

In addition to the above, we have three programs which are in pharmacokinetic, bioavailability and bioequivalence studies in the migraine and dermatology therapeutic areas.

*Patents.* Our Proprietary Products segment had the following patents filed and issued as of March 31, 2014:

Category	USPTO <sup>(1)</sup> (# Filed)	USPTO <sup>(1)</sup> (# Granted)	PCT <sup>(2)</sup> (# Filed)	India (# Filed)	India (# Granted)
Anti-diabetic	85	17	62	117	45
Anti-cancer	18	11	14	45	15
Anti-bacterial	8	7	10	22	4
Anti-inflammation/cardiovascular	42	21	35	23	3
Anti-ulcerant	1	1		1	
Miscellaneous	4+1 (provisional)	1	3	23	8

Differentiated formulations	3+4 (provisional)	1	7	6+1 (provisional)	
<b>TOTAL</b>	<b>166</b>	<b>59</b>	<b>131</b>	<b>238</b>	<b>75</b>

- (1) USPTO means the United States Patent and Trademark Office.
- (2) PCT means the Patent Cooperation Treaty, an international treaty that facilitates foreign patent filings for residents of member countries when obtaining patents in other member countries.

## **Table of Contents**

*Stages of Testing Development.* The stages of testing required before a pharmaceutical product can be marketed in the United States are generally as follows:

### **Stage of**

#### **Development Description**

Preclinical	Animal studies and laboratory tests to evaluate safety and efficacy, demonstrate activity of a product candidate and identify its chemical and physical properties.
Phase I	Clinical studies to test safety and pharmacokinetic profile of a drug in humans.
Phase II	Clinical studies conducted with groups of patients to determine preliminary efficacy, dosage and expanded evidence of safety.
Phase III	Larger scale clinical studies conducted in patients to provide sufficient data for statistical proof of efficacy and safety.

For ethical, scientific and legal reasons, animal studies are required in the discovery and safety evaluation of new medicines. Preclinical tests assess the potential safety and efficacy of a product candidate in animal models. The results of these studies must be submitted to the U.S. FDA as part of an Investigational New Drug ( IND ) application before human testing may proceed.

U.S. law further requires that studies conducted to support approval for product marketing be adequate and well controlled. In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice requirements, and adverse event and other reporting requirements must be followed.

The clinical trial process can take five to ten years or more to complete, and there can be no assurance that the data collected will be in compliance with good clinical practice regulations, will demonstrate that the product is safe or effective, or, in the case of a biologic product, pure and potent, or will provide sufficient data to support U.S. FDA approval of the product. The U.S. FDA may place clinical trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Trials may also be terminated by institutional review boards, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization.

## **Competition**

The pharmaceutical and biotechnology industries are highly competitive. We face intense competition from organizations such as large pharmaceutical companies, biotechnology companies and academic and research organizations. The major pharmaceutical organizations competing with us have greater capital resources, larger overall research and development staff and facilities and considerably more experience in drug development. Biotechnology companies competing with us may have these advantages as well.

In addition to competition from collaborators and investors, these companies and institutions also compete with us in recruiting and retaining highly qualified scientific and management personnel.

## **Government regulations**

Virtually all pharmaceutical and biologics products that we or our collaborative partners develop will require regulatory approval by governmental agencies prior to commercialization. The nature and extent to which these regulations apply varies depending on the nature of the products and also vary from country to country. In particular, human pharmaceutical products are subject to rigorous preclinical and clinical testing and other approval procedures by the relevant regulatory agency. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country.

In India, under the Drugs and Cosmetics Act, 1940, the regulation of the manufacture, sale and distribution of drugs is primarily the concern of the state authorities while the Central Drug Control Administration is responsible for approval of new drugs, clinical trials in the country, establishing the standards for drugs, control over the quality of imported drugs, coordination of the activities of state drug control organizations and providing expert advice with a view of bringing about the uniformity in the enforcement of the Drugs and Cosmetics Act, 1940.

## **Table of Contents**

In order to market a drug in the United States, we or our partners will be subject to regulatory requirements governing human clinical trials, marketing approval and post-marketing activities for pharmaceutical products and biologics. Various federal, and in some cases state, statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record-keeping and marketing of these products. The process of obtaining these approvals and the subsequent compliance with applicable statutes and regulations is time consuming and requires substantial resources, and the approval outcome is uncertain.

Generally, in order to gain U.S. FDA approval, a company first must conduct pre-clinical studies in the laboratory and in animal models to gain preliminary information on a compound's activity and to identify any safety problems. Pre-clinical studies must be conducted in accordance with U.S. FDA regulations. The results of these studies are submitted as part of an IND application that the U.S. FDA must review before human clinical trials of an investigational drug can start. If the U.S. FDA does not respond with any questions, a drug developer can commence clinical trials thirty days after the submission of an IND.

In order to eventually commercialize any products, we or our collaborator first will be required to sponsor and file an IND and will be responsible for initiating and overseeing the clinical studies to demonstrate the safety and efficacy that is necessary to obtain U.S. FDA marketing approval. Clinical trials are normally done in three phases and generally take several years to complete. The clinical trials have to be designed taking into account the applicable U.S. FDA guidelines. Furthermore, the U.S. FDA may suspend clinical trials at any time if the U.S. FDA believes that the subjects participating in trials are being exposed to unacceptable risks or if the U.S. FDA finds deficiencies in the conduct of the trials or other problems with our product under development.

After completion of clinical trials of a new product, U.S. FDA marketing approval must be obtained. If the product is classified as a new pharmaceutical, we or our collaborator will be required to file a New Drug Application ( NDA ), and receive approval before commercial marketing of the drug. The testing and approval processes require substantial time and effort. NDAs submitted to the U.S. FDA can take several years to obtain approval and the U.S. FDA is not obligated to grant approval at all.

Even if U.S. FDA regulatory clearances are obtained, a marketed product is subject to continual review. If and when the U.S. FDA approves any of our or our collaborators' products under development, the manufacture and marketing of these products will be subject to continuing regulation, including compliance with cGMP, adverse event reporting requirements and prohibitions on promoting a product for unapproved uses. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Various federal and, in some cases, state statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products.

Our research and development processes involve the controlled use of hazardous materials and controlled substances. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste products.

### ***Promius Pharma***

Promius Pharma is our subsidiary in Princeton, New Jersey in the United States focusing on our U.S. Specialty Business i.e., development and sales of branded specialty products. It has a portfolio of in-licensed patented dermatology products. It also has an internal pipeline of dermatology products that are in different stages of development. Promius Pharma's current portfolio contains innovative products for the treatment of seborrheic dermatitis, acne and steroid responsive dermatoses. It has commercialized four products: EpiCeram®, which is a skin

barrier emulsion for the treatment of atopic dermatitis; Scytera<sup>®</sup>, which is foam for the treatment of psoriasis; Promiseb<sup>®</sup>, which is a cream for the treatment for seborrheic dermatitis; and Cloderm<sup>®</sup> (clocortolone pivalate 0.1%), which is a cream used for treating dermatological inflammation.

Promius Pharma leverages our research, development and manufacturing facilities in Hyderabad, India. Promius Pharma also works with various third party research organizations in conducting product development, pre-clinical and clinical studies. Promius Pharma has 53 sales representatives, six regional sales managers and one sales director in the field. Its sales force targets physicians in the field of dermatology and is supported by a direct marketing team and a public relations program. The manufacturing of Promius Pharma's products has been outsourced to third party manufacturers based in the United States and Europe.

**Table of Contents****4.C. Organizational structure**

Dr. Reddy's Laboratories Limited is the parent company in our group. We had the following subsidiary companies where our direct and indirect ownership was more than 50% as of March 31, 2014:

<b>Name of the subsidiary</b>	<b>Country of Incorporation</b>	<b>Percentage of Direct/Indirect Ownership Interest</b>
Aurigene Discovery Technologies (Malaysia) Sdn. Bhd.	Malaysia	100% <sup>(3)</sup>
Aurigene Discovery Technologies Inc.	U.S.A.	100% <sup>(3)</sup>
Aurigene Discovery Technologies Limited	India	100%
beta Institut gemeinnützige GmbH	Germany	100% <sup>(8)</sup>
betapharm Arzneimittel GmbH	Germany	100% <sup>(8)</sup>
Cheminor Investments Limited	India	100%
Chienna BV (from February 15, 2013)	Netherlands	100% <sup>(14)</sup>
Chiretech Technology Limited	United Kingdom	100% <sup>(5)</sup>
DRANU LLC (from July 9, 2012)	U.S.A.	50% <sup>(16)</sup>
Dr. Reddy's Bio-Sciences Limited	India	100%
Dr. Reddy's Farmaceutica Do Brasil Ltda.	Brazil	100%
Dr. Reddy's Laboratories (Australia) Pty. Limited	Australia	100% <sup>(10)</sup>
Dr. Reddy's Laboratories Canada, Inc. (from August 29, 2013)	Canada	100% <sup>(10)</sup>
Dr. Reddy's Laboratories (EU) Limited	United Kingdom	100% <sup>(10)</sup>
Dr. Reddy's Laboratories Inc.	U.S.A.	100% <sup>(10)</sup>
Dr. Reddy's Laboratories International SA	Switzerland	100% <sup>(10)</sup>
Dr. Reddy's Laboratories, LLC Ukraine	Ukraine	100% <sup>(10)</sup>
Dr. Reddy's Laboratories Louisiana LLC	U.S.A.	100% <sup>(6)</sup>
Dr. Reddy's Laboratories New York, Inc.	U.S.A.	100% <sup>(10)</sup>
Dr. Reddy's Laboratories (Proprietary) Limited	South Africa	100% <sup>(10)</sup>
Dr. Reddy's Laboratories Romania S.R.L.	Romania	100% <sup>(10)</sup>
Dr. Reddy's Laboratories SA	Switzerland	100%
Dr. Reddy's Laboratories Tennessee, LLC	U.S.A.	100% <sup>(6)</sup>
Dr. Reddy's Laboratories (UK) Limited	United Kingdom	100% <sup>(5)</sup>
Dr. Reddy's New Zealand Limited.	New Zealand	100% <sup>(10)</sup>
Dr. Reddy's Pharma SEZ Limited	India	100%
Dr. Reddy's Singapore PTE Limited, Singapore (from October 22, 2013)	Singapore	100% <sup>(10)</sup>
Dr. Reddy's Srl	Italy	100% <sup>(11)</sup>
Dr. Reddy's Venezuela, C.A.	Venezuela	100% <sup>(10)</sup>
DRL Impex Limited	India	100%
Eurobridge Consulting B.V.	Netherlands	100% <sup>(1)</sup>
Industrias Químicas Falcon de Mexico, S.A. de CV	Mexico	100%
Idea2Enterprises (India) Pvt. Limited	India	100%
I-Ven Pharma Capital Limited	India	100% <sup>(2)(12)</sup>
Kunshan Rotam Reddy Pharmaceutical Co. Limited (JV)	China	51.33% <sup>(4)</sup>
Lacock Holdings Limited	Cyprus	100% <sup>(10)</sup>
OOO Dr. Reddy's Laboratories Limited	Russia	100% <sup>(10)</sup>



OOO DRS LLC	Russia	100% <sup>(9)</sup>
OctoPlus N.V. (from February 15, 2013)	Netherlands	100% <sup>(13)</sup>
OctoPlus Development B.V. (from February 15, 2013)	Netherlands	100% <sup>(14)</sup>
OctoPlus Sciences B.V. (from February 15, 2013)	Netherlands	100% <sup>(14)</sup>
OctoPlus PolyActive Sciences B.V. (from February 15, 2013)	Netherlands	100% <sup>(15)</sup>
OctoPlus Technologies B.V. (from February 15, 2013)	Netherlands	100% <sup>(14)</sup>
OctoShare B.V. (from February 15, 2013)	Netherlands	100% <sup>(14)</sup>

**Table of Contents**

<b>Name of the subsidiary</b>	<b>Country of Incorporation</b>	<b>Percentage of Direct/Indirect Ownership Interest</b>
Promius Pharma LLC	U.S.A.	100% <sup>(6)</sup>
Reddy Antilles N.V.	Netherlands	100%
Reddy Specialities GmbH (formerly Reddy beta GmbH)	Germany	100% <sup>(8)</sup>
Reddy Cheminor S.A.	France	100% <sup>(2)</sup>
Reddy Holding GmbH	Germany	100% <sup>(10)</sup>
Reddy Netherlands B.V.	Netherlands	100% <sup>(10)</sup>
Reddy Pharma Iberia SA	Spain	100%
Reddy Pharma Italia S.p.A.	Italy	100% <sup>(7)</sup>
Reddy US Therapeutics Inc. (until July 3, 2013)	U.S.A.	100% <sup>(1)</sup>

- (1) Indirectly owned through Reddy Antilles N.V.
- (2) Subsidiary under liquidation.
- (3) Indirectly owned through Aurigene Discovery Technologies Limited.
- (4) Kunshan Rotam Reddy Pharmaceutical Co. Limited is a subsidiary, as we hold a 51.33% stake. However, we account for this investment by the equity method and do not consolidate it in our financial statements.
- (5) Indirectly owned through Dr. Reddy's Laboratories (EU) Limited.
- (6) Indirectly owned through Dr. Reddy's Laboratories Inc.
- (7) Indirectly owned through Lacock Holdings Limited.
- (8) Indirectly owned through Reddy Holding GmbH.
- (9) Indirectly owned through Eurobridge Consulting B.V.
- (10) Indirectly owned through Dr. Reddy's Laboratories SA.
- (11) Indirectly owned through Reddy Pharma Italia S.p.A.
- (12) Indirectly owned through DRL Impex Limited
- (13) Indirectly owned through Reddy Netherlands B.V.
- (14) Indirectly owned through OctoPlus N.V.
- (15) Indirectly owned through OctoPlus Sciences B.V.
- (16) DRANU LLC is consolidated in accordance with guidance available in IFRS 10.

**Table of Contents****4.D. Property, plant and equipment**

The following table sets forth current information relating to our principal facilities:

Sl. No.	Location	Approximate Area (Square feet)	Built up Area (Square feet)	Certifications	Installed Capacity	Actual Production
<b>Within India</b>						
1	API Hyderabad Plant 1, Telangana, India	734,013	399,339	U.S. FDA and EUGMP	4,792 <sup>(8)(11)</sup>	3,542 <sup>(8)(11)</sup>
2	API Hyderabad Plant 2, Telangana, India	725,274	405,956	U.S. FDA and EUGMP	See above <sup>(11)</sup>	See above <sup>(11)</sup>
3	API Hyderabad Plant 3, Telangana, India	715,610	217,515	U.S. FDA and EUGMP	See above <sup>(11)</sup>	See above <sup>(11)</sup>
4	API Hyderabad Plant 4, Telangana, India	228,033	141,035	U.S. FDA and EUGMP	See above <sup>(11)</sup>	See above <sup>(11)</sup>
5	API Nalgonda Plant, Telangana, India	3,402,907	576,570	U.S. FDA and EUGMP	See above <sup>(11)</sup>	See above <sup>(11)</sup>
6	API Srikakulam Plant, Andhra Pradesh, India	4,047,595	1,859,056	U.S. FDA and EUGMP	See above <sup>(11)</sup>	See above <sup>(11)</sup>
7	API Srikakulam Plant (SEZ), Andhra Pradesh, India	11,001,863	414,351		N/A	N/A
8	Technology Development Centre Hyderabad 1, Telangana, India	113,256	95,394	ISO 27001: 2005 Information Security Management System	N/A	N/A
9	Technology Development Centre Hyderabad 2, Telangana, India	68,825	23,538	ISO 27001: 2005 Information Security Management System	N/A	N/A
10	Formulations Hyderabad Plant 1, Telangana, India	217,729	154,217	(2)	10,636 <sup>(6)(13)(15)</sup>	5,456 <sup>(6)(13)</sup>
11	Formulations Hyderabad Plant 2, Telangana, India	1,306,372	832,559	(3)	See above <sup>(13)</sup>	See above <sup>(13)</sup>
12	Formulations Yanam Plant, Pondicherry, India	457,000	63,738		See above <sup>(13)</sup>	See above <sup>(13)</sup>
13		786,261	217,546	WHO-GMP	See above <sup>(13)</sup>	See above <sup>(13)</sup>

	Formulations Baddi Plant 1, Himachal Pradesh, India					
14	Formulations Baddi Plant 2, Himachal Pradesh, India	378,190	205,284		See above <sup>(13)</sup>	See above <sup>(13)</sup>
15	Biologics Hyderabad, Telangana, India	789,727	213,002	(2)	123,682 <sup>(9)(14)</sup>	66,657 <sup>(9)</sup>
16	Formulations Hyderabad Plant 3, Telangana, India	783,823	833,841	(4)	11,600 <sup>(6)(10)</sup>	6,501 <sup>(6)</sup>
17	Formulations Srikakulam Plant (SEZ), Andhra Pradesh, India <sup>(16)</sup>	879,034	308,316		N/A	N/A
18	Formulations Visakhapatnam Plant (SEZ), Andhra Pradesh, India	908,800	179,451	U.S. FDA, ANVISA, Brazil and BfARM, Germany	127 <sup>(6)(7)</sup>	2 <sup>(6)</sup>
19	Formulations Visakhapatnam Plant 2 (SEZ), Andhra Pradesh, India	251,784	15,332		N/A	N/A
20	ADTL Hyderabad, Telangana, India <sup>(7)</sup>	187,308	118,012		N/A	N/A
<b>Outside India</b>						
21	API Cuernavaca Plant, Mexico	2,361,840	689,719	(1)	3,500 <sup>(8)</sup>	2,046 <sup>(8)</sup>
22	API Mirfield Plant, United Kingdom	1,785,960	653,400	ISO 9001:2008, MHRA (UK), U.S. FDA and Korean FDA (Travapost)	(12)	(12)
23	API Middleburgh Plant, New York, United States <sup>(5)</sup>	292,000	26,000		50-100 <sup>(17)</sup>	N/A
24	Technology Development Centre, Cambridge, United Kingdom <sup>(5)</sup>	32,966	32,966		N/A	N/A
25	Technology Development Centre, OctoPlus N.V., Leiden, the Netherlands <sup>(5)</sup>	56,500	18,700	EUGMP	2 <sup>(7)(8)</sup>	0.07 <sup>(7)(8)</sup>
26	Formulations Beverley Plant, East Yorkshire, United Kingdom	81,000	32,500	U.K. Medicine Control Agency, British Retail Consortium	N/A	N/A
27		1,817,123	335,000	U.S. FDA	5,875 <sup>(6)(10)</sup>	3,376 <sup>(6)</sup>

Formulations Shreveport Plant, Louisiana, United States						
28	Formulations Bristol Plant, TN, United States	1,742,400	390,000	U.S. FDA	2,460 <sup>(6)(10)</sup>	218 <sup>(6)</sup>

## **Table of Contents**

- (1) U.S. FDA; European Directorate for the Quality of Medicines & HealthCare ( EDQM ); Ministry of Health, Labour and Welfare, Japan; Secretaría de Salud, Mexico; Ministry of Health, Romania.
- (2) Ministry of Health, Uganda; Brazilian National Agency of Sanitary Surveillance ( ANVISA ), Brazil; National Medicines Agency, Romania; Ministry of Health, Ukraine; Gulf Cooperation Council ( GCC ) group of countries.
- (3) Medicine Control Council, Republic of South Africa; The State Company for Marketing Drugs and Medical Appliances, Ministry of Health, Iraq; Sultanate of Oman, Ministry of Health, Muscat; Ministry of Health, State of Bahrain; State Pharmaceutical Inspection, Republic of Latvia; Pharmaceutical and Herbal Medicines, Registration and Control Administrations, Ministry of Health, Kuwait. National Medicines Agency, Romania; Ministry of Health, Ukraine; Ministry of Health, Indonesia; Health Authorities, Nigeria; Ministry of Health, Kirgystan; World Health Organization, cGMP; ANVISA, Brazil; Medicines and Health Care Products Regulatory Agencies ( MHRA ), U.K., British Retail Consortium; Danish Medicines Agency; BfARM, Germany.
- (4) U.S. FDA; Medicines and Healthcare Products Regulatory Agency, U.K.; Ministry of Health, United Arab Emirates; Medicines Control Council, South Africa; ANVISA, Brazil; National Medicines Agency, Romania; Danish Medicines Agency, Environmental Management System ISO 14001; Occupational Health and Safety Management System OHSAS 18001; Quality Management System-ISO 9001:2000; BfARM, Germany.
- (5) Leased facilities.
- (6) Million units.
- (7) On a single shift basis.
- (8) Tons.
- (9) Grams.
- (10) Three shift basis
- (11) Represents the aggregate capacity and production for the facilities serially numbered from 1 to 6 in this table.
- (12) Capacity and production at this facility is not separately tracked.
- (13) Represents the aggregate capacity and production for the facilities serially numbered from 10 to 14 in this table.
- (14) Installed capacity is variable and subject to changes in product mix, and utilization of manufacturing facilities given the nature of production.
- (15) On a two shift basis.
- (16) This facility is part of our PSAI segment's Special Economic Zone ( SEZ ) in Devunipalavalasa, Srikakulam, Andhra Pradesh, India.
- (17) Kilograms.

Except for as indicated in the notes above, we own all of our facilities. All properties identified above, including leased properties, are either used for manufacturing and packaging of pharmaceutical products or for research and development activities. In addition, we have sales, marketing and administrative offices, some of which are owned and some others are leased properties. We believe that our facilities are optimally utilized.

## **Global Generics**

During the year ended March 31, 2014, we set up a new manufacturing facility in a Special Economic Zone in Duvvada, Visakhapatnam, Andhra Pradesh, India for the manufacture of parenteral (injectable form) products. This will ease the manufacturing pressure and optimize the capacities across our plants.

During the year ended March 31, 2013, we also expanded our biosimilars facility in Hyderabad, Telangana, India to meet growing demand in emerging markets.

We are also in the process of obtaining approvals from the U.S. FDA for products to be manufactured from a recently commissioned oral solid dosage form facility in a Special Economic Zone in Devunipalavalasa, Srikakulam, Andhra

Pradesh, India. The new plant is intended for the manufacture of new molecules, and certain high volume products of our Global Generics segment.

## **Table of Contents**

### **Pharmaceutical Services and Active Ingredients**

During the year ended March 31, 2013, we also set up a new manufacturing facility in a Special Economic Zone located in Devunipalavalasa, Srikakulam, Andhra Pradesh, India. We have begun filing some of our new DMFs from this location and we expect to file some more during the year ending March 31, 2015. This plant is adjacent to an existing plant, in a newly acquired area of approximately 250 acres under a Pharmaceutical-Sector specific Special Economic Zone for fiscal benefits. This location also houses our Global Generics segment's recently commissioned oral solid dosage form facility. The formal governmental approval for designating the property as a Special Economic Zone has been obtained.

### **Material plans to construct, expand and improve facilities**

As of March 31, 2014, we had capital work-in-progress and capital commitments of Rs.6,675 million and Rs.2,920 million, respectively, for expansion of our manufacturing and research facilities, primarily relating to facilities located in India and the United States. We currently intend to finance our additional expansion plans entirely through our operating cash flows and through cash and other investments. A majority of these projects are expected to be completed during the fiscal years ending March 31, 2015 and March 31, 2016.

### **Environmental laws and regulations**

We are subject to significant national and state 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 at the above facilities. Non-compliance with the applicable laws and regulations may subject us to penalties and may also result in the closure of our facilities.



## **Table of Contents**

### **ITEM 4A. UNRESOLVED STAFF COMMENTS**

None.

### **ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

#### **Overview**

We are an integrated global pharmaceutical company committed to providing affordable and innovative medicines. We derive our revenues from the sale of finished dosage forms, active pharmaceutical ingredients and intermediates, development and manufacturing services provided to innovator pharmaceutical and biotechnology companies, and license fees from marketing authorizations for our products.

The Chief Operating Decision Maker ( CODM ) evaluates our performance and allocates resources based on an analysis of various performance indicators by reportable segments. Our reportable segments are as follows:

Global Generics;

Pharmaceutical Services and Active Ingredients ( PSAI ); and

Proprietary Products.

**Global Generics:** This segment consists of finished pharmaceutical products ready for consumption by the patient, marketed under a brand name (branded formulations) or as generic finished dosages with therapeutic equivalence to branded formulations (generics). This segment includes the operations of our biologics business.

**Pharmaceutical Services and Active Ingredients ( PSAI ):** This segment includes active pharmaceutical ingredients and intermediates, also known as active pharmaceutical products or bulk drugs, which are the principal ingredients for finished pharmaceutical products. Active pharmaceutical ingredients and intermediates become finished pharmaceutical products when the dosages are fixed in a form ready for human consumption, such as a tablet, capsule or liquid using additional inactive ingredients. This segment also includes contract research services and the manufacture and sale of active pharmaceutical ingredients and steroids in accordance with specific customer requirements.

**Proprietary Products:** This segment includes the discovery and development of new chemical entities and differentiated formulations for subsequent commercialization. Our differentiated formulations portfolio consists of new, synergistic combinations and technologies that improve safety and/or efficacy by modifying pharmacokinetics of existing medicines. This segment also includes our specialty pharmaceuticals business, which conducts sales and marketing operations for in-licensed and co-developed dermatology products.

The CODM reviews revenue and gross profit as the performance indicator, and does not review the total assets and liabilities for each reportable segment. The measurement of each segment's revenues, expenses and assets is consistent with the accounting policies that are used in preparation of our consolidated financial statements.



## **Table of Contents**

### **Critical Accounting Policies**

Critical accounting policies are defined as those that in our view are the most important to the portrayal of our financial condition and results and that require the most exercise of management's judgment. We consider the policies discussed under the following paragraphs to be critical for an understanding of our financial statements. Our significant accounting policies and application of these are discussed in detail in Notes 2 and 3 to our consolidated financial statements.

### **Accounting estimates and judgments**

While preparing financial statements in conformity with IFRS, we make certain estimates and assumptions that require difficult, subjective and complex judgments. These judgments affect the application of accounting policies and the reported amount of assets, liabilities, income and expenses, disclosure of contingent liabilities at the statement of financial position date and the reported amount of income and expenses for the reporting period. Financial reporting results rely on our estimate of the effect of certain matters that are inherently uncertain. Future events rarely develop exactly as forecast and the best estimates require adjustments, as actual results may differ from these estimates under different assumptions or conditions. We continually evaluate these estimates and assumptions based on the most recently available information.

Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. In particular, information about significant areas of estimation uncertainty and critical judgments in applying accounting policies that have the most significant effect on the amounts recognized in the financial statements are as below:

Assessment of functional currency for foreign operations;

Financial instruments;

Useful lives of property, plant and equipment and other intangibles;

Measurement of recoverable amounts of cash-generating units;

Assets and obligations relating to employee benefits;

Provisions;

Sales returns, rebates and chargeback provisions;

Evaluation of recoverability of deferred tax assets;

Inventory obsolescence;

Business combinations; and

Contingencies.

**Revenue**

*Sale of goods*

Revenue is recognized when the significant risks and rewards of ownership have been transferred to the buyer, recovery of the consideration is probable, the associated costs and possible return of goods can be estimated reliably, there is no continuing management involvement with the goods and the amount of revenue can be measured reliably. Revenue from the sale of goods includes excise duty and is measured at the fair value of the consideration received or receivable, net of returns, sales tax and applicable trade discounts and allowances. Revenue includes shipping and handling costs billed to the customer.

Revenue from sales of generic products in India is recognized upon delivery of products to distributors by our clearing and forwarding agents. Revenue from sales of active pharmaceutical ingredients and intermediates in India is recognized on delivery of products to customers, from our factories. Revenue from export sales is recognized when the significant risks and rewards of ownership of products are transferred to the customers, which occurs upon delivery of the products to the customers unless the terms of the applicable contract provide for specific revenue generating activities to be completed, in which case revenue is recognized once all such activities are completed.

Sales of generic products in India are made through clearing and forwarding agents to distributors. Significant risks and rewards in respect of ownership of generic products are transferred by us when the goods are delivered to distributors from clearing and forwarding agents. Clearing and forwarding agents are generally compensated on a commission basis as a percentage of sales made by them.

Sales of active pharmaceutical ingredients and intermediates in India are made directly to the end customers (generally formulation manufacturers) from our factories. Significant risks and rewards in respect of ownership of active pharmaceutical ingredients are transferred by us upon delivery of the products to the customers. Sales of active pharmaceutical ingredients and intermediates outside India are made directly to the end customers (generally distributors or formulations manufacturers) from our parent company or subsidiaries. Significant risks and rewards in respect of ownership of active pharmaceutical ingredients are transferred by us upon delivery of the products to the customers, unless the terms of the applicable contract provide for specific revenue generating activities to be completed, in which case revenue is recognized once all such activities are completed.

**Table of Contents***Profit share revenues*

From time to time, we enter into marketing arrangements with certain business partners for the sale of our products in certain markets. Under such arrangements, we sell our products to the business partners at a non-refundable base purchase price agreed upon in the arrangement, and we are also entitled to a profit share which is over and above the base purchase price. The profit share is typically dependent on the business partner's ultimate net sale proceeds or net profits, subject to any reductions or adjustments that are required by the terms of the arrangement. Such arrangements typically require the business partner to provide confirmation of units sold and net sales or net profit computations for the products covered under the arrangement.

Revenue in an amount equal to the base purchase price is recognized in these transactions upon delivery of products to the business partners. An additional amount representing the profit share component is recognized as revenue in the period which corresponds to the ultimate sales of the products made by business partners only when the collectability of the profit share becomes probable and a reliable measurement of the profit share is available. Otherwise, recognition is deferred to a subsequent period pending satisfaction of such collectability and reliability requirements. In measuring the amount of profit share revenue to be recognized for each period, we use all available information and evidence, including any confirmations from the business partner of the profit share amount owed to us, to the extent made available before the date our Board of Directors authorizes the issuance of our financial statements for the applicable period.

*Milestone payments and out licensing arrangements*

Revenues include amounts derived from product out-licensing agreements. These arrangements typically consist of an initial up-front payment upon inception of the license and subsequent payments dependent on achieving certain milestones in accordance with the terms prescribed in the agreement. Non-refundable up-front license fees received in connection with product out-licensing agreements are deferred and recognized over the period in which we have continuing performance obligations. Milestone payments which are contingent on achieving certain clinical milestones are recognized as revenues either on achievement of such milestones, if the milestones are considered substantive, or over the period we have continuing performance obligations, if the milestones are not considered substantive. If milestone payments are creditable against future royalty payments, the milestones are deferred and released over the period in which the royalties are anticipated to be paid.

*Provision for chargeback, rebates and discounts*

In our U.S. Generics business, our gross revenues are significantly reduced by chargebacks, rebates, sales returns, discounts, shelf stock adjustments, Medicaid payments and similar gross-to-net adjustments. The estimates of gross-to-net adjustments for our operations in India and other countries outside of the U.S. relate mainly to sales return allowances in all such operations, and certain rebates to healthcare insurance providers are specific to our German operations. The pattern of such sales return allowances is generally consistent with our gross sales. In Germany, the rebates to healthcare insurance providers mentioned above are contractually fixed in nature and do not involve significant estimations by us.

*Chargebacks:* Chargebacks are issued to wholesalers for the difference between our invoice price to the wholesaler and the contract price through which the product is resold in the retail part of the supply chain. The information that we consider for establishing a chargeback accrual includes the historical average chargeback rate over a period of time, current contract prices with wholesalers and other customers, and

estimated inventory holding by the wholesaler. With this methodology, we believe that the results are more realistic and closest to the potential chargeback claims that may be received in the future period relating to inventory on which a claim is yet to be received as at the end of the reporting period. In addition, as part of our books closure process, a chargeback validation is performed in which we track and reconcile the volume of sold inventory for which we should carry an appropriate provision for chargeback. We procure the inventory holding statements and data through an electronic data interface with our wholesalers (representing approximately 90% of the total value of chargebacks outstanding at every reporting date) as part of this reconciliation. On the basis of this volume reconciliation, chargeback accrual is validated. For the chargeback rate computation, we consider different contract prices for each product across our customer base. This chargeback rate is adjusted (if necessary) on a periodic basis for expected future price reductions.

*Rebates:* Rebates (direct and indirect) are generally provided to customers as an incentive to stock and sell our products. Rebate amounts are based on a customer's purchases made during an applicable period. Rebates are paid to wholesalers, chain drug stores, health maintenance organizations or pharmacy buying groups under a contract with us. We determine our estimates of rebate accruals primarily based on the contracts entered into with our wholesalers

**Table of Contents**

and other direct customers and the information received from them for secondary sales made by them. For direct rebates, liability is accrued whenever we invoice to direct customers. For indirect rebates, the accruals are based on a representative weighted average percentage of the contracted rebate amount applied to inventory sold and delivered by us to wholesalers or other direct customers.

*Sales Return Allowances:* We account for sales returns by recording a provision based on our estimate of expected sales returns. We deal in various products and operate in various markets. Accordingly, our estimate of sales returns is determined primarily by our experience in these markets. In respect of established products, we determine an estimate of sales returns provision primarily based on historical experience of such sales returns. Additionally, other factors that we consider in determining the estimate include levels of inventory in the distribution channel, estimated shelf life, product discontinuances, price changes of competitive products, and introduction of competitive new products, to the extent each of these factors impact our business and markets. We consider all of these factors and adjust the sales return provision to reflect our actual experience. With respect to new products introduced by us, those have historically been either extensions of an existing product line where we have historical experience or in a general therapeutic category where established products exist and are sold either by us or our competitors.

We have not yet introduced products in a new therapeutic category where the sales returns experience of such products by us or our competitors (as we understand based on industry publications) is not known. The amount of sales returns for our newly launched products have not historically differed significantly from sales returns experience of the then current products marketed by us or our competitors (as we understand based on industry publications). Accordingly, we do not expect sales returns for new products to be significantly different from expected sales returns of current products. We evaluate sales returns of all our products at the end of each reporting period and record necessary adjustments, if any.

*Medicaid Payments:* We estimate the portion of our sales that may get dispensed to customers covered under Medicaid programs based on the proportion of units sold in the previous two quarters for which a Medicaid claim could be received as compared to the total number of units sold in the previous two quarters. The proportion is based on an analysis of the actual Medicaid claims received for the preceding four quarters. In addition, we also apply the same percentage on the derived estimated inventory sold and delivered by us to our wholesalers and other direct customers to arrive at the potential volume of products on which a Medicaid claim could be received. We use this approach because we believe that it corresponds to the approximate six month time period it takes for us to receive claims from the various Medicaid programs. After estimating the number of units on which a Medicaid claim is to be paid, we use the latest available Medicaid reimbursement rate per unit to calculate the Medicaid accrual. In the case of new products, accruals are done based on specific inputs from our marketing team or data from the publications of IMS Health.

*Shelf Stock Adjustments:* Shelf stock adjustments are credits issued to customers to reflect decreases in the selling price of products sold by us, and are accrued when the prices of certain products decline as a result of increased competition upon the expiration of limited competition or exclusivity periods. These credits are customary in the pharmaceutical industry, and are intended to reduce the customer inventory cost to better reflect the current market prices. The determination to grant a shelf stock adjustment to a customer is based on the terms of the applicable contract, which may or may not specifically limit the age of the stock on which a credit would be offered.



*Cash Discounts:* We offer cash discounts to our customers, generally at 2% of the gross sales price, as an incentive for paying within invoice terms, which generally range from 45 to 90 days. Accruals for such cash discounts do not involve any significant variables, and the estimates are based on the gross sales price and agreed cash discount percentage at the time of invoicing.

We believe our estimation processes are reasonable methods of determining accruals for the gross-to-net adjustments. Chargeback accrual accounts for the highest element among the gross-to-net adjustments, and constituted approximately 67% of such gross-to-net adjustments for our U.S. Generics business for the year ended March 31, 2014. For the purpose of the following discussion, we are therefore restricting our explanations to this specific element. While chargeback accruals depend on multiple variables, the most pertinent variables are our estimates of inventories on which a chargeback claim is yet to be received and the unit price at which the chargeback will be processed. To determine the chargeback accrual applicable for a reporting period, we perform the following procedures to calculate these two variables:

- a) *Estimated inventory* Inventory volumes on which a chargeback claim that is expected to be received in the future are determined using the validation process and methodology described above (see Chargebacks above). When such a validation process is performed, we note that the difference represents an immaterial variation. Therefore, we believe that our estimation process in regard to this variable is reasonable.

**Table of Contents**

- b) *Unit pricing rate* At any point in time, inventory volumes on which we carry our chargeback accrual represents up to 1.5 months of sales volumes. Therefore, the sensitivity of price changes on our chargeback accrual only relates to such volumes. Assuming that the chargebacks were processed within such period, we analyzed the impact of changes of prices for the periods beginning April 1, 2013, 2012 and 2011, respectively, and ended March 31, 2014, 2013 and 2012, respectively, on our estimated inventory levels computed based on the methodology described above (see Chargebacks above). We note that the impact on net sales on account of such price variation was negligible.

In view of this, we believe that the calculations are not subject to a level of uncertainty that warrants a probability-based approach. Accordingly, we believe that we have been reasonable in our estimates for future chargeback claims and that the amounts of reversals or adjustments made in the current period pertaining to the previous year's accruals are immaterial. Further, this data is not determinable except on occurrence of specific instances or events during a period, which warrant an adjustment to be made for such accruals.

A roll-forward for each major accrual for our U.S. Generics operations is presented below for our fiscal years ended March 31, 2012, 2013 and 2014, respectively:

Particulars	Chargebacks	Rebates	Medicaid	Sales Returns
	<i>(All values in U.S. \$ millions)</i>			
Beginning Balance: April 1, 2011	80	40	4	9
Current provisions relating to sales in current year	886	158	8	13
Provisions and adjustments relating to sales in prior years	*	4	0	0
Credits and payments**	(842)	(142)	(5)	(8)
Ending Balance: March 31, 2012	124	60	7	14
Beginning Balance: April 1, 2012	124	60	7	14
Current provisions relating to sales in current year	1,162	246	14	19
Provisions and adjustments relating to sales in prior years	*	1	1	
Credits and payments**	(1,119)	(194)	(10)	(13)
Ending Balance: March 31, 2013	167	113	12	20
Beginning Balance: April 1, 2013	167	113	12	20
Current provisions relating to sales in current year	1,029	355	17	24
Provisions and adjustments relating to sales in prior years	*	2	0	
Credits and payments**	(1,070)	(340)	(14)	(16)
Ending Balance: March 31, 2014	126	130	15	28

\* Currently, we do not separately track provisions and adjustments, in each case to the extent relating to prior years for chargebacks. However, the adjustments are expected to be non-material. The volumes used to calculate the closing balance of chargebacks represent an average of 1 to 1.5 months equivalent of sales, which corresponds to the pending chargeback claims yet to be processed.

\*\* Currently, we do not separately track the credits and payments, in each case to the extent relating to prior years for chargebacks, rebates, medicaid payments or sales returns.

*Services*

Revenue from services rendered, which primarily relate to contract research, is recognized in the consolidated income statement as the underlying services are performed. Upfront non-refundable payments received under these arrangements are deferred and recognized as revenue over the expected period over which the related services are expected to be performed.

*Export entitlements*

Export entitlements from government authorities are recognized in the consolidated income statement as a reduction from cost of revenues when the right to receive credit as per the terms of the scheme is established in respect of the exports made by us, and where there is no significant uncertainty regarding the ultimate collection of the relevant export proceeds.

## **Table of Contents**

### ***Shipping and handling costs***

Shipping and handling costs incurred to transport products to customers and internal transfer costs incurred to transport the products from our factories to various points of sale are included in selling, general and administrative expenses.

### ***Financial instruments***

#### **Non-derivative financial instruments**

Non-derivative financial instruments consist of investments in mutual funds, equity securities, trade and other receivables, cash and cash equivalents, loans and borrowings, trade and other payables and certain other assets and liabilities.

Non-derivative financial instruments are recognized initially at fair value plus any directly attributable transaction costs, except for those instruments that are designated as being fair value through profit and loss upon initial recognition. Subsequent to initial recognition, non-derivative financial instruments are measured as described below.

#### ***Cash and cash equivalents***

Cash and cash equivalents consist of cash on hand, demand deposits and short-term, highly liquid investments that are readily convertible into known amounts of cash and which are subject to insignificant risk of changes in value. For this purpose, short-term means investments having maturity of three months or less from the date of investment. Bank overdrafts that are repayable on demand and form an integral part of our cash management are included as a component of cash and cash equivalents for the purpose of the statement of cash flows.

#### ***Other investments***

Other investments consist of term deposits with original maturities of more than three months, mutual funds and equity securities.

Investments in mutual funds and equity securities are classified as available-for-sale financial assets. Subsequent to initial recognition, they are measured at fair value and changes therein, other than impairment losses, are recognized in other comprehensive income/(loss) and presented within equity. When an investment is derecognized, the cumulative gain or loss in equity is transferred to the consolidated income statement.

#### ***Trade payables***

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade payables are classified as current liabilities if payment is expected within one year or within the normal operating cycle of the business.

#### ***Trade receivables***

Trade receivables are amounts due from customers for merchandise sold or services performed in the ordinary course of business. Trade receivables are classified as current assets if the collection is expected within one year or within the normal operating cycle of the business.

*Debt instruments and other financial liabilities*

We initially recognize debt instruments issued on the date that they originate. All other financial liabilities are recognized initially on the trade date, which is the date we become a party to the contractual provisions of the instrument. These are recognized initially at fair value plus any directly attributable transaction costs. Subsequent to initial recognition, these financial liabilities are measured at amortized cost using the effective interest method.

*Others*

Other non-derivative financial instruments are measured at amortized cost using the effective interest method, less any impairment losses.

Derivative financial instruments

We are exposed to exchange rate risks which arise from our foreign exchange revenues, expenses and borrowings primarily in U.S. dollars, U.K. pounds sterling, Russian roubles and Euros, and foreign currency debt in U.S. dollars, Russian roubles and Euros.

## **Table of Contents**

We use derivative financial instruments, including forward exchange contracts, option contracts and currency swap contracts, to mitigate our risk of changes in foreign currency exchange rates and interest rates. We also use non-derivative financial instruments as part of our foreign currency exposure risk mitigation strategy.

### *Hedges of highly probable forecasted transactions*

We classify our derivative financial instruments that hedge foreign currency risk associated with highly probable forecasted transactions as cash flow hedges and measure them at fair value. The effective portion of such cash flow hedges is recorded in our hedging reserve, as a component of equity, and re-classified to the consolidated income statement as revenue in the period corresponding to the occurrence of the forecasted transactions. The ineffective portion of such cash flow hedges is recorded in the consolidated income statement as finance costs immediately.

We also designate certain non-derivative financial liabilities, such as foreign currency borrowings from banks, as hedging instruments for hedge of foreign currency risk associated with highly probable forecasted transactions. Accordingly, we apply cash flow hedge accounting to such relationships. Remeasurement gain/loss on such non-derivative financial liabilities is recorded in our hedging reserve, as a component of equity, and reclassified to the consolidated income statement as revenue in the period corresponding to the occurrence of the forecasted transactions.

Upon initial designation of a hedging instrument, we formally document the relationship between the hedging instrument and hedged item, including the risk management objectives and strategy in undertaking the hedge transaction and the hedged risk, together with the methods that will be used to assess the effectiveness of the hedging relationship. We make an assessment, both at the inception of the hedge relationship as well as on an ongoing basis, of whether the hedging instruments are expected to be highly effective in offsetting the changes in the fair value or cash flows of the respective hedged items attributable to the hedged risk, and whether the actual results of each hedge are within a range of 80%-125% relative to the gain or loss on the hedged items. For cash flow hedges to be highly effective, a forecast transaction that is the subject of the hedge must be highly probable and must present an exposure to variations in cash flows that could ultimately affect profit or loss.

If the hedging instrument no longer meets the criteria for hedge accounting, expires or is sold, terminated or exercised, then hedge accounting is discontinued prospectively. The cumulative gain or loss previously recognized in other comprehensive income/(loss), remains there until the forecast transaction occurs. If the forecast transaction is no longer expected to occur, then the balance in other comprehensive income/(loss) is recognized immediately in the consolidated income statement.

### *Hedges of recognized assets and liabilities*

Changes in the fair value of derivative financial instruments (such as forward contracts and option contracts) that economically hedge monetary assets and liabilities in foreign currencies, and for which no hedge accounting is applied, are recognized in the consolidated income statement. The changes in fair value of such derivative financial instruments, as well as the foreign exchange gains and losses relating to the monetary items, are recognized as part of net finance income/(expense) in the consolidated income statement.

### *Hedges of changes in the interest rates*

Consistent with our risk management policy, we use interest rate swaps to mitigate the risk of changes in interest rates. We do not use such instruments for trading or speculative purposes.

### *De-recognition of financial assets and liabilities*

We derecognize a financial asset when the contractual right to the cash flows from that asset expires, or we transfer the rights to receive the contractual cash flows on the financial asset in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred. If we retain substantially all the risks and rewards of ownership of a transferred financial asset, we continue to recognize the financial asset and also recognize a collateralized borrowing, at amortized cost, for the proceeds received.

We derecognize a financial liability when its contractual obligations are discharged, cancelled or expired. The difference between the carrying amount of the derecognized financial liability and the consideration paid is recognized as profit or loss.

*Offsetting financial assets and liabilities*

Financial assets and liabilities are offset and the net amount presented in the statement of financial position when, and only when, we have a legal right and ability to offset the amounts and intend either to settle on a net basis or to realize the asset and settle the liability simultaneously.

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**Table of Contents**

***Foreign currency***

***Functional currency***

The consolidated financial statements are presented in Indian rupees, which is the functional currency of our parent company, DRL. Functional currency of an entity is the currency of the primary economic environment in which the entity operates.

In respect of all non-Indian subsidiaries that operate as marketing arms of our parent company in their respective countries/regions, the functional currency has been determined to be the functional currency of our parent company (i.e., the Indian rupee). The operations of these subsidiaries are largely restricted to the import of finished goods from our parent company in India, sale of these products in the foreign country and remittance of the sale proceeds to our parent company. The cash flows realized from sale of goods are readily available for remittance to our parent company and cash is remitted to our parent company on a regular basis. The costs incurred by these subsidiaries are primarily the cost of goods imported from our parent company. The financing of these subsidiaries is done directly or indirectly by our parent company.

In respect of subsidiaries whose operations are self-contained and integrated within their respective countries/regions, the functional currency has been determined to be the local currency of those countries/regions.

***Foreign currency transactions and foreign operations***

Transactions in foreign currencies are translated to the respective functional currencies of entities within our company group at exchange rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies at the reporting date are retranslated to the functional currency at the exchange rate at that date. Exchange differences arising on the settlement of monetary items or on translating monetary items at rates different from those at which they were translated on initial recognition during the period or in previous financial statements are recognized in profit or loss in the period in which they arise.

Foreign exchange gains and losses arising from a monetary item receivable from a foreign operation, the settlement of which is neither planned nor likely in the foreseeable future, are considered to form part of the net investment in the foreign operation and are recognized in other comprehensive income/(loss) and presented within equity as a part of foreign currency translation reserve ( FCTR ).

In case of foreign operations whose functional currency is different from Indian rupees (our parent company's functional currency), the assets and liabilities of such foreign operations, including goodwill and fair value adjustments arising upon acquisition, are translated to the reporting currency at exchange rates at the reporting date. The income and expenses of such foreign operations are translated to the reporting currency at the monthly average exchange rates prevailing during the year. Resulting foreign currency differences are recognized in other comprehensive income/(loss) and presented within equity as part of FCTR. When a foreign operation is disposed of, in part or in full, the relevant amount in the FCTR is transferred to the consolidated income statement.

***Business combinations***

We use the acquisition method of accounting to account for any business combination that occurred on or after April 1, 2009. The acquisition date is the date on which control is transferred to the acquirer. Judgment is applied in determining the acquisition date and determining whether control is transferred from one party to another. Control exists when we are exposed to, or have rights to, variable returns from our involvement with the entity and have the



ability to affect, those returns through power over the entity. In assessing control, potential voting rights are considered only if the rights are substantive.

We measure goodwill as of the applicable acquisition date at the fair value of the consideration transferred, including the recognized amount of any non-controlling interest in the acquiree, less the net recognized amount of the identifiable assets acquired and liabilities assumed. When the fair value of the net identifiable assets acquired and liabilities assumed exceeds the consideration transferred, a bargain purchase gain is recognized immediately in the consolidated income statement. Consideration transferred includes the fair values of the assets transferred, liabilities incurred by us to the previous owners of the acquiree, and equity interests issued by us. Consideration transferred also includes the fair value of any contingent consideration. Consideration transferred does not include amounts related to settlement of pre-existing relationships. Any goodwill that arises on account of such business combination is tested annually for impairment. A contingent liability of the acquiree is assumed in a business combination only if such a liability represents a present obligation and arises from a past event, and its fair value can be measured reliably. On an acquisition-by-acquisition basis, we recognize any non-controlling interest in the acquiree either at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets. Transaction costs incurred by us in connection with a business combination, such as finder's fees, legal fees, due diligence fees and other professional and consulting fees, are expensed as incurred.

## **Table of Contents**

Acquisitions of non-controlling interests are accounted for as transactions with equity holders in their capacity as equity holders. The difference between any consideration paid and the relevant share acquired of the carrying value of net assets of the subsidiary is recorded in equity.

### ***Goodwill and other intangible assets***

#### ***Goodwill***

Goodwill represents the excess of consideration transferred, together with the amount of non-controlling interest in the acquiree, over the fair value of our share of identifiable net assets acquired.

Goodwill is measured at cost less accumulated impairment losses. In respect of equity accounted investees, the carrying amount of goodwill is included in the carrying amount of the investment, and any impairment loss on such an investment is not allocated to any asset, including goodwill, that forms part of the carrying value of the equity accounted investee.

#### ***Other intangible assets***

Other intangible assets that are acquired by us, which have finite useful lives, are measured at cost less accumulated amortization and accumulated impairment losses.

Subsequent expenditures are capitalized only when they increase the future economic benefits embodied in the specific asset to which they relate.

#### ***Research and development***

Expenditures on research activities undertaken with the prospect of gaining new scientific or technical knowledge and understanding are recognized in profit or loss when incurred.

Expenditures on development activities involving a plan or design for the production of new or substantially improved products and processes are capitalized only if:

development costs can be measured reliably;

the product or process is technically and commercially feasible;

future economic benefits are probable; and

we intend to and have sufficient resources to complete development and to use or sell the asset.

Our internal drug development expenditures are capitalized only if they meet the recognition criteria as mentioned above. Where regulatory and other uncertainties are such that the criteria are not met, the expenditures are recognized in profit or loss as incurred. This is almost invariably the case prior to approval of the drug by the relevant regulatory authority. However, where the recognition criteria are met, intangible assets are capitalized and amortized on a

straight-line basis over their useful economic lives from product launch. As of March 31, 2014, no internal drug development expenditure amounts have met the recognition criteria. The expenditures to be capitalized include the cost of materials and other costs directly attributable to preparing the asset for its intended use. Other development expenditures are recognized in profit or loss as incurred.

In conducting our research and development activities related to differentiated formulations and new chemical entities ( NCEs ), we seek to optimize our expenditures and to limit our risk exposures. Most of our current research and development projects related to differentiated formulations and NCEs are at an early discovery/development phase. These early development stage exploratory projects are numerous and are characterized by uncertainty with respect to timing and cost of completion. At such time as a research and development project related to a differentiated formulation or NCE progresses into the more costly clinical study phases, where the costs can be tracked separately, such project is considered to be significant if:

- a) it is expected to account for more than 10% of our total research and development costs; and
- b) the costs and efforts to develop the project can be reasonably estimated and the product resulting from the project has a high probability of launch.

Historically, none of our development projects have met the significance thresholds listed above.

A substantial portion of our current research and development activities relates to the development of bio-equivalent products, which do not require full scale clinical trials to be conducted prior to the filing by us of applications with regulatory authorities to allow the marketing and sale of such products. Our total research and development costs for the year ended March 31, 2014 were Rs.12,402 million, which was approximately 9% of our total revenue for the year. The amounts spent on research and development related to our bio-equivalent products for the years ended March 31, 2014, 2013 and 2012 represented approximately 62%, 60% and 71%, respectively, of our total research and development expenditures.

## **Table of Contents**

For each of our bio-equivalent generic product research and development projects, the timing and cost of completion varies depending on numerous factors, including, among others: the intellectual property patented by the innovator for the applicable product; the patent regimes of the countries in which we seek to market the product; our development strategy for such product; the complexity of the molecule for such product; and the time required to address any development challenges that arise during the development process. For any particular bio-equivalent generic product, these factors and other product launch requirements may vary across the numerous geographies in which we seek to market the product. In addition, bio-equivalent research and development projects often may relate to a number of different therapeutic areas. At any particular point of time, we tend to have a very high number of bio-equivalent generic product research and development projects ongoing simultaneously, in various developmental stages, with the exact number of such active projects changing regularly. As a result, we believe it would be impractical for us to state the exact number of ongoing projects and the estimated timing or cost to complete such projects.

Payments to third parties that generally take the form of up-front payments and milestones for in-licensed products, compounds and intellectual property are capitalized. Our criteria for capitalization of such assets are consistent with the guidance given in paragraph 25 of International Accounting Standard 38 ( IAS 38 ) (i.e., receipt of economic benefits out of the separately purchased transaction is considered to be probable).

Intangible assets relating to products in development, other intangible assets not available for use and intangible assets having indefinite useful life are subject to impairment testing at each reporting date. All other intangible assets are tested for impairment when there are indications that the carrying value may not be recoverable. All impairment losses are recognized immediately in the consolidated income statement.

### *Amortization*

Amortization is recognized in the consolidated income statement on a straight-line basis over the estimated useful lives of intangible assets or on any other basis that reflects the pattern in which the asset's future economic benefits are expected to be consumed by the entity. Intangible assets that are not available for use are amortized from the date they are available for use.

### ***Impairment***

#### *Financial assets*

A financial asset is assessed at each reporting date to determine whether there is any objective evidence that it is impaired. A financial asset is considered to be impaired if objective evidence indicates that one or more events have had a negative effect on the estimated future cash flows of that asset.

An impairment loss in respect of a financial asset measured at amortized cost is calculated as the difference between its carrying amount, and the present value of the estimated future cash flows discounted at the original effective interest rate. An impairment loss in respect of an available-for-sale financial asset is calculated by reference to its fair value.

Significant financial assets are tested for impairment on an individual basis.

All impairment losses are recognized in the consolidated income statement. When the fair value of available-for-sale financial assets declines below acquisition cost and there is objective evidence that the asset is impaired, the cumulative loss that has been recognized in other comprehensive income is transferred to the statement of income. An impairment loss may be reversed in subsequent periods, if the indicators for the impairment no longer exist. Such

reversals are recognized in other comprehensive income.

*Non-financial assets*

The carrying amounts of our non-financial assets, other than inventories and deferred tax assets, are reviewed at each reporting date to determine whether there is any indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated. For goodwill and intangible assets that have indefinite lives or that are not yet available for use, an impairment test is performed each year at March 31.

The recoverable amount of an asset or cash-generating unit (as defined below) is the greater of its value in use and its fair value less costs to sell. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset or the cash-generating unit. For the purpose of impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of the cash inflows of other assets or groups of assets (the cash-generating unit).

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**Table of Contents**

The goodwill acquired in a business combination is, for the purpose of impairment testing, allocated to cash-generating units that are expected to benefit from the synergies of the combination.

An impairment loss is recognized if the carrying amount of an asset or its cash-generating unit exceeds its estimated recoverable amount. Impairment losses are recognized in the consolidated income statement. Impairment losses recognized in respect of cash-generating units are allocated first to reduce the carrying amount of any goodwill allocated to the units and then to reduce the carrying amount of the other assets in the unit on a pro-rata basis.

An impairment loss in respect of goodwill is not reversed. In respect of other assets, impairment losses recognized in prior periods are assessed at each reporting date for any indications that the loss has decreased or no longer exists. An impairment loss is reversed if there has been a change in the estimates used to determine the recoverable amount. An impairment loss is reversed only to the extent that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortization, if no impairment loss had been recognized. Goodwill that forms part of the carrying amount of an investment in an associate is not recognized separately, and therefore is not tested for impairment separately. Instead, the entire amount of the investment in an associate is tested for impairment as a single asset when there is objective evidence that the investment in an associate may be impaired.

***Income tax***

Income tax expense consists of current and deferred tax. Income tax expense is recognized in profit or loss except to the extent that it relates to items recognized directly in equity, in which case it is recognized in equity. Current tax is the expected tax payable on the taxable income for the year, using tax rates enacted or substantively enacted at the reporting date, and any adjustment to tax payable in respect of previous years.

Deferred tax is recognized using the balance sheet method, providing for temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognized for the following temporary differences: the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit; differences relating to investments in subsidiaries and jointly controlled entities to the extent that it is probable that they will not reverse in the foreseeable future; and taxable temporary differences arising upon the initial recognition of goodwill. Deferred tax is measured at the tax rates that are expected to be applied to the temporary differences when they reverse, based on the laws that have been enacted or substantively enacted by the reporting date. Deferred tax assets and liabilities are offset if there is a legally enforceable right to offset current tax liabilities and assets, and they relate to income taxes levied by the same tax authority on the same taxable entity, or on different tax entities, but they intend to settle current tax liabilities and assets on a net basis or their tax assets and liabilities will be realized simultaneously.

A deferred tax asset is recognized to the extent that it is probable that future taxable profits will be available against which the temporary difference can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

Any deferred tax asset or liability arising from deductible or taxable temporary differences in respect of unrealized inter-company profit or loss on inventories held by us in different tax jurisdictions is recognized using the tax rate of the jurisdiction in which such inventories are held. Withholding tax arising out of payment of dividends to shareholders under the Indian Income tax regulations is not considered as tax expense for us and all such taxes are recognized in the statement of changes in equity as part of the associated dividend payment.

***Inventories***

Inventories consist of raw materials, stores and spares, work in progress and finished goods, and are measured at the lower of cost and net realizable value. The cost of all categories of inventories is based on the weighted average method. Stores and spares consists of packing materials, engineering spares (such as machinery spare parts) and consumables (such as lubricants, cotton waste and oils) that are used in operating machines or consumed as indirect materials in the manufacturing process. Cost includes expenditures incurred in acquiring the inventories, production or conversion costs and other costs incurred in bringing them to their existing location and condition. In the case of finished goods and work in progress, cost includes an appropriate share of overheads based on normal operating capacity.

Net realizable value is the estimated selling price in the ordinary course of business, less the estimated costs of completion and selling expenses.

## **Table of Contents**

The factors that we consider in determining the allowance for slow moving, obsolete and other non-saleable inventory includes estimated shelf life, planned product discontinuances, price changes, aging of inventory and introduction of competitive new products, to the extent each of these factors impact our business and markets. We consider all these factors and adjust the inventory provision to reflect our actual experience on a periodic basis.

### ***Litigations***

We are involved in disputes, lawsuits, claims, governmental and/or regulatory inspections, inquiries, investigations and proceedings, including patent and commercial matters that arise from time to time in the ordinary course of business. Most of the claims involve complex issues. We assess the need to make a provision for a liability for such claims and record a provision when we determine that a loss related to a matter is both probable and reasonably estimable.

Because litigation and other contingencies are inherently unpredictable, our assessment can involve judgments about future events. Often, these issues are subject to uncertainties and therefore the probability of a loss, if any, being sustained and an estimate of the amount of any loss are difficult to ascertain. This is due to a number of factors, including: the stage of the proceedings (in many cases trial dates have not been set) and the overall length and extent of pre-trial discovery; the entitlement of the parties to an action to appeal a decision; clarity as to theories of liability; damages and governing law; uncertainties in timing of litigation; and the possible need for further legal proceedings to establish the appropriate amount of damages, if any. We also believe that disclosure of the amount of damages sought by plaintiffs, if that is known, would not be meaningful with respect to those legal proceedings.

Consequently, for a majority of these claims, it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. In these cases, we disclose information with respect to the nature and facts of the case.

### ***Other provisions***

We recognize a provision if, as a result of a past event, we have a present legal or constructive obligation that can be estimated reliably, and it is probable (i.e., more likely than not) that an outflow of economic benefits will be required to settle the obligation. If the effect of the time value of money is material, provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. Where discounting is used, the increase in the provision due to the passage of time is recognized as a finance cost.

### ***Restructuring***

A provision for restructuring is recognized when we have approved a detailed and formal restructuring plan, and the restructuring either has commenced or has been announced publicly. Future operating costs are not provided.

### ***Onerous contracts***

A provision for onerous contracts is recognized when the expected benefits to be derived by us from a contract are lower than the unavoidable cost of meeting its obligations under the contract. The provision is measured at the present value of the lower of the expected cost of terminating the contract and the expected net cost of continuing with the contract. Before a provision is established, we recognize any impairment loss on the assets associated with that contract.



*Reimbursement rights*

Expected reimbursements for expenditures required to settle a provision are recognized only when receipt of such reimbursements is virtually certain. Such reimbursements are recognized as a separate asset in the statement of financial position, with a corresponding credit to the specific expense for which the provision has been made.

**Table of Contents****5.A. Operating results**

The following table sets forth, for the periods indicated, our consolidated revenues by segment:

	For the Year Ended March 31,					
	2012		2013		2014	
			(Rs. in millions)			
	Revenues	Revenues (Segment % of Total)	Revenues	Revenues (Segment % of Total)	Revenues	Revenues (Segment % of Total)
Global Generics	Rs. 70,243	72%	Rs. 82,563	71%	Rs. 105,164	80%
Pharmaceutical Services and Active Ingredients	23,812	25%	30,702	26%	23,974	18%
Proprietary Products	1,078	1%	1,468	1%	1,778	1%
Others	1,604	2%	1,533	2%	1,254	1%
<b>Total</b>	<b>Rs. 96,737</b>	<b>100%</b>	<b>Rs. 116,266</b>	<b>100%</b>	<b>Rs. 132,170</b>	<b>100%</b>

The following table sets forth, for the periods indicated, our gross profits by segment:

	For the Year Ended March 31,					
	2012		2013		2014	
			(Rs. in millions)			
	Gross Profit	Gross Profit (% of Segment Revenue)	Gross Profit	Gross Profit (% of Segment Revenue)	Gross Profit	Gross Profit (% of Segment Revenue)
Global Generics	Rs. 44,263	63%	Rs. 48,721	59%	Rs. 69,148	66%
Pharmaceutical Services and Active Ingredients	7,508	32%	9,970	32%	4,848	20%
Proprietary Products	903	84%	1,324	90%	1,606	90%
Others	631	39%	564	37%	199	16%
<b>Total</b>	<b>Rs. 53,305</b>	<b>55%</b>	<b>Rs. 60,579</b>	<b>52%</b>	<b>Rs. 75,801</b>	<b>57%</b>

The following table sets forth, for the periods indicated, financial data as percentages of total revenues and the increase (or decrease) by item as a percentage of the amount over the comparable period in the previous years.

	Percentage of Sales				
	For the Year Ended March 31,			Percentage Increase/(Decrease)	
	2012	2013	2014	2012 to 2013	2013 to 2014
Revenues	100.0%	100.0%	100.0%	20%	14%

<b>Gross profit</b>	<b>55.1%</b>	<b>52.1%</b>	<b>57.4%</b>	<b>14%</b>	<b>25%</b>
Selling, general, and administrative expenses	30.9%	29.5%	29.3%	15%	13%
Research and development expenses	6.1%	6.6%	9.4%	30%	62%
Other (income)/expense, net	(0.8%)	(2.1%)	(1.1%)	224%	(43%)
<b>Results from operating activities</b>	<b>18.9%</b>	<b>18.2%</b>	<b>19.8%</b>	<b>16%</b>	<b>23%</b>
Finance (expense)/income, net	0.2%	0.4%	0.3%	187%	(13%)
<b>Profit before income taxes</b>	<b>19.1%</b>	<b>18.6%</b>	<b>20.1%</b>	<b>17%</b>	<b>23%</b>
Income tax expense, net	(4.3%)	(4.2%)	(3.9%)	17%	4%
<b>Profit for the period</b>	<b>14.7%</b>	<b>14.4%</b>	<b>16.3%</b>	<b>18%</b>	<b>28%</b>

**Fiscal Year Ended March 31, 2014 compared to Fiscal Year Ended March 31, 2013**

## Revenues

Our overall consolidated revenues were Rs.132,170 million for the year ended March 31, 2014, an increase of 14% as compared to Rs.116,266 million for the year ended March 31, 2013. Revenue growth for the year ended March 31, 2014 was largely driven by our Global Generics segment's operations in the United States and our Emerging Markets (which is comprised of Russia, other countries of the former Soviet Union, and certain other countries from our Rest of the World markets, primarily South Africa, Venezuela and Australia).

**Table of Contents**

The following table sets forth, for the periods indicated, our consolidated revenues by geography:

	For the Year Ended March 31,					
	2012	% of Total	2013	% of Total	2014	% of Total
	Revenues	Revenue*	Revenues	Revenue*	Revenues	Revenue*
	(Rs. in millions)					
<b>Global Generics</b>	<b>Rs. 70,243</b>	<b>72%</b>	<b>Rs. 82,563</b>	<b>71%</b>	<b>Rs. 105,164</b>	<b>80%</b>
North America (the United States and Canada)	31,889	45%	37,846	46%	55,303	53%
Europe	8,259	12%	7,716	9%	6,970	6%
India	12,931	18%	14,560	18%	15,713	15%
Russia and other countries of the former Soviet Union	13,260	19%	16,908	20%	19,819	19%
Rest of the World	3,904	6%	5,533	7%	7,359	7%
<b>Pharmaceutical Services and Active Ingredients</b>	<b>Rs. 23,812</b>	<b>25%</b>	<b>Rs. 30,702</b>	<b>26%</b>	<b>Rs. 23,974</b>	<b>18%</b>
North America (the United States and Canada)	4,272	18%	5,744	19%	3,820	16%
Europe	8,424	35%	12,007	39%	9,058	38%
India	3,586	15%	4,638	15%	3,787	16%
Rest of the World	7,531	32%	8,313	27%	7,309	30%
<b>Proprietary Products and Others</b>	<b>Rs. 2,682</b>	<b>3%</b>	<b>Rs. 3,001</b>	<b>3%</b>	<b>Rs. 3,032</b>	<b>2%</b>
<b>Total</b>	<b>Rs. 96,737</b>	<b>100%</b>	<b>Rs. 116,266</b>	<b>100%</b>	<b>Rs. 132,170</b>	<b>100%</b>

\* The percentage of geography revenue to total represents the respective geography's revenue to the total segment's revenue.

During the year ended March 31, 2014, the Indian rupee depreciated by approximately 10%, 14%, and 4% against the U.S. dollar, the Euro and the Russian rouble, respectively, as compared to the year ended March 31, 2013. This change in the exchange rates resulted in higher reported revenues because of the increase in Indian rupee realization from sales in U.S. dollars, Euros and Russian roubles. However, our higher realization for the U.S. dollar was partially offset by net losses incurred on cash flow hedges undertaken by us to hedge the foreign currency risk associated with highly probable forecasted sales transactions. Accordingly, on a net basis, our realizations of U.S. dollar denominated revenues reported in Indian rupees were higher by 15% during the year ended March 31, 2014, as compared to our revenues during the year ended March 31, 2013 adjusted for losses on such cash flow hedges, on account of depreciation of the Indian rupee.

Our provision for sales returns as at March 31, 2014 was Rs.2,504 million, as compared to a provision of Rs.1,904 million as at March 31, 2013. This increase in our provision was primarily due to higher sales recorded during the year ended March 31, 2014. Consistent with our accounting policy for creating provisions for sales returns (discussed in Note 3(1) of our consolidated financial statements), we periodically assess the adequacy of our allowance for sales returns based on the criteria discussed in our Critical Accounting Policies, as well as sales returns actually processed during the year. For further information regarding our sales return provisions, see Notes 3(1) and 21 to our consolidated financial statements.

## **Segment analysis**

### ***Global Generics***

Revenues from our Global Generics segment were Rs.105,164 million for the year ended March 31, 2014, an increase of 27% as compared to Rs.82,563 million for the year ended March 31, 2013. North America (the United States and Canada), India and our Emerging Markets (which is comprised of Russia, other countries of the former Soviet Union, and certain other countries from our Rest of the World markets, primarily South Africa, Venezuela and Australia), contributed approximately 93% of the revenues of this segment for the year ended March 31, 2014.

After taking into account the favorable impact of depreciation of the Indian rupee against multiple currencies in the markets in which we operate, the foregoing increase in revenues of this segment was attributable to the following factors:

an increase of approximately 20% resulting from the introduction of new products during the year ended March 31, 2014;

an increase of approximately 3% resulting from the net impact of increases in sales prices of products; and

an increase of approximately 4% resulting from increased sales volumes of existing products;

**Table of Contents**

**North America (the United States and Canada):** Our Global Generics segment's revenues from North America (the United States and Canada) for the year ended March 31, 2014 were Rs.55,303 million, an increase of 46% as compared to our revenues of Rs.37,846 million for the year ended March 31, 2013. In U.S. dollar absolute currency terms (i.e., U.S. dollars without taking into account the effect of currency exchange rates), this segment's revenues from such geography grew by 25% in the year ended March 31, 2014 as compared to the year ended March 31, 2013. This growth was largely attributable to the following:

Revenues from 9 new products launched in the year ended March 31, 2014. The following table sets forth, for the year ended March 31, 2014, products that we launched in the United States:

<b>Product</b>	<b>Innovator's Brand</b>	<b>Innovator</b>
Zoledronic acid (5mg/100ml)	Reclast®	Novartis AG
Lamotrigine Extended Release	Lamictal® XR	GlaxoSmithKline
Azacitidine	Vidaza®	Celgene Corporation
Divalproex Extended Release	Depakote® ER	GlaxoSmithKline
Donepezil 23 mg	Aricept® 23 mg	Eisai Inc.
Decitabine	Dacogen®	Eisai Inc.
Amlodipine besylate and atorvastatin calcium	Caduet®	Pfizer Inc.
Sumatriptan Auto Injector	Imitrex STATdose Pen®	Pfizer Inc.
Moxifloxacin	Avelox®	Bayer AG

Market share expansion in our existing key products, such as metoprolol succinate and atorvastatin. During the year ended March 31, 2014, we made 13 U.S. filings, which includes one NDA filing under section 505(b)(2) and 12 ANDA filings, bringing our cumulative ANDA filings to 209. We now have 62 ANDAs pending approval at the U.S. FDA, out of which 39 are Paragraph IV filings and we believe 9 to have first to file status. We have also received a tentative approval for one of our NDAs filed under section 505(b)(2).

A significant portion of our Global Generics segment's revenue growth in North America (the United States and Canada) during the year ended March 31, 2014 was on account of sales from launches of new products. However, revenues from the launch of new products in North America (the United States and Canada) by this segment were significantly high during the year ended March 31, 2014, and may not contribute towards revenue growth as significantly during the year ending March 31, 2015. Nonetheless, we are optimistic about garnering additional market shares in some of our existing products during the year ending March 31, 2015.

**India:** Our revenues from India in the year ended March 31, 2014 were Rs.15,713 million, an increase of 8% as compared to the year ended March 31, 2013. During the year ended March 31, 2014, the Government of India released drug price notifications for a majority of the 348 products listed in the National List of Essential Medicines that are subject to price controls under the Drugs (Price Control) Order, 2013. The reduced prices from these price controls adversely impacted the revenues from our India business by approximately 3% (the annualized impact is approximately 4%) for the year ended March 31, 2014.

Despite the adverse impact of the aforesaid reduction in prices, growth was largely driven by an increase in sales volumes across our key brands, as well as revenues from 11 new products launched during the year ended March 31,

2014. According to IMS Health, as per its moving annual total report for the 12 months ended March 31, 2014, our sales value grew by 12.2%. In comparison, the Indian pharmaceutical market grew by 9.9% during such period.

Bio-similar products are one of the key contributors to our revenues from India, and represented approximately 7% of our revenues from India during the year ended March 31, 2014.

***Emerging Markets:*** Our revenues from our Emerging Markets (which is comprised of Russia, other countries of the former Soviet Union, and certain other countries from our Rest of the World markets, primarily South Africa, Venezuela and Australia), for the year ended March 31, 2014 were Rs.27,178 million, an increase of 21% over the year ended March 31, 2013. The reasons for this growth are set forth below in the separate discussions of these geographies.

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**Table of Contents**

**Russia:** Our revenues from Russia for the year ended March 31, 2014 were Rs.16,333 million, an increase of 16% over the year ended March 31, 2013. In Russian rouble absolute currency terms (i.e., Russian roubles without taking into account the effect of currency exchange rates), such revenues grew by 11% in the year ended March 31, 2014 as compared to the year ended March 31, 2013. The growth was largely driven by an increase in sales across our key brands (such as Nise, Omez, Ketorol, Senade and Cetrine) as well as new product launches. According to IMS Health, as per its moving annual total report for the 12 months ended March 31, 2014, our sales value and volume growths for the year ended March 31, 2014 were 7.7% and 4.1%, respectively, as compared to the Russian pharmaceutical market value growth and volume decrease of 1.9% and 5.0%, respectively. During the same period, our volume market share increased from 1.64% to 1.80%, according to IMS Health. Our sales of OTC products have grown significantly, and accounted for 34% of the total sales made by us in Russia during the year ended March 31, 2014. We intend to further increase our OTC sales by various branding and other marketing initiatives. According to IMS Health, in the year ended March 31, 2014, we have improved our rank by five positions in the OTC segment as compared to the year ended March 31, 2013. As per IMS Health's moving annual total report for the 12 months ended March 31, 2014, our OTC sales value and volume growths in Russia for the year ended March 31, 2014 were 18.8% and 16.8%, respectively, as compared to the Russian OTC pharmaceutical market value growth and volume decrease of 1.4% and 6.0%, respectively.

**Other countries of the former Soviet Union:** Our revenues from other countries of the former Soviet Union for the year ended March 31, 2014 were Rs.3,486 million, an increase of 22% over the year ended March 31, 2013. This growth was largely led by increased revenues resulting from higher prices from sales in Ukraine and increased sales volumes from sales in Uzbekistan, Belarus and Kazakhstan. This growth also benefitted from the depreciation of the Indian rupee against the U.S. dollar and the Ukrainian hryvnia.

**Rest of the World Markets:** We refer to all markets of this segment other than North America, Europe, Russia and other countries of the former Soviet Union and India as our Rest of the World markets. Our revenues from our Rest of the World markets were Rs.7,359 million in the year ended March 31, 2014, an increase of 33% as compared to the year ended March 31, 2013. The growth was largely led by increased revenues resulting from higher prices and increased sales volumes from South Africa and Venezuela, and was partially offset by the impact of devaluation of the Venezuelan bolivar.

**Pharmaceutical Services and Active Ingredients ( PSAI )**

Our Pharmaceutical Services and Active Ingredients ( PSAI ) segment's revenues for the year ended March 31, 2014 were Rs.23,974 million, a decrease of 22% as compared to the year ended March 31, 2013. After taking into account the favorable impact of depreciation of the Indian rupee against multiple currencies in the markets in which we operate, such decrease was largely attributable to:

decreased sales of active pharmaceutical ingredients, as some of our key customers lost market share during the year, coupled with lower sales from launch molecules (i.e., API sales to customers to support their generic product launches related to impending patent expirations) to our customers in the year ended March 31, 2014, which decreased our PSAI segment's revenues by 16%; and

decreased customer orders in our pharmaceutical development services for certain products provided to innovator companies which decreased our PSAI segment's revenues by 6%.



In the year ended March 31, 2014, our PSAI segment filed 61 Drug Master Files ( DMFs ) worldwide, of which 12 were filed in the United States, 13 were filed in Europe and 36 were filed in other countries. Cumulatively, our total DMFs filed worldwide as of March 31, 2014 were 631, including 196 DMFs filed in the United States.

### **Gross Profit**

Our total gross profit was Rs.75,801 million in the year ended March 31, 2014, representing 57.4% of our total revenues for this period, as compared to Rs.60,579 million in the year ended March 31, 2013, representing 52.1% of our total revenues for this period.

**Table of Contents**

The following table sets forth, for the periods indicated, our gross profit by segment:

	For the Year Ended March 31,					
	2012	% of	2013	% of	2014	% of
	Gross Profit	Segment Revenue	Gross Profit	Segment Revenue	Gross Profit	Segment Revenue
	(Rs. in millions)					
Global Generics	Rs. 44,263	63.0%	Rs. 48,721	59.0%	Rs. 69,148	65.8%
Pharmaceutical Services and Active Ingredients	7,508	31.5%	9,970	32.5%	4,848	20.2%
Proprietary Products	903	83.7%	1,324	90.2%	1,606	90.3%
Others	631	39.3%	564	36.8%	199	15.8%
<b>Total</b>	<b>Rs. 53,305</b>	<b>55.1%</b>	<b>Rs. 60,579</b>	<b>52.1%</b>	<b>Rs. 75,801</b>	<b>57.4%</b>

After taking into account the favorable impact of depreciation of the Indian rupee against multiple currencies in the markets in which we operate, the gross profits from our Global Generics segment increased from 59.0% in the year ended March 31, 2013 to 65.8% in the year ended March 31, 2014, on account of:

the favorable impact of changes in our existing business mix (i.e., an increase in the proportion of sales of higher gross margin products and a decrease in the proportion of sales of lower gross margin products) primarily attributable to an increased proportion of sales from new product launches with better margins; and

higher price realizations from existing products, primarily due to the favorable impact of the depreciation of the Indian rupee against the U.S. Dollar.

The gross profits from our PSAI segment decreased from 32.5% during the year ended March 31, 2013 to 20.2% during the year ended March 31, 2014, due to the following:

the unfavorable impact of changes in our existing business mix (i.e., a decrease in the proportion of sales of higher gross margin products and an increase in the proportion of sales of lower gross margin products) primarily on account of lower sales from launch molecules (i.e., API sales to customers to support their generic product launches related to impending patent expirations) to our customers during the year; and

increased pricing pressures on key products.

**Selling, general and administrative expenses**

Our selling, general and administrative expenses for the year ended March 31, 2014 were Rs.38,783 million, an increase of 13% as compared to Rs.34,272 million for the year ended March 31, 2013. After taking into account the unfavorable impact of depreciation of the Indian rupee against multiple currencies in the markets in which we operate,

this increase was largely attributable to the following:

increased personnel costs, due to annual raises and new recruitments, which increased our selling, general and administrative expenses by 5.2%;

increased sales and marketing costs, due to expenditures towards select brand building activities in Emerging Markets (which is comprised of Russia, other countries of the former Soviet Union, and certain other countries from our Rest of the World markets, primarily South Africa, Venezuela and Australia), which increased our selling, general and administrative expenses by 4.8%; and

increased legal and professional services cost, which increased our selling, general and administrative expenses by 2.0%.

As a proportion of our total revenues, our selling, general and administrative expenses have marginally decreased from 29.5% during the year ended March 31, 2013 to 29.3% during the year ended March 31, 2014.

#### **Research and development expenses**

Our research and development expenses in the year ended March 31, 2014 were Rs.12,402 million, an increase of 62% as compared to Rs.7,674 million in the year ended March 31, 2013. This increase was in accordance with our strategy to expand our research and development efforts in complex formulations, differentiated formulations and biosimilar compounds. Our research and development expenditures accounted for 9.4% of our total revenues in the year ended March 31, 2014, as compared to 6.6% in the year ended March 31, 2013. Approximately 62% of our research and development expenses during the year ended March 31, 2014 were spent towards the development of bio-equivalent products and the other 38% was dedicated to innovative and bio-pharmaceutical research.

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**Table of Contents**

**Reversal of impairment losses**

Consequent to the increase in expected cash flows of some of the products forming part of the product related intangibles pertaining to our Global Generics segment, we estimated the recoverable amount of such intangible assets and assessed that the impairment loss recorded in an earlier period should be reversed. Accordingly, a reversal of impairment loss of Rs.497 million for such product related intangibles was recorded for the year ended March 31, 2014 under Selling, general and administrative expenses in the consolidated income statement. The expected cash flows increased primarily due to various market dynamics, such as reduced competition and favorable pricing position.

**Other income, net**

Our net other income was Rs.1,416 million for the year ended March 31, 2014, as compared to a net other income of Rs.2,479 million for the year ended March 31, 2013. The decrease in net other income by Rs.1,063 million was largely attributable to the following:

during March 2013, we entered into an agreement with Nordion Inc. (formerly known as MDS Inc.) to settle our ongoing litigation for alleged breach of service obligations by Nordion Inc. during the years 2000 to 2004. As part of the settlement, we received a one-time settlement amount of Rs.1,220 million (U.S.\$22.5 million) from Nordion Inc., out of which Rs.108 million (U.S.\$2 million) was towards reimbursement of research and development cost and was recorded as reduction in such cost. The balance of Rs.1,112 million (U.S.\$20.5 million) was compensation for lost profits and was recorded as part of other income; and

other income for the year ended March 31, 2014 includes Rs.415 million (CAD6.75 million) from the resolution of litigation associated with the sale of one of our generic products in North America.

**Finance income, net**

Our net finance income was Rs.400 million for the year ended March 31, 2014, as compared to net finance income of Rs.460 million for the year ended March 31, 2013. The decrease in net finance income by Rs.60 million was largely attributable to an increase in our net interest expense, which was Rs.189 million for the year ended March 31, 2014 as compared to Rs.118 million for the year ended March 31, 2013.

**Profit before income taxes**

As a result of the above, profit before income taxes was Rs.26,606 million for the year ended March 31, 2014, an increase of 23% as compared to Rs.21,676 million for the year ended March 31, 2013.

**Income tax expense**

Our consolidated weighted average tax rates for the years ended March 31, 2014 and 2013 were 19.1% and 22.6%, respectively. Income tax expense was Rs.5,094 million for the year ended March 31, 2014, as compared to income tax expense of Rs.4,900 million for the year ended March 31, 2013. The decrease in effective tax rate by 3.5% for the year ended March 31, 2014 was primarily attributable to the following:

a decrease in the effective tax rate by approximately 3.2% as a result of a favorable order from the Income Tax Appellate Tribunal, Hyderabad over a previously litigated tax matter;

a decrease in the effective tax rate by approximately 0.9% on account of impairment losses and reversal of impairment losses; and

a decrease in the effective tax rate by approximately 1.6% due to increased research and development expenditures which were eligible for weighted tax deduction. This decrease was largely offset by an increase in the effective tax rate on account of unrecognized deferred tax assets, primarily pertaining to OctoPlus N.V., Dr. Reddy's Laboratories New York, Inc. and Dr. Reddy's Srl.

**Profit for the period**

As a result of the above, our net result was a net profit of Rs.21,512 million in the year ended March 31, 2014, as compared to a net profit of Rs.16,776 million in the year ended March 31, 2013.

**Table of Contents****Fiscal Year Ended March 31, 2013 Compared to Fiscal Year Ended March 31, 2012****Revenues**

Our overall consolidated revenues were Rs.116,266 million for the year ended March 31, 2013, an increase of 20% as compared to Rs.96,737 million for the year ended March 31, 2012. Our revenues for the year ended March 31, 2012 included a profit share pursuant to our agreement with Teva Pharmaceutical Industries Ltd. of Rs.4,500 million, attributable to sales of olanzapine 20 mg tablets in the United States with a 180 days marketing exclusivity. Excluding this impact, revenues increased by 26% for the year ended March 31, 2013 as compared to the year ended March 31, 2012. Revenue growth for the year ended March 31, 2013 was largely driven by our Global Generics segment's operations in the United States, India and our Emerging Markets (which is comprised of Russia, other countries of the former Soviet Union, and certain other countries from our Rest of the World markets, primarily South Africa, Venezuela and Australia), as well as our Pharmaceutical Services and Active Ingredients segment's operations.

The following table sets forth, for the periods indicated, our consolidated revenues by geography:

	For the Year Ended March 31,					
	2011 Revenues	% of Total Revenue*	2012 Revenues (Rs. in millions)	% of Total Revenue*	2013 Revenues	% of Total Revenue*
<b>Global Generics</b>	<b>Rs. 53,340</b>	<b>71%</b>	<b>Rs. 70,243</b>	<b>72%</b>	<b>Rs. 82,563</b>	<b>71%</b>
North America (the United States and Canada)	18,996	36%	31,889	45%	37,846	46%
Europe	8,431	16%	8,259	12%	7,716	9%
India	11,690	22%	12,931	18%	14,560	18%
Russia and other countries of the former Soviet Union	10,858	20%	13,260	19%	16,908	20%
Rest of the World	3,365	6%	3,904	6%	5,533	7%
<b>Pharmaceutical Services and Active Ingredients</b>	<b>Rs. 19,648</b>	<b>26%</b>	<b>Rs. 23,812</b>	<b>25%</b>	<b>Rs. 30,702</b>	<b>26%</b>
North America (the United States and Canada)	3,170	16%	4,272	18%	5,744	19%
Europe	7,020	36%	8,424	35%	12,007	39%
India	2,619	13%	3,586	15%	4,638	15%
Rest of the World	6,838	35%	7,531	32%	8,313	27%
<b>Proprietary Products and Others</b>	<b>Rs. 1,705</b>	<b>3%</b>	<b>Rs. 2,682</b>	<b>3%</b>	<b>Rs. 3,001</b>	<b>3%</b>
<b>Total</b>	<b>Rs. 74,693</b>	<b>100%</b>	<b>Rs. 96,737</b>	<b>100%</b>	<b>Rs. 116,266</b>	<b>100%</b>

\* The percentage of geography revenue to total represents the respective geography's revenue to the total segment's revenue.

During the year ended March 31, 2013, the Indian rupee depreciated by approximately 12%, 6%, and 7% against the U.S. dollar, the Euro and the Russian rouble, respectively, as compared to the year ended March 31, 2012. This change in the exchange rates resulted in higher reported revenues because of the increase in Indian rupee realization from sales in U.S. dollars, Euros and Russian roubles. However for the U.S. dollar, our higher realization was partially offset on account of net losses incurred on cash flow hedges undertaken by us to hedge the foreign currency risk associated with highly probable forecasted sales transactions. Accordingly, on a net basis, our realizations of U.S. dollar denominated revenues reported in Indian rupees were higher by 9% during the year ended March 31, 2013 on account of depreciation of the Indian rupee.

Our provision for sales returns as at March 31, 2013 was Rs.1,904 million, as compared to a provision of Rs.1,335 million as at March 31, 2012. This increase in our provision is primarily due to higher sales recorded during the year ended March 31, 2013. Consistent with our accounting policy for creating provisions for sales returns (discussed in Note 3.1. of our consolidated financial statements), we periodically assess the adequacy of our allowance for sales returns based on the criteria discussed in our Critical Accounting Policies, as well as sales returns actually processed during the year. For further information regarding our sales return provisions, see Note 21 to our consolidated financial statements.

**Table of Contents****Segment analysis*****Global Generics***

Revenues from our Global Generics segment were Rs.82,563 million for the year ended March 31, 2013, an increase of 18% as compared to Rs.70,243 million for the year ended March 31, 2012. This segment's revenues for the year ended March 31, 2012 included a profit share pursuant to our agreement with Teva Pharmaceutical Industries Ltd. of Rs.4,500 million, attributable to sales of olanzapine 20 mg tablets in the United States subject to 180 days marketing exclusivity. Excluding this impact, revenues from our Global Generics segment increased by 26% for the year ended March 31, 2013 as compared to the year ended March 31, 2012. North America (the United States and Canada), our Emerging Markets (which is comprised of Russia, other countries of the former Soviet Union, and certain other countries from our Rest of the World markets, primarily South Africa, Venezuela and Australia) and India, contribute approximately 91% of the revenues of this segment for the year ended March 31, 2013.

Excluding the impact of profit share revenues from sales of olanzapine 20 mg, the 26% increase in revenues of this segment was attributed to the following factors: approximately 16% of the increase resulted from an increase in the sales volumes of existing products in this segment, approximately 12% of the increase resulted from the introduction of new products in this segment, offset by an approximately 2% decrease resulting from decline in sales prices (net of currency depreciation) of products in this segment.

***North America (the United States and Canada):*** Our Global Generics segment's revenues from North America (the United States and Canada) for the year ended March 31, 2013 were Rs.37,846 million, an increase of 19% as compared to our revenues of Rs.31,889 million for the year ended March 31, 2012. In U.S. dollar absolute currency terms (i.e., U.S. dollars without taking into account the effect of currency exchange rates), this segment's revenues from such geography grew by 10% in the year ended March 31, 2013 as compared to the year ended March 31, 2012.

Excluding the impact of Olanzapine profit share revenues from Teva Pharmaceuticals Ltd. of Rs.4,500 million during the year ended March 31, 2012, the revenues from North America (the United States and Canada) for the year ended March 31, 2013 increased by 38% as compared to the year ended March 31, 2012. In U.S. dollar absolute currency terms (i.e., U.S. dollars without taking into account the effect of currency exchange rates), this segment's revenues from such geography grew by 29% in the year ended March 31, 2013 as compared to the year ended March 31, 2012. This growth was largely attributable to the following:

Revenues from 14 new products launched in the year ended March 31, 2013, including the 180 days marketing exclusivity of finasteride 1 mg (our generic version of Propecia®) and clopidogrel 300 mg (our generic version of Plavix®). The following table sets forth, for the year ended March 31, 2013, products that we launched in the United States:

<b>Product</b>	<b>Therapeutic Category</b>	<b>Innovator's Brand</b>
Olanzapine (other than 20 mg)	Antipsychotic	Zyprexa®
Lansoprazole OTC	Gastro-intestinal	Prevacid®
Clopidogrel	Cardiovascular	Plavix®
Ropinirole hydrochloride XR	Central nervous system	Requip XL®
Atorvastatin	Cardiovascular	Lipitor®
Ibandronate sodium	Calcium regulator	Boniva®



Montelukast sodium, Montelukast sodium chewable, and Montelukast sodium oral granules	Respiratory	Singulair®
Metoprolol succinate ER	Cardiovascular	Toprol - XL®
Amoxicillin (tablets, capsules and oral suspension)	Anti-infective	Amoxil®
Sildenafil	Cardiovascular	Revatio®
Finasteride	Alopecia agent	Propecia®
Desloratadine ODT	Anti-infective	Clarinx® Reditabs®
Zoledronic acid injection	Calcium regulator	Zometa®
Zenatane™	Dermatology	Accutane®

Market share expansion in our existing key products such as ziprasidone and fondaparinux, ramp-up in our antibiotics portfolio and higher contributions by our facility in Shreveport, Louisiana, U.S.A. Our facility in Shreveport, Louisiana, U.S.A. accounted for approximately 4% of the revenue growth of this segment in North America (the United States and Canada), primarily due to a new multi-year contract signed with a customer during the previous year.

## **Table of Contents**

During the year ended March 31, 2013, we made 19 U.S. filings, which includes one NDA filing under section 505(b)(2) and 18 ANDA filings, bringing our cumulative ANDA filings to 200. We now have 65 ANDAs pending approval at the U.S. FDA, out of which 38 are Paragraph IV filings and we believe 8 to have first to file status.

During the year ending March 31, 2014, we expect to launch a few more key products, and we remain optimistic about the long term growth opportunity in this market.

**India:** Our revenues from India for the year ended March 31, 2013 were Rs.14,560 million, an increase of 13% as compared to the year ended March 31, 2012. This growth was driven by an increase in sales volumes across our key brands, such as Omez, Nise, Stamlo, Razo and Reditux, as well as revenues from 24 new brands launched during the year. According to IMS Health, a market research firm, as per its moving annual total report for the 12 months ended March 31, 2013, our sales value grew by 13.7%. In comparison, the Indian pharmaceutical market grew by 10.2% during such period.

Bio-similar products are one of our key growth drivers in India, and represent approximately 8% of our revenues from India in the year ended March 31, 2013.

**Emerging Markets:** Our revenues from our Emerging Markets (which is comprised of Russia, other countries of the former Soviet Union, and certain other countries from our Rest of the World markets, primarily South Africa, Venezuela and Australia), for the year ended March 31, 2013 were Rs.22,441 million, an increase of 31% over the year ended March 31, 2012. This growth was due to the reasons set forth in the below discussions of these geographies.

**Russia:** Our revenues from Russia for the year ended March 31, 2013 were Rs.14,048 million, an increase of 27% over the year ended March 31, 2012. In Russian rouble absolute currency terms (i.e., Russian roubles without taking into account the effect of currency exchange rates), such revenues grew by 18% in the year ended March 31, 2013 as compared to the year ended March 31, 2012. The growth was largely driven by an increase in sales across our key brands (such as Nise, Omez, Ketorol, Senade and Cetrine) as well as new product launches. According to IMS Health, a market research firm, as per its moving annual total report for the 12 months ended March 31, 2013, our sales value and volume growths for the year ended March 31, 2013 were 4.9% and 2.7%, respectively, as compared to the Russian pharmaceutical market value growth and volume decrease of 8.5% and 0.7%, respectively. During the same period, our volume market share increased from 1.65% to 1.70%. We launched 5 new brands in Russia during the year ended March 31, 2013. OTC products represented approximately 34% of our overall sales in Russia and we intend to further strengthen our OTC sales by continuous branding initiatives.

**Other countries of the former Soviet Union:** Our revenues from other countries of the former Soviet Union for the year ended March 31, 2013 were Rs.2,860 million, an increase of 28% over the year ended March 31, 2012. This growth was largely led by increased revenues resulting from higher prices and increased sales volumes from sales in Ukraine, Belarus and Kazakhstan, and partly benefitted by depreciation of the Indian rupee against the U.S. dollar and Ukrainian hryvnia.

**Rest of the World Markets:** We refer to all markets of this segment other than North America, Europe, Russia and other countries of the former Soviet Union and India as our Rest of the World markets. Our revenues from our Rest of the World markets were Rs.5,533 million in the year ended March 31, 2013, an increase of 42% as compared to the year ended March 31, 2012. The growth was largely led by increased revenues resulting from higher prices and increased sales volumes from South Africa, Australia and Venezuela, and was partially offset by the impact of devaluation of the Venezuelan bolivar.

***Pharmaceutical Services and Active Ingredients ( PSAI )***

Our Pharmaceutical Services and Active Ingredients ( PSAI ) segment's revenues for the year ended March 31, 2013 were Rs.30,702 million, an increase of 29% as compared to the year ended March 31, 2012. This was largely attributable to:

increases in the sales of active pharmaceutical ingredients to generic customers to support their generic product launches related to impending patent expirations, which increased our PSAI segment's revenues by 9%;

a strong recovery of customer orders in our PSAI segment primarily due to increased pharmaceutical development services for certain products provided to our innovator company customers, which increased our PSAI segment's revenues by 8%; and

the impact of depreciation of the Indian rupee against multiple currencies, which increased our PSAI segment's revenues by 12%.

**Table of Contents**

In the year ended March 31, 2013, our PSAI segment filed 47 Drug Master Files ( DMFs ) worldwide, of which 5 were filed in the United States, 10 were filed in Europe and 32 were filed in other countries. Cumulatively, our total DMFs filed worldwide as of March 31, 2013 were 577, including 184 DMFs filed in the United States.

**Gross Margin**

Our total gross margin was Rs.60,579 million for the year ended March 31, 2013, representing 52% of our total revenues for this period, as compared to Rs.53,305 million for the year ended March 31, 2012, representing 55% of our total revenues for this period.

The following table sets forth, for the periods indicated, our gross margin by segment:

	For the Year Ended March 31,					
	2011	% of	2012	% of	2013	% of
	Gross	Segment	Gross	Segment	Gross	Segment
	Margin	Revenue	Margin	Revenue	Margin	Revenue
	(Rs. in millions)					
Global Generics	Rs. 34,499	65%	Rs. 44,263	63%	Rs. 48,721	59%
Pharmaceutical Services and Active						
Ingredients	5,105	26%	7,508	32%	9,970	32%
Proprietary Products	382	72%	903	84%	1,324	90%
Others	277	24%	631	39%	564	37%
<b>Total</b>	<b>Rs. 40,263</b>	<b>54%</b>	<b>Rs. 53,305</b>	<b>55%</b>	<b>Rs. 60,579</b>	<b>52%</b>

The change in gross margin was primarily on account of the following:

the favorable impact of depreciation of the Indian rupee against multiple currencies in the markets in which we operate;

the impact of one time profit share revenues from the sale of olanzapine 20 mg tablets in the United States during the year ended March 31, 2012, which resulted in higher gross margins during such year;

the unfavorable impact of price erosions in some of our existing products in the United States and Germany; and

the unfavorable impact of higher power and fuel costs in India due to an increase in tariff rates as well as imposition of certain fuel surcharge adjustments.

Adjusting for the impact of the one time profit share revenues from the sale of olanzapine 20 mg tablets in the United States during the year ended March 31, 2012 which resulted in higher gross margins during such year, the gross

margin for the year ended March 31, 2013 did not change significantly as compared to the gross margin for the year ended March 31, 2012.

**Selling, general and administrative expenses**

Our selling, general and administrative expenses for the year ended March 31, 2013 were Rs.34,272 million, an increase of 15% as compared to Rs.29,907 million for the year ended March 31, 2012. Including the unfavorable impact of depreciation of the Indian rupee against multiple currencies in the markets in which we operate, this increase was primarily on account of the following:

increased personnel costs, due to annual raises and new recruitments, which increased our selling, general and administrative expenses by 9%; and

higher distribution costs, due to increases in sales volumes and freight cost increases, which increased our selling, general and administrative expenses by 3%.

Our selling, general and administrative expenses as a percentage of sales have gradually declined and were at 30% for the year ended March 31, 2013 as compared to 31% and 32% for the years ended March 31, 2012 and 2011, respectively.

## **Table of Contents**

### **Research and development expenses**

Our research and development expenses for the year ended March 31, 2013 were Rs.7,674 million, an increase of 30% as compared to Rs.5,911 million during the year ended March 31, 2012. The increase in research and development expenditure was primarily due to increased spending in our innovative and bio-pharmaceutical research. Our research and development expenditures accounted for 6.6% of our total revenues during the year ended March 31, 2013, as compared to 6.1% during the year ended March 31, 2012. Approximately 60% of our research and development expenses during the year ended March 31, 2013 were spent towards the development of bio-equivalent generic products and the other 40% was dedicated to innovative and bio-pharmaceutical research.

### **Impairment loss on goodwill and other intangible assets**

Based on the business performance and expected cash flows from our business in Italy, we carried out an impairment test of Dr. Reddy's SRL's cash-generating unit and recorded an impairment loss of goodwill amounting to Rs.181 million during the year ended March 31, 2013. Further, we also recorded an impairment loss on intangibles amounting to Rs.10 million during the year ended March 31, 2013 pertaining to this cash-generating unit.

Consequent to the decline in expected cash flows of some of the products forming part of the product related intangibles pertaining to our Global Generics segment, we carried out an impairment test of such product related intangibles and recorded an impairment loss of Rs.497 million during the year ended March 31, 2013.

The above impairment losses were recorded under 'Selling, general and administrative expenses' in the consolidated income statement.

### **Other income, net**

In the year ended March 31, 2013, our net other income was Rs.2,479 million as compared to the net other income of Rs.765 million in the year ended March 31, 2012. The increase was primarily on account of the following:

During March 2013, we entered into an agreement with Nordion Inc. (formerly known as MDS Inc.) to settle our ongoing litigation for alleged breach of service obligations by Nordion Inc. during the years 2000 to 2004. As part of the settlement, we received a one-time settlement amount of Rs.1,220 million (U.S.\$22.5 million) from Nordion Inc., out of which Rs.108 million (U.S.\$2 million) was towards reimbursement of research and development cost and was recorded as reduction in such cost. The balance of Rs.1,112 million (U.S.\$20.5 million) was compensation for lost profits and was recorded as part of other income; and

a net increase in sales of spent chemicals by Rs.208 million.

### **Finance income, net**

Net finance income was Rs.460 million for the year ended March 31, 2013, as compared to net finance income of Rs.160 million for the year ended March 31, 2012. The change was primarily on account of the following:

our net foreign exchange gain was Rs.365 million for the year ended March 31, 2013, as compared to a net foreign exchange gain of Rs.689 million for the year ended March 31, 2012;

our net interest expense was Rs.118 million for the year ended March 31, 2013, as compared to net interest expense of Rs.690 million for the year ended March 31, 2012 primarily due to increased interest income on our higher term deposits; and

our dividend and profit on sale of investments was Rs.213 million for the year ended March 31, 2013, as compared to Rs.161 million for the year ended March 31, 2012.

**Profit before income taxes**

As a result of the above, profit before income taxes was Rs.21,676 million for the year ended March 31, 2013, an increase of 17% as compared to Rs.18,466 million for the year ended March 31, 2012.

**Income tax expense**

Income tax expense was Rs.4,900 million for the year ended March 31, 2013, as compared to income tax expense of Rs.4,204 million for the year ended March 31, 2012.

Our consolidated effective tax rate was 22.6% for the year ended March 31, 2013, as compared to a consolidated effective tax rate of 22.8% for the year ended March 31, 2012.

**Profit for the period**

As a result of the above, our net result was a net profit of Rs.16,776 million for the year ended March 31, 2013, as compared to a net profit of Rs.14,262 million for the year ended March 31, 2012.

**Table of Contents****Fiscal Year Ended March 31, 2012 Compared to Fiscal Year Ended March 31, 2011****Revenues**

Our overall consolidated revenues were Rs.96,737 million for the year ended March 31, 2012, an increase of 30% as compared to Rs.74,693 million for the year ended March 31, 2011. Revenue growth for the year ended March 31, 2012 was largely driven by our Global Generics segment's operations in the markets of North America (the United States and Canada) and Russia and our Pharmaceutical Services and Active Ingredients segment's operations.

The following table sets forth, for the periods indicated, our consolidated revenues by geography:

	For the Year Ended March 31,					
	2010 Revenues	% of Total Revenue*	2011 Revenues (Rs. in millions)	% of Total Revenue*	2012 Revenues	% of Total Revenue*
<b><i>Global Generics</i></b>	<b>Rs. 48,606</b>	<b>69%</b>	<b>Rs. 53,340</b>	<b>71%</b>	<b>Rs. 70,243</b>	<b>72%</b>
North America (the United States and Canada)	16,817	35%	18,996	36%	31,889	45%
Europe	9,643	20%	8,431	16%	8,259	12%
India	10,158	21%	11,690	22%	12,931	18%
Russia and other countries of the former Soviet Union	9,119	19%	10,858	20%	13,260	19%
Rest of the World	2,869	6%	3,365	6%	3,904	6%
<b><i>Pharmaceutical Services and Active Ingredients</i></b>	<b>Rs. 20,404</b>	<b>29%</b>	<b>Rs. 19,648</b>	<b>26%</b>	<b>Rs. 23,812</b>	<b>25%</b>
North America (the United States and Canada)	3,673	18%	3,170	16%	4,272	18%
Europe	6,652	33%	7,020	36%	8,424	35%
India	2,646	13%	2,619	13%	3,586	15%
Rest of the World	7,433	36%	6,838	35%	7,531	32%
<b><i>Others</i></b>	<b>Rs. 1,267</b>	<b>2%</b>	<b>Rs. 1,705</b>	<b>3%</b>	<b>Rs. 2,682</b>	<b>3%</b>
<b>Total</b>	<b>Rs. 70,277</b>	<b>100%</b>	<b>Rs. 74,693</b>	<b>100%</b>	<b>Rs. 96,737</b>	<b>100%</b>

\* The percentage of geography revenue to total represents the respective geography's revenue to the total segment's revenue.

During the year ended March 31, 2012, the Indian rupee depreciated by approximately 5%, 9%, and 7% against the U.S. dollar, the Euro and the Russian rouble, respectively, as compared to the year ended March 31, 2011.



This change in the exchange rates resulted in higher reported revenue growth rates because of the increase in Indian rupee realization from sales in U.S. dollars, Euros and Russian roubles.

Our provision for sales returns during the year ended March 31, 2012 was Rs.1,335 million, as compared to Rs.731 million during the year ended March 31, 2011. This increase in our provision is primarily due to higher sales recorded during the year ended March 31, 2012. Consistent with our accounting policy for creating provisions for sales returns (discussed in Note 3.1. of our consolidated financial statements), we periodically assess the adequacy of our allowance for sales returns based on the criteria discussed in our Critical Accounting Policies, as well as sales returns actually processed during the year. For further information regarding our sales return provisions, see Note 22 to our consolidated financial statements.

## **Segment analysis**

### ***Global Generics***

Revenues from our Global Generics segment were Rs.70,243 million for the year ended March 31, 2012, an increase of 32% as compared to Rs.53,340 million for the year ended March 31, 2011. North America (the United States and Canada), Germany, India and Russia were the four key markets for our Global Generics segment, contributing approximately 86% of the revenues of this segment for the year ended March 31, 2012.

*North America (the United States and Canada).* Our revenues from North America (the United States and Canada) for the year ended March 31, 2012 were Rs.31,889 million, an increase of 68% as compared to our revenues of Rs.18,996 million for the year ended March 31, 2011. In U.S. dollar absolute currency terms (i.e., U.S dollars without taking into account the effect of currency exchange rates), such revenues grew by 62% in the year ended March 31, 2012 as compared to the year ended March 31, 2011. This growth was largely attributable to the following:

Revenues from 15 new products launched in the year ended March 31, 2012, including the 180 days marketing exclusivity of olanzapine (our generic version of Zyprexa®) and ziprasidone (our generic version of Geodon®).

**Table of Contents**

The following table sets forth, for the year ended March 31, 2012, products that we launched in North America (the United States and Canada):

<b>Product</b>	<b>Innovator s Brand</b>	<b>Total annual market size* (U.S.\$Billions)</b>
Donepezil HCL	Aricept®	U.S.\$ 2.10
Venlafaxine-XR	Effexor XR®	2.50
Letrozole	Femara®	0.70
Levofloxacin	Levaquin®	1.70
Topotecan injection		