DR REDDYS LABORATORIES LTD
Form 20-F
June 26, 2014
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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	**TELANGANA, INDIA**
(Translation of Registrant s name into English)	**(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.

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

*** Not for trading, but only in connection with the registration of American depositary shares, pursuant to the requirements of the Securities and Exchange Commission**.

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

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

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

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 x 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 x

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 x No ¨

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

Yes ¨ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer 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 x 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 x

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 x

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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 financia 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 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, 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.

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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

		For the Year Ended March 31,				
	2014	**2014**	**2013**	**2012**	**2011**	**2010**
		(Rs. in millions, U.S.$ in millions, both except share and per share data)				
	Convenience translation into U.S.$					
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
Gross profit	**1,263**	**75,801**	**60,579**	**53,305**	**40,263**	**36,340**
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)
Results from operating activities	**434**	**26,032**	**21,112**	**18,252**	**12,629**	**2,008**

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
Profit/(loss) before income tax		**443**		**26,606**		**21,676**		**18,466**		**12,443**		**2,053**
Income tax expense		(85)		(5,094)		(4,900)		(4,204)		(1,403)		(985)
Profit/(loss) for the year		**359**		**21,512**		**16,776**		**14,262**		**11,040**		**1,068**
Attributable to:												
Equity holders of the Company		359		21,515		16,777		14,262		11,040		1,068
Non-controlling interests		0		(3)		(1)						
Profit/(loss) for the year	**U.S.$**	**359**	**Rs.**	**21,512**	**Rs.**	**16,776**	**Rs.**	**14,262**	**Rs.**	**11,040**	**Rs.**	**1,068**
Earnings/(loss) per share												
Basic	U.S$	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
Weighted average number of equity shares used in computing earnings/(loss) per equity share*												
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
Cash dividend per equity share**	U.S.$	0.25	Rs.	15	Rs.	13.75	Rs.	11.25	Rs.	11.25	Rs.	6.25

* Each ADR represents one equity share.
** Excludes corporate dividend tax.

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Statement of Financial Position Data

	As of March 31,					
	2014	2014	2013 Restated*	2012 Restated*	2011 Restated*	2010
	(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

* The figures for total equity are restated for the years ended March 31, 2013, 2012 and 2011 on account of the adoption of revised IAS 19. See Note 2(f)(vi) to our consolidated financial statements for further details.

Convenience translation

For the convenience of the reader, our consolidated financial statements as of March 31, 2014 have been translated into U.S. dollars 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.

Exchange Rates

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

Year Ended	Period End	Average	High	Low

March 31,				
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.

Month	**High**	**Low**
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.

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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

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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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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.

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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.

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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.