DR REDDYS LABORATORIES LTD
Form 20-F
July 10, 2013
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, 2013

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	**ANDHRA PRADESH, INDIA**
(Translation of Registrant s name into English)	**(Jurisdiction of incorporation or organization)**

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

Hyderabad, Andhra Pradesh 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, Andhra Pradesh 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.

169,836,475 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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

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

Item 17 ¨ Item 18 ¨

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

Yes ¨ No x

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 the United States ar references to 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 , DRL , Dr. Reddy s or the Company shall mean 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 = 54.52, as published by Federal Reserve Board of Governors on March 29, 2013. No representation is made that the Indian rupee amounts have been, could have been or could be converted into U.S. dollars at such a rate or any other rate. As of July 5, 2013 that rate was 60.23 per U.S.$1.00.

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

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

Forward-Looking and Cautionary Statement

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

Table of Contents

TABLE OF CONTENTS

PART I	
ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS	4
ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE	4
ITEM 3. KEY INFORMATION	4
ITEM 4. INFORMATION ON THE COMPANY	24
ITEM 4A. UNRESOLVED STAFF COMMENTS	53
ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS	53
ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES	88
ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS	102
ITEM 8. FINANCIAL INFORMATION	104
ITEM 9. THE OFFER AND LISTING	111
ITEM 10. ADDITIONAL INFORMATION	112
ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	122
ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES	124
PART II	
ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES	127
ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS	127
ITEM 15. CONTROLS AND PROCEDURES	127
ITEM 16. [RESERVED]	129
ITEM 16.A. AUDIT COMMITTEE FINANCIAL EXPERT	129
ITEM 16.B. CODE OF ETHICS	129
ITEM 16.C. PRINCIPAL ACCOUNTANT FEES AND SERVICES	129
ITEM 16.D. EXEMPTION FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES	129
ITEM 16.E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS	129
ITEM 16.F. CHANGE IN REGISTRANT S CERTIFYING ACCOUNTANT	130
ITEM 16.G. CORPORATE GOVERNANCE	130
PART III	
ITEM 17. FINANCIAL STATEMENTS	132
ITEM 18. FINANCIAL STATEMENTS	132
ITEM 19. EXHIBITS	133
SIGNATURES	134

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, 2013, 2012, 2011, 2010 and 2009 and the selected consolidated statement of financial position data as of March 31, 2013, 2012, 2011, 2010 and 2009 have been prepared and presented in accordance with IFRS as issued by the IASB, and have been derived from our audited consolidated financial statements and related notes included elsewhere herein. The selected consolidated financial data below has been presented for the five most recent fiscal years. Historical results are not necessarily indicative of future results.

Income Statement Data

			For the Year Ended March 31,			
	2013	**2013**	**2012**	**2011**	**2010**	**2009**
	Convenience translation into U.S.$	**(in millions, U.S.$ in millions, both except share and per share data)**				
Revenues	U.S.$ 2,133	116,266	96,737	74,693	70,277	69,441
Cost of revenues	1,021	55,687	43,432	34,430	33,937	32,941
Gross profit	**U.S.$ 1,111**	**60,579**	**53,305**	**40,263**	**36,340**	**36,500**
Selling, general and administrative expenses	616	33,584	28,867	23,689	22,505	21,020
Research and development expenses	141	7,674	5,911	5,060	3,793	4,037
Impairment loss on intangible assets	9	507	1,040		3,456	3,167
Impairment loss on goodwill	3	181			5,147	10,856
Other (income)/expense, net	(45)	(2,479)	(765)	(1,115)	(569)	254
Results from operating activities	**U.S.$ 387**	**21,112**	**18,252**	**12,629**	**2,008**	**(2,834)**
Finance (expense)/income, net	8	460	160	(189)	(3)	(1,186)
Share of profit of equity accounted investees, net of income tax	2	104	54	3	48	24
Profit/(loss) before income tax	**U.S.$ 398**	**21,676**	**18,466**	**12,443**	**2,053**	**(3,996)**

Income tax expense	(90)	(4,900)	(4,204)	(1,403)	(985)	(1,172)
Profit/(loss) for the year	**308**	**16,776**	**14,262**	**11,040**	**1,068**	**(5,168)**
Attributable to:						
Equity holders of the Company	308	16,777	14,262	11,040	1,068	(5,168)
Non-controlling interests	(0)	(1)				
Profit/(loss) for the year	**308**	**16,776**	**14,262**	**11,040**	**1,068**	**(5,168)**
Earnings/(loss) per share						
Basic	U.S.$ 1.81	98.82	84.16	65.28	6.33	(30.69)
Diluted	U.S.$ 1.81	98.44	83.81	64.95	6.30	(30.69)
Weighted average number of equity shares used in computing earnings/(loss) per equity share*						
Basic		169,777,458	169,469,888	169,128,649	168,706,977	168,349,139
Diluted		170,432,680	170,177,944	169,965,282	169,615,943	168,349,139
Cash dividend per equity share ( )**	0.25	13.75	11.25	11.25	6.25	3.75

* Each ADR represents one equity share.

** Excludes corporate dividend tax.

4

Table of Contents

Statement of Financial Position Data

	2013	2013	2012	2011	2010	2009
			As of March 31, (in millions, U.S.$ in millions)			
	Convenience translation into U.S.$					
Cash and cash equivalents	U.S.$ 94	5,136	7,379	5,729	6,584	5,596
Total assets	2,611	142,369	119,477	95,005	80,330	83,792
Total long term debt, excluding current portion	232	12,625	16,335	5,271	5,385	10,132
Total equity	U.S.$ 1,341	73,105	57,444	45,990	42,915	42,045

Convenience translation

For the convenience of the reader, our consolidated financial statements as of March 31, 2013 have been translated into U.S. dollars at the certified foreign exchange rate of U.S.$1 = 54.52, as published by Federal Reserve Board of Governors on March 29, 2013. 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 March 31,	Period End	Average	High	Low
2009	50.87	46.32	51.96	39.73
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

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 2012	54.10	51.74
November 2012	55.70	53.75
December 2012	55.06	54.23
January 2013	55.20	53.21
February 2013	54.47	52.99
March 2013	54.92	54.06

On July 5, 2013, the noon buying rate in the city of New York was 60.23 per U.S. dollar.

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

Not applicable.

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

Not applicable.

Table of Contents

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, 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. Furthermore, failure to manage our research and development collaboration arrangements with various partners and suppliers can result in delayed product filings and/or product launches.

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

Our research and development activities are heavily regulated. If we fail to comply fully with applicable regulations, then there could be a delay in the submission or approval of potential new products for marketing approval. In addition, the submission of an application to a regulatory authority does not guarantee that approvals required to market the product will be granted. Each authority may impose its own requirements and/or delay or refuse to grant approval, even when a product has already been approved in another country. In many of the international markets into which we sell our products, including the United States, the approval process for a new product is complex, lengthy and expensive. The time taken to obtain approval varies by country but generally takes from six months to several years from the date of application. This approval process increases the cost to us of developing new products and increases the risk that we will not be able to successfully sell such new products.

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

Additionally, governmental authorities, including among others the U.S. Food and Drug Administration (U.S. FDA) and the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), heavily regulate the manufacturing of our products, including manufacturing quality standards. Periodic audits are conducted on our manufacturing sites, and if the regulatory and quality standards and systems are not found adequate, it could result in an audit observation (on Form 483, if from the U.S. FDA), or a subsequent investigative letter which may require further corrective actions. 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 (e.g., see the description in Item 4.a. below of the June 2011 import ban for our manufacturing facility at Cuernavaca, Mexico), 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. Failure to comply fully with such regulations could also lead to a delay in the approval of our new products.

Table of Contents

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.

Our over-the-counter products business sells over-the-counter medicines. In recent years, significant questions have arisen regarding the safety, efficacy and potential for misuse of certain over-the-counter medicine products. Litigation, particularly in the United States, sometimes gives rise to these questions. As a result, health authorities around the world have begun to re-evaluate some important over-the-counter products, leading to restrictions on the sale of some of them and even the banning of certain products. For example, in 2010, the U.S. FDA undertook a review of one cough medicine ingredient to consider whether over-the-counter sales of the ingredient remained appropriate. While the U.S. FDA has not, to date, changed the ingredient s status, further regulatory or legislative action may follow. Additional actions and litigation regarding over-the-counter products are possible in the future. If the U.S. FDA or another regulator were to review one or more of our over-the-counter products for such purposes, and 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.

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

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.

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.

Table of Contents

In addition, in many less-developed markets, we rely heavily on 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 engaging in improper activities to influence the procurement decisions of government agencies, physicians, pharmacies, hospitals or other health care professionals, we may not be able to effectively manage these third parties. Many of these third parties may not have adequate internal compliance resources. 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 and subjected to civil and criminal penalties for the noncompliance of these third parties under applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act, which may have a material adverse effect on our reputation and our business, financial condition or results of operations.

Significant portions of our 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.

Historically, in the event a patient or group of patients suffered adverse events from taking the generic version of a branded drug in the United States, generic pharmaceutical manufacturers relied on U.S. laws which permitted them to pass that liability back to the innovator pharmaceutical company that originally brought the branded drug to market. However, in recent years, courts in the United States have begun to hold generic manufacturers directly responsible for the safety of their drugs and have found them to be strictly liable for injuries emanating from the use of generics.

Product liability claims, regardless of their merits or the ultimate success of the defense against them, are costly. Although we maintain product liability coverage with respect to products that we manufacture and the clinical trials that we conduct, if any product liability claim sustained against us is not covered by insurance or exceeds the policy limits, it could harm our business and financial condition.

This risk is likely to increase as we develop our own new-patented products in addition to making generic versions of drugs that have been in the market for some time. In addition, 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.

Product liability insurance coverage for pharmaceutical companies is becoming more expensive and, from time to time, the pharmaceutical industry has experienced difficulty in obtaining desired amounts of product liability insurance coverage. As a result, it is possible 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.

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.

Table of Contents

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 are being released in a phased manner by the National Pharmaceutical Pricing Authority. Based on these notifications and, for the products where these notifications are not yet released, based on the information on prices of manufactures available as per IMS Health, we believe that we could be adversely impacted by approximately 3% to 5% of our annual revenues from sales of all of our products in India.

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, including the enactment in December 2003 of expanded Medicare coverage for drugs, which became effective in January 2006.

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 contains various provisions which could adversely affect our business, including the following:

The PPACA imposes on pharmaceutical manufacturers a variety of additional rebates, discounts and fees. Among other things, the PPACA includes annual, non-deductible fees for entities that manufacture or import certain prescription drugs and biologics. This fee is calculated based upon each organization s percentage share of total branded prescription drug and biologics sales to U.S. government programs (such as Medicare, Medicaid and 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 the fee.

In April 2013, we received an invoice from the United States Internal Revenue Service (the IRS) estimating our liability for the manufacturers fee for calendar year 2013 to be $12,251, 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% 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 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.

Table of Contents

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.

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. As of July 2, 2013, this compliance must be confirmed in writing by the competent authority of the exporting country. The provisions of the Directive are intended to reduce the risk of counterfeit medicines entering the supply chain. In practice, the full implementation of the Directive by July 2013 could delay the import of API for many important medicines into European Union countries in those cases where manufacturers will be unable to supply the required documentation.

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. Penalties for non-compliance with this new law have not yet been clarified.

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, 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 competitors 180-day period of abbreviated new drug application (ANDA) exclusivity under the Hatch-Waxman Act. These challenges have come in the form of Citizen Petitions filed with the U.S. FDA, lawsuits alleging violation of the antitrust and consumer protection laws, and seeking legislative intervention. For example, in February 2011, legislation was introduced in both the U.S. Senate and the U.S. House of Representatives that would prohibit 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, 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 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 the marketing and sale 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.

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.

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.

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.

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, including growth through our acquisitions of companies and brands. 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.

Table of Contents

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), and timing of our retailers promotional programs. Such fluctuations may result in volatility in the price of our equity shares and our ADSs. In such an event, the trading price of our shares and ADSs may be adversely affected.

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

A substantial portion of the value of our assets pertains to various intangible assets and goodwill 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 were significantly impacted as a result of the impairments pertaining to our Germany operations.

Concentration of sales to customers

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, 2013, our ten largest customers accounted for approximately 80% 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.

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.

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.

Table of Contents

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

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.

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 the Annual Report on Form 20-F for the year ended March 31, 2013, our management assessed our internal controls over financial reporting, and determined that our internal controls were effective as of March 31, 2013. As we continue to undertake management assessments of our internal control over financial reporting in connection with annual reports on Form 20-F for future years, any deficiencies uncovered by these assessments or any inability of our auditors to issue an unqualified opinion could harm our reputation and result in a loss of investor confidence in the reliability of our financial statements, which could cause the price of our equity shares and ADSs to decline.

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

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

In addition, in many less-developed markets, we rely heavily on third-party distributors and other agents for the marketing and distribution of our products. Many of these third parties do not have internal compliance resources comparable to ours. 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, which may have a material adverse effect on our reputation and our business, financial condition or results of operations.

Table of Contents

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. As a result of our policy to comply with the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws in jurisdictions that have experienced higher levels of bribery and corruption.

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

If flooding, droughts, earthquakes, volcanic eruptions or other natural disasters were to directly damage, destroy or disrupt our manufacturing facilities, it could disrupt our operations, delay new production and shipments of existing inventory or result in costly repairs, replacements or other costs, all of which would negatively impact our business. A significant portion of our manufacturing facilities are situated around Hyderabad, India, a region that has experienced earthquakes, floods and droughts in the past.

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

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

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

Several areas of the world, including India, have experienced terrorist acts and retaliatory operations in recent years. If the economy of our key markets (including but not limited to the United States, the United Kingdom, Germany, India 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 25.56% of our issued shares as at March 31, 2013. 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, even if that was in our best interest. As a result, the value of the ADSs of our minority shareholders may be adversely affected or our minority shareholders might be deprived of a potential opportunity to sell their ADSs at a premium.

RISKS RELATING TO INVESTMENTS IN INDIAN COMPANIES

We are an Indian com