DR REDDYS LABORATORIES LTD
Form 20-F
July 20, 2011

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

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

OR

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

For the Fiscal Year Ended March 31, 2011

OR

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

OR

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

Date of event requiring this shell company report _____

For the transition period from _____ to _____

Commission File Number: 1-15182

DR. REDDY S LABORATORIES LIMITED

(Exact name of Registrant as specified in its charter)

Not Applicable	**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)

Umang Vohra, *Chief Financial Officer,* +91-40-49002005, umangvohra@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.

169,252,732 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 þ No o

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 o No þ

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 þ No o

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 o No þ

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 þ Accelerated filer o Non-accelerated filer o Smaller reporting company o

(Do not check if a smaller reporting company)

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

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

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 o Item 18 o

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 o No þ

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Currency of Presentation and Certain Defined Terms

In this annual report on Form 20-F, references to $ or U.S.$ or dollars or U.S. dollars are to the legal currency of United States and references to or rupees or Indian rupees are to the legal currency of India. Our financial statements are presented in Indian rupees and translated into U.S. dollars and are prepared in accordance with International Financial Reporting Standards, or IFRS , as issued by the International Accounting Standards Board, or IASB . References to Indian GAAP are to Indian Generally Accepted Accounting Principles and references to U.S. GAAP are to United States Generally Accepted Accounting Principles. References to a particular fiscal year are to our fiscal year ended March 31 of such year. References to our ADSs are to our American Depositary Shares.

References to U.S. or United States are to the United States of America, its territories and its possessions. References to India are to the Republic of India. References to EU are to the European Union. All references to we, us , our Dr. Reddy s or the Company shall mean Dr. Reddy s Laboratories Limited and its subsidiaries. Dr. Reddy s 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. (IMS Health), a provider of market research to the pharmaceutical industry, unless otherwise stated.

Except as otherwise stated in this report, all translations from Indian rupees to U.S. dollars are based on the noon buying rate in the City of New York on March 31, 2011 for cable transfers in Indian rupees as certified for customs purposes by the Federal Reserve Bank of New York, which was 44.54 per U.S.$1.00. No representation is made that the Indian rupee amounts have been, could have been or could be converted into U.S. dollars at such a rate or any other rate. As of July 8, 2011 that rate was 44.41 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.

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PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

3.A. *Selected financial data*

You should read the selected consolidated financial data below in conjunction with our consolidated financial statements and the related notes, as well as the section titled Operating and Financial Review and Prospects, all of which are included elsewhere in this Annual Report on Form 20-F. The selected consolidated statements of income for the four years ended March 31, 2011, 2010, 2009 and 2008 and the selected consolidated statement of financial position data as of March 31, 2011 and 2010 have been prepared and presented in accordance with IFRS as issued by the IASB, and have been derived from our audited consolidated financial statements and related notes included elsewhere herein. The selected consolidated financial data below has been presented for the four most recent fiscal years. Historical results are not necessarily indicative of future results.

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

Income Statement Data

		For the Year Ended March 31,				
		2011	**2011**	**2010**	**2009**	**2008**
		(in millions, U.S.$ in millions except share and per share data)				
		Convenience translation into U.S.$				
Revenues	U.S.$	1,677	74,693	70,277	69,441	50,006
Cost of revenues		773	34,430	33,937	32,941	24,598
Gross profit	**U.S.$**	**904**	**40,263**	**36,340**	**36,500**	**25,408**
Selling, general and administrative expenses		532	23,689	22,505	21,020	16,835
Research and development expenses		114	5,060	3,793	4,037	3,533
Impairment loss on other intangible assets				3,456	3,167	3,011
Impairment loss on goodwill				5,147	10,856	90
Other (income)/expense, net		(25)	(1,115)	(569)	254	(402)
Results from operating activities	**U.S.$**	**284**	**12,629**	**2,008**	**(2,834)**	**2,341**
Finance (expense)/income, net		(4)	(189)	(3)	(1,186)	521
Share of profit of equity accounted investees, net of income tax			3	48	24	2

Profit/(loss) before income tax	**279**	**12,443**	**2,053**	**(3,996)**	**2,864**
Income tax (expense)/benefit	(31)	(1,403)	(985)	(1,172)	972

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	For the Year Ended March 31,				
	2011	2011	2010	2009	2008
	(in millions, U.S.$ in millions except share and per share data)				
	Convenience translation into U.S.$				
Profit/(loss) for the year	U.S.$ 248	**11,040**	1,068	(5,168)	3,836
Earnings/(loss) per share					
Basic	U.S.$ 1.47	65.28	6.33	(30.69)	22.88
Diluted	U.S.$ 1.46	64.95	6.30	(30.69)	22.80
Weighted average number of equity shares used in computing earnings/(loss) per equity share*					
Basic		169,128,649	168,706,977	168,349,139	168,075,840
Diluted		169,965,282	169,615,943	168,349,139	168,690,774
Cash dividend per equity share ()**		11.25	6.25	3.75	3.75

* Each ADR represents one equity share.

** Excludes corporate dividend tax

Statement of Financial Position Data

	As of March 31,		
	2011	2011	2010
	(in millions, U.S.$ in millions)		
	Convenience translation into U.S.$		
Cash and cash equivalents	U.S.$ 129	5,729	6,584
Total assets	2,133	95,005	80,330
Total long term debt, excluding current portion	118	5,271	5,385
Total equity	U.S.$ 1,033	45,990	42,915

Convenience translation

For the convenience of the reader, our consolidated financial statements as of March 31, 2011 have been translated into U.S. dollars at the noon buying rate in New York City on March 31, 2011 for cable transfers in Indian rupees, as certified for customs purposes by the Federal Reserve Bank of New York, of U.S.$1.00 = 44.54. 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
2008	40.02	40.00	43.05	38.48
2009	50.87	46.32	51.96	39.73
2010	44.95	47.36	50.48	44.94
2011	44.54	45.49	47.49	43.90

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 2010	44.55	44.05
November 2010	45.83	43.90
December 2010	45.54	44.70
January 2011	45.92	44.59
February 2011	45.66	45.06
March 2011	45.24	44.54

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On July 8, 2011, the noon buying rate in the city of New York was 44.41 per U.S. dollar.

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

Not applicable.

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

Not applicable.

3.D. ***Risk factors***

You should carefully consider all of the information set forth in this Form 20-F and the following risk factors that we face and that are faced by our industry. The risks below are not the only ones we face. Additional risks not currently known to us or that we presently deem immaterial may also affect our business operations. Our business, financial condition or results of operations could be materially or adversely affected by any of these risks. This Form 20-F also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere. See Forward-Looking Statements.

RISKS RELATING TO OUR COMPANY AND OUR BUSINESS

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

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

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

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

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

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

Also, governmental authorities, including the U.S. Food and Drug Administration (U.S. FDA), heavily regulate the 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 a Detention Without Physical Examination (DWPE) import ban, which in turn could lead to product shortages, 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.

For example, recently our Mexico facility received a warning letter from the U.S. FDA seeking further clarifications on some of their audit observations provided earlier to us in a Form 483 and, thereafter, the U.S. FDA posted on its website a DWPE alert for our Mexico facility. As a consequence of the DWPE alert, our Mexico facility is unable to export intermediates and active pharmaceutical ingredients and steroids to U.S. customers until these matters are resolved to the satisfaction of the U.S. FDA. We are working collaboratively with the U.S. FDA to resolve these matters.

An increasing portion of our portfolio are 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 which 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 which 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 our inadvertent non-compliance with such regulations, which could lead to government-enforced shutdowns and other sanctions, as well as the withholding or delay of regulatory approvals for new products.

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 medicines. 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, and litigation sometimes follows actions such as these, particularly in the United States.

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, it could have a significant adverse effect on our sales of such over-the-counter products and, thus, our overall profitability.

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

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

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

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

During 2011, several countries in Latin America, the Middle East and North Africa have experienced wide-spread civil unrest and political instability. We conduct business in several of these countries, most significantly Venezuela. Such civil unrest or political instability may, among other things: threaten the safe operation of our facilities and operations in those countries; increase our cost of operations in those countries; interrupt or otherwise adversely affect our ability to import our products to such countries; result in our inability to repatriate income or capital from such countries; result in inflation or local currency devaluation; result in changes in laws, regulations and commercial norms; result in delays or denials of necessary governmental approvals; or adversely affect the financial condition of our direct and indirect customers and reimbursement schemes in those countries (e.g., wholesalers, retail pharmacies, government programs, private insurance companies and individual patients), which may reduce sales of our products in those countries. Both the likelihood of such occurrences and their overall impact upon us vary greatly from country to country and are not predictable. Realization of these risks could have an adverse impact on the results of operations and financial condition of our operations located in the affected country.

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 across the United States have begun to hold the 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.

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Product liability claims, regardless of their merits or the ultimate success of the defense against them, are costly. Although we have obtained product liability coverage with respect to products that we manufacture and the clinical trials that we conduct, if any product liability claim sustained against us 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.

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

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

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

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

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

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

In order to attract multinational corporations into co-development and licensing arrangements, it is necessary for us to maintain the position of a leading pharmaceutical company in India. Multinational corporations have been increasing their outsourcing of both active pharmaceutical ingredients and generic formulations to highly regarded companies that can produce high quality products at low cost that conform to standards set in developed markets. If we cannot maintain our current position in the market, we may not be able to attract outsourcing or licensing partners and may

lose market share.

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

Our success will depend in part on the extent to which government and health administration authorities, private health insurers and other third-party payors will pay for our products. Increasing expenditures for health care has been the subject of considerable public attention in almost every jurisdiction where we conduct business. Both private and governmental entities are seeking ways to reduce or contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products. 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 in the year ended March 31, 2012 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.

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. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), were signed into law. The PPACA is one of the most significant healthcare reform measures in the United States in decades, and is expected to significantly impact the U.S. pharmaceutical industry. We may see an increase in revenues by virtue of the PPACA s anticipated extension of health insurance to tens of millions of previously uninsured Americans and the prohibitions on denials of health insurance coverage due to pre-existing diseases and on lifetime value limits on insurance policy coverages. However, the PPACA contains various provisions which could adversely affect our business, including the following:

The PPACA imposes on pharmaceutical manufacturers a variety of additional rebates, discounts and fees. Among other things, the PPACA includes annual, non-deductible fees for entities that manufacture or import certain prescription drugs and biologics. The first year for which the fee will apply is calendar year 2011, and the fee will first due by September 30 of the following calendar year (i.e., 2012). This fee will be 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 would generally be treated as branded products. 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-generics business. Conversely, the PPACA has some anti-generic provisions that could adversely affect our bio-generics business, including provisions granting the innovator of a biological drug product 12 years of exclusive use before generic drugs can be approved based on being biosimilar.

The PPACA makes several important changes to the federal anti-kickback statute, false claims laws, and health care fraud statutes that may make it easier for the government or whistleblowers to pursue such fraud and abuse violations. In addition, the PPACA increases penalties for fraud and abuse violations. If our past, present or future operations are found to be in violation of any of the laws described above or other similar

governmental regulations to which we are subject, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and our financial results. To further facilitate the government s efforts to coordinate and develop comparative clinical effectiveness research, the PPACA establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in such research. The manner in which the comparative research results would be used by third-party payors is uncertain.

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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 PPACA that prohibit the use of preexisting condition exclusions, eliminate lifetime and annual dollar limits on benefits, restrict contract rescissions, and provide patient protections. However, there are many PPACA programs and requirements for which regulations have not yet been issued or consequences are not fully understood. The full impact of the PPACA will be seen as it continues to be implemented, by promulgation of additional regulations and other administrative and judicial actions.

During the year ended March 31, 2011, the PPACA s changes to manufacturer rebates under the Medicaid Drug Rebate Program impacted our U.S. Generics business, but the impact was not material. The manufacturers fee for calendar year 2011 is based upon our sales of branded prescription drugs and biologics for calendar year 2009, which were below the $5 million threshold, and thus we are not subject to the fee for calendar year 2011. We are continuing to evaluate the impact of the PPACA and how it may affect our financial condition, results of operations and cash flows.

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

In addition, governments throughout the world heavily regulate the marketing of products. Most countries also place restrictions on the manner and scope of permissible marketing to physicians, pharmacies and other health care professionals. The effect of such regulations may be to limit the amount of revenue that we may be able to derive from a particular product. Moreover, if we fail to comply fully with such regulations, then civil or criminal actions could be brought against us.

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

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

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

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

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

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

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

The policy of the U.S. FDA regarding the award of 180 days of market exclusivity to generic manufacturers who challenge patents relating to specific products continues to be the subject of extensive litigation in the United States. During this 180-day market exclusivity period, the generic manufacturer who won exclusivity relating to the specific product usually is the only company marketing that product. The U.S. FDA s current interpretation of the Hatch-Waxman Act of 1984 is to award 180 days of exclusivity to the first generic manufacturer who files a Paragraph IV certification under the Hatch-Waxman Act challenging the patent of the branded product, regardless of whether that generic manufacturer was sued for patent infringement.

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

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

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

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 which 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 which 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.

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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 will suffer.

If competitors are successful in limiting competition for certain authorized generic products through their legislative, regulatory and litigation efforts, our sales of certain generic products may suffer.

Recently, some U.S. generic pharmaceutical companies who obtained rights to market and distribute under a brand manufacturer s NDA a generic alternative of the brand product (i.e., an authorized generics arrangement) have experienced challenges to their ability to distribute authorized generics during a competitors 180-day period of 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, resulting in a decrease in revenues, or we could be subject to substantial liabilities that would lower our profits.

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

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

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

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

For example, in April 2006, we launched, and continue to sell fexofenadine, the generic version of Allegra®, despite the fact that litigation with the company that holds the patents for and sells this branded product is still ongoing. Also, during the year ended March 31, 2009, we incurred damages of approximately 916 million as a result of the German Federal Court of Justice upholding the validity of an olanzapine patent held by Eli Lilly. In Canada, we continue to sell olanzapine tablets (the generic version of Eli Lilly s Zyprexa® tablets) through a partnership with Pharmascience, Inc., despite the fact that Pharmascience has agreed to pay damages if Eli Lilly is successful in its olanzapine patent

litigation against Novopharm, and our partnership arrangement with Pharmascience would require us to share a portion of any such damages obligation realized by Pharmascience.

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Furthermore, there may be risks involved in entering into in-licensing arrangements for products, which are often conditioned upon the licensee s sharing in the patent-related risks. For example, in the case of our brand Oxycodon beta in Germany, our supplier, Cimex Pharma AG, required us to enter into a cost sharing agreement under which we will pay up to 20% of the losses resulting from any innovator damage claims.

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

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

As of March 31, 2011, our products were marketed in numerous countries. In large overseas markets, our products are usually marketed through our subsidiaries or joint ventures. Since we do not have the resources to market and distribute our products ourselves in all our export markets, we also market and distribute our products through third parties by way of marketing and agency arrangements. These arrangements may be terminated by either party providing the other with notice of termination or when the contract regarding the arrangement expires. We may not be able to successfully negotiate these third party arrangements or find suitable joint venture partners in the future. Any of these arrangements may not be available on commercially reasonable terms. Additionally, our marketing partners may make important marketing and other commercialization decisions with respect to products we develop without our input. As a result, many of the variables that may affect our revenues and net income are not exclusively within our control when we enter into arrangements like these.

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

We may incur substantial costs complying with requirements of environmental laws and regulations. In addition, we may discover currently unknown environmental problems or conditions. In all countries in which we have production facilities, we are subject to significant environmental laws and regulations which govern the discharge, emission, storage, handling and disposal of a variety of substances that may be used in or result from our operations. 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 which 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.

There has been increasing worldwide concern about global climate change in recent years. A number of international, national and regional measures to limit greenhouse gas emissions have been enacted. For example, more than 160 nations are signatories to the 1992 Framework Convention on Global Climate Change, commonly known as the Kyoto Protocol . The Kyoto Protocol is set to expire in 2012. The nations subject to the Kyoto Protocol have not yet reached agreement upon a successor to the Kyoto Protocol, but the parties have taken note of the Copenhagen Accord, a voluntary agreement to work to curb climate change. The majority of our manufacturing plants are based in India, which currently has sustainability requirements that are largely voluntary, and therefore we do not anticipate any material impact on our operations in the foreseeable future from climate change laws. However, there can be no assurance that India or other countries in which we operate will not in the future enact legislation focused on reducing climate change that could impact our operations. We intend to keep track of further developments on this in future fiscal periods.

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

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

- general market conditions,
- speculative trading in our shares and ADSs, and
- developments relating to our peer companies in the pharmaceutical industry.

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

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

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

If we have difficulty in identifying acquisition candidates or consummating acquisitions, our competitiveness and our growth prospects may be harmed.

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

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

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

- We may fail to successfully integrate our acquisitions in accordance with our business strategy.
- The initial rationale for the acquisition may not remain viable due to a variety of factors, including unforeseen regulatory changes and market dynamics after the acquisition, and this may result in a significant delay and/or reduction in the profitability of the acquisition.

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- Integration of acquisitions may divert management s attention away from our primary product offerings, resulting in the loss of key customers and/or personnel, and may expose us to unanticipated liabilities.
- We may not be able to retain the skilled employees and experienced management that may be necessary to operate the businesses we acquire. If we cannot retain such personnel, we may not be able to locate or hire new skilled employees and experienced management to replace them.
- We may purchase a company that has contingent liabilities that include, among others, known or unknown patent or product liability claims.
- Our acquisition strategy may require us to obtain additional debt or equity financing, resulting in additional leverage, or increased debt obligations as compared to equity, and dilution of ownership.
- We may purchase companies located in jurisdictions where we do not have operations and as a result we may not be able to anticipate local regulations and the impact such regulations have on our business.

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

Our principal shareholders have significant control over us and, if they take actions that are not in 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 25.65% of our issued shares as at March 31, 2011. As a result, these people, acting in concert, are likely to have the ability to exercise significant control over most matters requiring approval by our shareholders, including the election and removal of directors and significant corporate transactions. This significant control by these directors and their family members could delay, defer or prevent a change in control of us, impede a merger, consolidation, takeover or other business combination involving us, or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, even if that was in our best interest. As a result, the value of 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.

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

We handle dangerous materials including explosive, toxic and combustible materials like sodium azide, acrolein and acetyl chloride. If improperly handled or subjected to the wrong conditions, these materials could hurt our employees and other persons, cause damage to our properties and harm the environment. 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, which could lower our profits in the event we were found liable, and could also adversely impact our reputation.

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

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

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In the event that we experience a shortage in our supply of raw materials, we might be unable to fulfill all of the API needs of our Global Generics segment, which could result in a loss of production capacity for this segment. In addition, this could result in a conflict between the API needs of our Global Generics segment and the needs of customers of our Pharmaceutical Services and Active Ingredients segment, some of whom are also our competitors in the Global Generics segment. In either case, we could potentially lose business from adversely affected customers and we could be subjected to lawsuits.

Our key generics manufacturing sites also may have capacity constraints and, at times, we may not be able to generate sufficient supplies of finished goods, which may adversely affect our business or results of operations. Moreover, we may continue to be dependent on vendors, strategic partners and alliance partners for supplies of some of our existing products and new generic launches. Any unanticipated capacity or supply related constraints affecting such vendors, strategic partners or alliance partners can adversely affect our business or results of operations.

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

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

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

Our principal subsidiaries are located in the United States, United Kingdom, Germany, Switzerland, Mexico and Russia and each has significant local operations. A significant portion of our revenues are in currencies other than the Indian rupee, especially the U.S. dollar, euro, rouble and pound sterling, while a significant portion of our costs are in Indian rupees. As a result, if the value of the Indian rupee appreciates relative to these other currencies, our revenues measured in rupees may decrease.

We entered into a bank loan facility in connection with our acquisition of betapharm in the year ended March 31, 2006, although the loans were repaid and the facility was terminated during the year ended March 31, 2011. In the future, we may enter into additional borrowing arrangements in connection with acquisitions or for general working capital purposes. In the event interest rates increase, our costs of borrowing will increase and our results of operations may be adversely affected.

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

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

key person life insurance on any officer, employee or consultant.

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We operate in a highly competitive and rapidly consolidating industry.

Our competitors, which include major multinational corporations, are consolidating, and the strength of the combined companies could affect our competitive position in all of our business areas. Furthermore, if one of our competitors or their customers acquires any of our customers or suppliers, we may lose business from the customer or lose a supplier of a critical raw material.

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

We have grown very rapidly over the past few years, 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. Furthermore, to facilitate our growth, we are carrying out reorganizations to improve our focus on delivery, to build decisive competitive advantages or/and to build sustainable cost structures. There is also an increasing need to manage information and asset related security. If we are unable to hire and retain qualified employees, or if we do not invest in systems and processes to manage and support our rapid growth, the failure to do so may have a material adverse effect on our business, financial condition and results of operations.

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

Our quarterly revenues, operating results and cash flows have fluctuated significantly in the past and may fluctuate substantially from quarter to quarter in the future. Such fluctuations may result in volatility in the price of our equity shares and our ADSs. Our quarterly revenues, operating results and cash flows may fluctuate as a result of a variety of factors, including but not limited to:

- changes in demand for our products;
- the impact of seasons (weather severity, length and timing) on the price and availability of raw materials which we depend on;
- the timing of regulatory approvals and of launches of new products by us and our competitors, particularly where we obtain the 180-day period of market exclusivity in the United States provided under the Hatch-Waxman Act of 1984;
- changes in our pricing policies or those of our competitors;
- the magnitude and timing of our research and development investments;
- changes in the level of inventories maintained by our customers;
- the geographical mix of our sales and currency exchange rate fluctuations;
- adverse market events leading to impairment of any of our assets; and
- timing of our retailers promotional programs.

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

Significant disruptions of information technology systems could adversely affect our business.

Our business is dependent upon increasingly complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. While we mitigate the risks of and facilitate rapid recovery from system-downtimes through backup servers and other arrangements with our vendors, significant breakdown or interruption of these systems, whether due to computer viruses or other causes, may result in the loss of key information and/or disruption of production and business processes, which could materially and adversely affect our business.

In addition, our systems are potentially vulnerable to data security breaches whether by employees or others which 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 have a material adverse effect on our business, financial condition and results of operations.

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 which may give rise to liability, or which 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.

If our intercompany arrangements are challenged and determined to be inappropriate, our tax liabilities could increase.

We have potential tax exposures resulting from the varying application of statutes, regulations and interpretations, including exposures with respect to manufacturing, research and development, marketing, sales and distribution functions. Although our 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.

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

In the normal course of business, we periodically enter into agreements with vendors, customers, alliance partners, innovators and others which incorporate terms for indemnification provisions. Our indemnification obligations under such agreements may be unlimited in duration and amount. We maintain insurance coverage which we believe will effectively mitigate our obligations under certain of these indemnification provisions (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.

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, or shifting concentrations of payors and their preferences, may force our competitors and us to reduce prices. We have exposure to many different industries and counterparties, including our partners under our alliance, research and promotional services agreements, suppliers of raw materials, drug wholesalers and other customers, who may be unstable or may become unstable in the current economic environment.

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

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

The U.S. Foreign Corrupt Practices Act, the recently enacted 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 fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements or otherwise. Any violation of these laws or allegations of such violations, whether or not merited, could have a material adverse effect on our reputation and could cause the trading price of our ordinary shares and ADSs to decline.

Finally, we operate in certain jurisdictions that have experienced governmental corruption to some degree or are found to be low on the Transparency International Corruption Perceptions Index, 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.

Certain natural disasters, such as drought, floods, earthquakes or volcanic eruptions, could adversely affect our production operations or result in disruptions in distribution channels or supply chains, 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. Our main facilities are situated around Hyderabad, India. This region has experienced earthquakes, floods and droughts in the past and has experienced droughts in recent years. In the event of a drought so serious that the drinking water in the region is limited, the Government of India could cut the supply of water to all industries, including our facilities. This would adversely affect our production operations and reduce our revenues. Even if we take precautions to provide back-up support in the event of such a natural disaster, the disaster may nonetheless affect our facilities, harming production and ultimately our business. 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. 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.

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RISKS RELATING TO INVESTMENTS IN INDIAN COMPANIES

We are an Indian company. Our headquarters are located in India, a substantial part of our operations are conducted in India and a significant part of our infrastructure and other assets are located in India. In addition, a portion of our total revenues for the year ended March 31, 2011 continued to be derived from sales in India. As a result, the following additional risk factors apply.

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

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

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

India has experienced communal disturbances, terrorist attacks and riots during recent years. For example, Mumbai, India s commercial capital, was the target of serial railway bombings in July 2006 as well as the 26/11 attacks on November 26, 2008. Hyderabad, the city in which we are headquartered, was also subjected to terrorist acts in May and August 2007. In May 2008, the city of Jaipur in the state of Rajasthan, India was subjected to a series of co-ordinate bombings. If such disturbances continue or are exacerbated, our operational, sales and marketing activities may be adversely affected.

During the years ended March 31, 2010 and 2011, the state of Andhra Pradesh, where our headquarters is located, experienced political turbulence relating to a separatist movement seeking to bifurcate the existing state of Andhra Pradesh into two separate states of Telangana and Andhra . Due to civil disturbances and Bandhs (i.e., political protests in the form of worker strikes) called for, several productive days were lost from forced or precautionary closures of our production units and offices. If there are further strikes, political protests or civil unrest, our business and results of operations may be adversely affected as a consequence.

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

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

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

Due to various macro-economic factors, the rate of inflation has recently increased in India. According to the economic report released by the Department of Economic Affairs, Ministry of Finance in India, the annual inflation rate in India, as measured by the benchmark wholesale price index, Base 1993-94=100 was 9.4% for the year ended March 31, 2011 (as compared to 9.90% for the year ended March 31, 2010). This trend may continue and the rate of inflation may further rise. We may not be able to pass these costs on to our customers by increasing the price we charge for our products. If this occurs, our profits may decline.

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

Labor laws in India are more stringent than in other parts of the world. These laws may restrict our ability to have human resource policies that would allow us to react swiftly to the needs of our business. Approximately 8% of our employees belong to a number of different labor unions. If we experience problems with our labor unions, our production capacity and overall profitability could be negatively affected.

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

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

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

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

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

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

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

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

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

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

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

A company incorporated in India must offer its holders of shares preemptive rights to subscribe and pay for a proportionate number of shares to maintain their existing ownership percentages prior to the issuance of any shares, unless these rights have been waived by at least 75% of the company s shareholders present and voting at a shareholders general meeting. U.S. investors in our ADSs may be unable to exercise preemptive rights for the shares underlying our ADSs unless a registration statement under the Securities Act of 1933 is effective with respect to the rights or an exemption from the registration requirements of the Securities Act is available. Our decision to file a registration statement will depend on the costs and potential liabilities associated with a registration statement as well as the perceived benefits of enabling U.S. investors in our ADSs to exercise their preemptive rights and any other factors we consider appropriate at the time. We might choose not to file a registration statement under these circumstances. If we issue any of these securities in the future, such securities may be issued to the depositary, which may sell them in the securities markets in India for the benefit of the investors in our ADSs. There can be no assurances as to the value, if any, the depositary would receive upon the sale of these securities. To the extent that U.S. investors in our ADSs are unable to exercise preemptive rights, their proportional interests in us would be reduced.

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

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

We operate in jurisdictions that impose transfer pricing and other tax-related regulations on us, 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. In the event that we do not properly comply with transfer pricing and tax-related regulations, our profitability may be adversely affected.

ITEM 4. INFORMATION ON THE COMPANY

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

Dr. Reddy s Laboratories Limited was incorporated in India under the Companies Act, 1956, by its promoter and our current Chairman, Dr. K. Anji Reddy, as a Private Limited Company on February 24, 1984. We were converted to a Public Limited Company on December 6, 1985 and listed on the Indian Stock Exchanges in August 1986 and on the New York Stock Exchange on April 11, 2001. We are registered with the Registrar of Companies, Andhra Pradesh, Hyderabad, India as Company No. 4507 (Company Identification No. U85195AP1984 PLC 004507). Our registered office is situated at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500 034, India and the telephone number of our registered office is +91-40-49002900. The name and address of our registered agent in the United States is Dr. Reddy s Laboratories, Inc., 200 Somerset Corporate Boulevard (Bldg II), Bridgewater, New Jersey 08807.

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Key business developments:

On April 23, 2010, we launched amlodipine benazepril capsules (2.5 mg/10 mg, 5 mg/10 mg, 5 mg/20 mg and 10mg/20mg), a bioequivalent generic version of Novartis Lotrel® capsules, in the United States. In September 2009, we entered into a settlement agreement with Novartis for the dismissal of lawsuits in the United States related to amlodipine benazepril. The United States Food and Drug Administration (U.S. FDA) approved our abbreviated new drug application (ANDA) for amlodipine benazepril on April 15, 2010. Amlodipine benazepril is indicated for the treatment of hypertension in patients not adequately controlled with either agent and is taken once daily. According to IMS Health, amlodipine benazepril had a total annual market size of $1.04 billion in the United States at the time of our generic launch.

On May 20, 2010, we launched tacrolimus capsules (0.5 mg, 1 mg and 5 mg), a bioequivalent generic version of Astellas Pharma Inc. s Prograf® capsules, in the United States. The U.S. FDA approved our ANDA for tacrolimus capsules on May 13, 2010. Tacrolimus is indicated for the prophylaxis of organ rejection in patients receiving allogeneic liver, kidney or heart transplants. According to IMS Health, tacrolimus had a total annual market size of $955 million in the United States at the time of our generic launch.

In August 2010, Dr. Reddy s Laboratories (Proprietary) Limited became our wholly-owned subsidiary in South Africa as a result of our acquisition of the remaining 40% non-controlling interest from Calshelf Investments 214 (Proprietary) Limited. Previously we held a controlling interest of 60% in Dr. Reddy s Laboratories (Proprietary) Limited. South Africa is an important market and we are looking at increasing our presence, especially in the areas of central nervous system disorders, oncology and women s health.

On August 9, 2010, we launched Cresp® the first biosimilar darbepoetin alfa in the world, and the only darbepoetin alfa in India. Cresp® has been approved in India for the treatment of anemia due to chronic kidney disease and anemia due to chemotherapy. Darbepoetin alfa is a modified version of epoetin alfa (rHuEPO), which is engineered to have a longer half life, increasing (up to 3 times) the time it remains in the blood. This results in a reduced frequency of doses, providing a simpler and more convenient treatment option for patients and physicians as compared to treatment of anemia with epoetin which is the current standard of care in India. Cresp® offers convenient dosing, predictable rise and excellent long term control of hemoglobin.

On October 22, 2010, we launched lansoprazole delayed-release capsules (15 mg and 30 mg), a bioequivalent generic version of Prevacid® Delayed-Release Capsules, in the United States. The U.S. FDA approved our ANDA for lansoprazole delayed-release capsules on October 15, 2010. Lansoprazole is indicated for acid-reflux disorders (gastroesophageal reflux disease), peptic ulcer disease, duodenal ulcers, esophagitis, and zollinger-ellison syndrome. According to IMS Health, lansoprazole had a total annual market size of $1.4 billion in the United States at the time of our generic launch.

On October 25, 2010 we entered into an agreement with Cipla Limited for exclusive marketing rights of a portfolio of over-the-counter and prescription products in the Russian and Ukraine markets. As per the agreement, we have initiated sales and promotion of this portfolio of products from the quarter ended June 30, 2011 in select therapy areas in Russia. We anticipate that sales will be launched in Ukraine in calendar year 2012.

On November 15, 2010, the U.S. District Court of New Jersey granted our motion for summary judgment against AstraZeneca with respect to their claims of our infringement of AstraZeneca s zafirlukast product, Accolate®, clearing the way for the launch of our generic version of the product. On November 18, 2010, the U.S. FDA approved our ANDA for zafirlukast tablets and we launched the product on November 19, 2010. According to IMS Health, zafirlukast had a total annual market size of $50 million in the United States at the time of our generic launch.

On December 20, 2010 we entered into a licensing, technology transfer, manufacturing and marketing agreement with R-Pharm of Russia. The collaboration is in the area of high-technology and works on a profit sharing model. It entails licensing of manufacturing know-how of products by us, local manufacturing of products in Russia, co-development of high technology products and knowledge sharing between both parties at regular intervals.

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In January 2011, we entered into a settlement agreement with AstraZeneca regarding our ANDA submission for a generic version of AstraZeneca s esomeprazole product, Nexium® delayed-release capsules. Under the terms of the agreement, AstraZeneca has granted us a license, subject to regulatory approval, to launch a generic version of esomeprazole delayed-release capsules on May 27, 2014, or earlier in certain circumstances.

On January 20, 2011 we launched pantoprazole sodium delayed-release tablets (20 mg and 40 mg strengths), a bioequivalent generic version of Pfizer Inc. s Protonix® tablets in the United States. The U.S. FDA approved our ANDA for pantoprazole sodium delayed-release tablets on January 19, 2011. According to IMS Health, pantoprazole had a total annual market size of $1.8 billion in the United States at the time of our generic launch.

On January 31, 2011, we launched fexofenadine-pseudoephedrine (180/240 mg) in the United States after the Federal District Court for the District of New Jersey lifted the preliminary injunction previously granted to Sanofi-Aventis. The U.S. FDA, which had previously only approved fexofenadine for prescription sales in the United States, approved fexofenadine for over-the-counter sales in the United States in January 2011. We were allowed to liquidate our inventory in the United States after the approval of over-the-counter sales and this limited period launch contributed to our growth for the year ended March 31, 2011.

On March 24, 2011 we issued bonus debentures carrying a face value of 5 each in the ratio of 6 debentures for each equity share held by our shareholders as on March 18, 2011. These bonus debentures have a maturity of 36 months, at which time we must redeem them for cash in an amount equal to the face value of 5 each plus unpaid interest, if any. These debentures carry interest at the rate of 9.25% per annum, payable at the end of every 12, 24 and 36 months from the date of issue.

On March 25, 2011, we launched levocetirizine tablets (5 mg), a bioequivalent generic version of UCG s Xyzal® tablets, in the United States. The U.S. FDA approved our ANDA for levocetirizine tablets on February 24, 2011. According to IMS Health, levocetirizine had a total annual market size of $238 million in the United States at the time of our generic launch.

On March 29, 2011, we acquired from GlaxoSmithKline plc (GSK) a penicillin-based antibiotics manufacturing site in Bristol, Tennessee, U.S.A, the product rights for GSK s Augmentin® (branded and generic) and Amoxil® brands of oral penicillin-based antibiotics in the United States (GSK retained the existing rights for these brands outside the United States), certain raw materials and finished goods inventory associated with Augmentin®, and rights to receive certain transitional services from GSK. The acquisition enables us to enter the U.S. oral antibiotics market with a comprehensive product filing and a dedicated manufacturing site.

On March 31, 2011, through our wholly owned subsidiary Promius Pharma LLC, we entered into a collaboration agreement with Coria Laboratories Limited (a subsidiary of Valeant Pharmaceuticals International, Inc.) (Coria) for the right to manufacture, distribute and market its Cloderm® (clocortolone pivalate 0.1%) product in the United States. Cloderm® is a cream used for treating dermatological inflammation, and is an existing U.S. FDA approved product. In addition to acquiring all relevant U.S. FDA product regulatory approvals and intellectual property rights (other than trademarks) associated with Cloderm®, we also acquired an underlying raw material supply contract and an exclusive license to use the trademark Cloderm® for a period of 8 years. The rights and ownership of this trademark are to be transferred from Coria to us at the end of the 8th year, subject to our payment of all royalties under the contract.

In order to build a robust generics pipeline, in the year ended March 31, 2011 we filed 21 ANDAs in the United States. Cumulatively, we have 179 ANDAs (including ANDAs through partnerships). A total of 76 ANDAs were pending approval at the U.S. FDA, of which 38 are Paragraph IV filings and 10 have first to file status. In our Pharmaceutical Services and Active Ingredients segment we filed 56 Drug Master Files (DMF) in the year ended March 31, 2011 worldwide, 19 of which were filed in the United States, 7 in Europe and 30 in other countries. As of March 31, 2011, we had made a total of 486 DMF filings worldwide.

During the years ended March 31, 2011, 2010 and 2009, we invested 8,849 million, 4,068 million and 4,426 million (net of sales of capital assets), respectively, in capital expenditures for manufacturing, research and development facilities and other assets. We believe that these investments will create the capacity to support our strategic growth agenda. We also had contractual commitments of approximately 3,459 million for capital expenditures. These commitments included approximately 3,365 million to be spent in India and 94 million in other countries.

During the years ended March 31, 2011, 2010 and 2009, no third party made any public takeover offers in respect of our shares and we did not make any public offers to take over any other company.

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

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

- our Global Generics segment, which includes branded and unbranded prescription and over-the-counter (OTC) drug products business;
- our Pharmaceutical Services and Active Ingredients (PSAI) segment, which consists of our Active Pharmaceutical Ingredients business and our Custom Pharmaceutical Services business; and
- our Proprietary Products segment, which consists of our Generic Biopharmaceuticals business, our New Chemical Entities (NCEs) business, our Differentiated Formulations business and our dermatology focused specialty business operated through Promius Pharma.

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

OUR STRATEGY

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

Strengths in Science and Technology

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

Product Offerings

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

Branded Generics: We seek to have a portfolio that is strongly differentiated and offers compelling advantages to doctors and patients.

Unbranded Generics: We aim to ensure that we deliver first to market products to our customers, including pharmacy chains and distributors, and that they have high product availability from us combined with low inventories, resulting in superior inventory turns while addressing the customers needs.

Vertical integration and process innovation ensures that our products remain competitive.

b) Pharmaceutical Services and Active Ingredients: Our Pharmaceutical Services and Active Ingredients (PSAI) business is comprised of our Active Pharmaceutical Ingredients (API) business and our Custom Pharmaceutical Services (CPS) business.

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

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

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c) Proprietary Products: Our Proprietary Products business is comprised of our Differentiated Formulations business and our New Chemical Entity (NCE) research business.

Differentiated Formulations: Our emerging Differentiated Formulations portfolio, which consists of new, synergistic combinations as well as technologies that improve safety and/or efficacy by modifying pharmacokinetics of existing medicines, is focused on significant clinically unmet needs. We are also investigating new indications for existing medicines.

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

Execution Excellence (Building Blocks)

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

Lean Manufacturing Eliminating waste and reducing cycle time, with a focus on capacity constrained resources.

Quality by Design Building quality into all processes and using quality tools to eliminate process risks.

Principles of the Theory of Constraints We apply these principles primarily in supply chain and product development. This ensures high availability with low inventory through a pull-based logistics system. It also ensures speed in product development through critical chain project management.

Leadership Development Developing leaders, as well as enhancing leadership behavior across the organization.

OUR PRINCIPAL AREAS OF OPERATIONS

The following table shows our revenues and the percentage of total revenues of our segments for the years ended March 31, 2009, 2010 and 2011, respectively:

(in millions, U.S.$ in millions)

	Year Ended March 31,							
Segment	**2009**		**2010**		**2011**			
Global Generics	49,790	72%	48,606	69%	53,340	71%	U.S. $	1,198
Pharmaceutical Services and Active Ingredients	18,758	27%	20,404	29%	19,648	26%		441
Proprietary Products	294		513	1%	532	1%		12
Others	599	1%	754	1%	1,173	2%		26
Total Revenues	**69,441**	**100%**	**70,277**	**100%**	**74,693**	**100%**	**U.S. $**	**1,677**

Global Generics Segment

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

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During the year ended March 31, 2009, we reorganized our worldwide finished dosages businesses to focus on certain key geographies and gradually exited some very small, distributor driven markets. This move represented an important new focus to consolidate and grow our presence in the key geographies where we already had a considerable presence.

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

Our Global Generics segment s revenues were at 53,340 million in the year ended March 31, 2011, as compared to 48,606 million in the year ended March 31, 2010. The revenue growth was largely led by our key markets of North America (the United States and Canada), Russia and India. This growth was partly offset by a decrease in the German market on account of continuing pricing pressures due to competitive tenders.

The following is a discussion of the key markets in our Global Generics segment.

India

Approximately 22% of our Global Generics segment s revenues in the year ended March 31, 2011 were derived from sales in the Indian market. In India, we mainly focus on the therapeutic categories of gastro-intestinal, cardiovascular, pain management and oncology. Our Global Generics segment s revenues from India increased by 15% to 11,690 million for the year ended March 31, 2011, as compared to 10,158 million for the year ended March 31, 2010. This growth was primarily attributable to a 4% increase in revenues (amounting to 399 million) due to new product launches and an 11% increase in sales volumes of key brands such as: Reditux®, our brand of rituximab; Omez® and Omez DSR®, our brands of omeprazole and its combination with domperidone; Razo® and Razo D®, our brand of rabeprazole and its combination with domperidone; and Rozat®, our brand of rosuvastatin. Key new product launches during the year ended March 31, 2011 included: Cresp®, the world s first biosimilar darbepoetin alfa; Dialex D©, our brand of chlophenaramine maleate and codeine; Leon-OZ®, our brand of levofloxacin and ornidazole tablets; Rupanex M®, our brand of rupatidine and montelukast; and Supamove®, our brand of diclofenac and thiocolchicoside.

As of March 31, 2011, we had a total of 271 branded products in India. Our top ten branded products together accounted for 37% of our revenues in India in the year ended March 31, 2011. According to Operations Research Group International Medical Statistics (ORG IMS), a provider of market research to the pharmaceutical industry, in its Moving Annual Total (MAT) report for the 12-month period ended March 31, 2011, our secondary sales (i.e., sales made by our wholesalers to stockists and retailers) in India grew by 9.7% as compared to Indian pharmaceutical market growth of 15.3%. Our direct sales to hospitals and doctors, which bypass retailers, also experienced some additional growth that was not encompassed within IMS Health s secondary sales data. According to ORG IMS in the foregoing MAT report, as of March 31, 2011, we had 44 brands that were ranked either first or second in terms of secondary sales in India in their respective product categories. According to the Center for Marketing and Advertising Research Consultancy, a market research firm, in a report that measured doctors prescriptions for the period from November 2010 to February 2011, we were ranked ninth in terms of the number of prescriptions generated in India during such period.

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The following tables summarize the position of our top 10 brands in the Indian market for the years ended March 31, 2009, 2010 and 2011, respectively:

	Year Ended March 31,					
	2009		2010		2011	
BRAND	Revenues in millions	% Total(1)	Revenues in millions	% Total(1)	Revenues in millions	% Total(1)
Omez	776	9%	928	9%	1,065	9%
Nise	605	7%	690	7%	700	6%
Stamlo	422	5%	473	5%	507	4%
Reditux	199	2%	232	2%	405	3%
Omez-DSR	210	2%	310	3%	377	3%
Stamlo Beta	301	4%	326	3%	328	3%
Razo	214	3%	247	2%	285	2%
Atocor	269	3%	274	3%	278	2%
Mintop	172	2%	196	2%	209	2%
Razo D	138	2%	169	2%	200	2%
Others	5,172	61%	6,313	62%	7,336	64%
Total	**8,478**	**100%**	**10,158**	**100%**	**11,690**	**100%**

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

Sales, marketing and distribution network

We generate demand for our products by detailing them to doctors who prescribe them, and meeting with pharmacists to ensure that the pharmacists stock our brands. While we do not sell directly to doctors or pharmacists, our approximately 4,400 sales representatives (which include representatives engaged by us as independent contractors) and front line managers frequently visit doctors and pharmacists throughout the country to detail our products. During the year ended March 31, 2011, we increased our total sales personnel in India by 1,209 including the representatives engaged by us as independent contractors.

We sell our products primarily through clearing and forwarding agents to approximately 2,400 wholesalers who decide which brands to buy based on demand. The wholesalers pay for our products in an agreed credit period and in turn sell these products to retailers. Our clearing and forwarding agents are responsible for transporting our products to the wholesalers. We pay our clearing and forwarding agents on a commission basis. We have insurance policies that cover our products during shipment and storage at clearing and forwarding locations.

Competition

Of the top twenty participants in the Indian formulations market, four are multinational corporations and the rest are Indian corporations. We compete with different companies, depending upon therapeutic and product categories and, within each category, upon dosage strengths and drug delivery. On the basis of sales, we were the 15th largest pharmaceutical company in India, with a market share of 2.15%, according to ORG IMS in its MAT report for the 12-month period ended March 31, 2011. As discussed above, due to the methodology adopted to compile these statistics, we do not believe that these statistics adequately capture the sales performance of one of our largest divisions selling oncology products in India or some of our other divisions selling products to hospitals and institutions in India which, if captured appropriately, would result in our rank being higher.

Some of the key observations on the performance of the Indian pharmaceutical market, as published by ORG IMS in its MAT report for the period ended March 31, 2011, are as follows:

- The Indian pharmaceutical market registered a growth of 15.3% during the year ended March 31, 2011.
- New products launched in the preceding 24 months accounted for 6.5% of total Indian pharmaceutical growth during the year ended March 31, 2011.
- The top 300 existing brands grew at a rate of 17%, which was marginally higher than the Indian pharmaceutical market s overall average, and continued to account for 33% of the market s total sales.
- Legacy brands are performing better than new molecules.
- There was an increasing emergence of bio-similar products to address the needs of patients in the oncology therapeutic area.

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

Government regulations

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

- The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945;
- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954;
- The Narcotic Drugs and Psychotropic Substances Act, 1985;
- The Drugs (Price Control) Order, 1995, read in conjunction with the Essential Commodities Act, 1955; and
- The Medicinal and Toilet Preparations (Excise Duties) Act, 1955.

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

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

All pharmaceutical manufacturers that sell products in India are subject to regulations issued by its Ministry of Health (MoH). These regulations govern or influence the testing, manufacturing, packaging, labeling, storing, record-keeping, safety, approval, advertising, promotion, sale and distribution of products.

MoH approval of an application is required before a generic equivalent of an existing or referenced brand drug can be marketed. When processing a generics application, the MoH waives the requirement of conducting complete clinical studies, although it normally requires bio-availability and/or bio-equivalence studies. Bio-availability indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce a therapeutic effect. Bio-equivalence compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of the active drug substance in the body are the equivalent for the generic drug and the previously approved drug. A generic application may be submitted for a drug on the basis that it is the equivalent of a previously approved drug. Before approving a generic product, the MoH also requires that our procedures and operations conform to cGMP regulations, relating to good manufacturing practices as defined by various countries. We must follow the cGMP regulations at all times during the manufacture of our products. We continue to spend significant time, money and effort in the areas of production and quality testing to help ensure full compliance with cGMP regulations.

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

Under the present drug policy of the Government of India, certain drugs have been specified under the DPCO as subject to price control. The Government of India established the National Pharmaceutical Pricing Authority (NPPA) to control pharmaceutical prices. Under the DPCO, the NPPA has the authority to fix the maximum selling price for specified products. At present, more than 70 drugs and their formulations are categorized as specified products under the DPCO. A limited number of our formulation products fall in this category. Adverse changes in the DPCO list or in the span of price control can affect pricing, and hence, our Indian revenues.

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

Russia and Other Countries of the former Soviet Union

Russia

Russia accounted for 17% of our Global Generics segment s revenues in the year ended March 31, 2011. Pharmexpert, a market research firm, ranked us 15th in sales in Russia with a market share of 1.5% as of March 31, 2011 in its moving annual total report for the 12 months ended March 31, 2011 (the Pharmexpert MAT March 2011 report). Pharmexpert also reported that our Generics revenues from Russia grew by 18.6% in the year ended March 31, 2011, as compared to Russia s pharmaceutical market growth of 7.5%. We were the top ranked Indian pharmaceutical company in Russia.

The following table provides a summary of the revenues of our top 10 brands in the Russian market for the years ended March 31, 2009, 2010 and 2011, respectively:

	2009		2010		2011	
Brand	**Revenues in millions**	**% Total(1)**	**Revenues in millions**	**% Total(1)**	**Revenues in millions**	**% Total(1)**
Nise	1,249	21%	1,862	26%	2,311	26%
Omez	1,281	21%	1,458	20%	1,554	18%
Ketorol	1,078	18%	1,287	18%	1,376	16%
Ciprolet	701	12%	760	11%	778	9%
Senade		0%		0%	598	7%
Cetrine	339	6%	408	6%	590	7%
Enam	315	5%	337	5%	299	3%
Exifine	210	4%	220	3%	217	2%
Bion	171	3%	165	2%	201	2%
Mitotax	148	2%	107	1%	120	1%
Others	311	8%	628	8%	898	9%
Total	**5,803**	**100%**	**7,232**	**100%**	**8,942**	**100%**

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

Our top four brands, Omez, Nise, Ketorol and Ciprolet, accounted for 69% of our Global Generics segment s revenues in Russia in the year ended March 31, 2011. Omez (an anti-ulcerant product), Nise and Ketorol (pain management products) and Ciprolet (an anti-infective product) were ranked as the 45th, 15th, 64th and 153th best selling formulation brands, respectively, in the Russian market as of March 31, 2011 by Pharmexpert in its MAT March 2011 report.

Our strategy in Russia is to focus on the therapeutic areas of gastro-intestinal, pain management, anti-infectives, oncology and cardiovascular. Our focus is on building brand leaders in these therapeutic segments. Omez, Ciprolet, Nise and Ketorol continued to be brand leaders in their respective categories, as reported by Pharmexpert in its MAT March 2011 report.

Growth during the year was driven by targeted sales and marketing initiatives to specialists for prescription products and establishing a separate field force to promote certain over-the-counter medicines.

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Other Countries of the former Soviet Union

We operate in other countries of the former Soviet Union, including Ukraine, Kazakhstan, Belarus and Uzbekistan. For the year ended March 31, 2011, revenues from these countries accounted for approximately 3% of our total Global Generics segment s revenues. The Global Generics revenues from these countries was 1,887 million in the year ended March 31, 2011, as compared to 1,821 million in the year ended March 31, 2010. In all of these markets, we operate through third party distributors who purchase our goods and in turn sell them to wholesalers and retail pharmacies.

Sales, marketing and distribution network

During the year ended March 31, 2011, we further expanded our Russian field force.

Our sales and marketing efforts are driven by a team of 401 medical representatives, 38 regional managers, 6 zonal managers and 26 key account managers to detail our products to doctors in 67 cities in Russia. During the year ended March 31, 2011, we increased our field personnel in Russia by 73.

Our Russian OTC division has 147 medical representatives and is focused on establishing a network of relationships with key pharmacy chains and individual pharmacies. Our Russian hospital division has 39 hospital specialists and 17 key account managers, and is focused on expanding our present network of hospitals and institutes.

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

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

Healthcare reforms and reference pricing

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

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

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

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North America (the United States and Canada)

In North America (the United States and Canada), we sell generic drugs which are the chemical and therapeutic equivalents of reference branded drugs, typically sold under their generic chemical names at prices below those of their brand drug equivalents. Generic drugs are finished pharmaceutical products ready for consumption by the patient. These drugs are required to meet the U.S. FDA standards that are similar to those applicable to their brand-name equivalents and must receive regulatory approval prior to their sale.

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

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

Revenues from North America (the United States and Canada) generics sales increased by 13% to 18,996 million during the year ended March 31, 2011, as compared to 16,817 million in the year ended March 31, 2010. During the year ended March 31, 2011, North America (the United States and Canada) accounted for 36% of the total Global Generics segment s sales. The increase in sales for the year ended March 31, 2011 was mostly because of the revenues from new product launches.

During the year ended March 31, 2011, we launched ten new products. The new products included tacrolimus, fexofenadine pseudoephedrine 180/240 mg, amlodipine benazepril and lansoprazole.

Through the coordinated efforts of our teams in the United States and India, we constantly seek to expand our pipeline of generic products. During the year ended March 31, 2011, we filed 21 ANDAs in the United States, including 7 Paragraph IV filings. During the year ended March 31, 2011, the U.S. FDA granted us 14 final ANDA approvals and 5 tentative ANDA approvals. As of March 31, 2011, we had filed a cumulative total of 170 ANDAs in the United States, out of which 75 ANDAs were pending approval at the U.S. FDA, including 14 tentative approvals. The key product approvals during the year ended March 31, 2011 included tacrolimus capsules, amlodipine besylate and benazepril, lansoprazole delayed release capsules and zafirlukast tablets.

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Sales, Marketing and Distribution Network

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

During the year ended March 31, 2011, we completed a reorganization of our North American (the United States and Canada) generics business to centralize all commercial and business functions into our New Jersey office and centralize all operational functions into our Louisiana facility.

In the year ended March 31, 2008, we launched our own OTC products division and successfully introduced ranitidine 150 mg OTC in September 2007, cetirizine 10 mg OTC in January 2008 and omeprazole mg OTC in December 2009. During the year ended March 31, 2011, sales of our OTC business in the United States generated revenues of 2,734 million.

In Canada, in the year ended March 31, 2002, we entered into a profit sharing arrangement with distributors to market certain of our generic products. This business generated revenues of 596 million during the year ended March 31, 2011.

In April 2008, we acquired BASF s pharmaceutical contract manufacturing business and related facility in Shreveport, Louisiana in the United States of America. This business involves contract manufacturing of generic prescription drugs and OTC products for branded and generic companies in the United States. The acquisition strengthened our supply chain for North America (the United States and Canada) and provides a strong platform for pursuing additional growth opportunities. Expansions to the Shreveport facility are being undertaken as more fully described below under the section titled *Global Generics Manufacturing and Raw Materials* .

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

Competition

Revenues and gross profit derived from the sales of generic pharmaceutical products are affected by certain regulatory and competitive factors. As patents and regulatory exclusivity for brand name products expire, the first off-patent manufacturer to receive regulatory approval for generic equivalents of such products is generally able to achieve significant market penetration. As competing off-patent manufacturers receive regulatory approvals on similar products, market share, revenues and gross profit typically decline, in some cases significantly. Accordingly, the level of market share, revenues and gross profit attributable to a particular generic product is normally related to the number of competitors in that product s market and the timing of that product s regulatory approval and launch, in relation to competing approvals and launches. Consequently, we must continue to develop and introduce new products in a timely and cost-effective manner to maintain our revenues and gross margins. In addition, the other competitive factors critical to this business include price, product quality, prompt delivery, customer service and reputation. Many of our competitors seek to participate in sales of generic products by, among other things, collaborating with other generic pharmaceutical companies or by marketing their own generic equivalent to their branded products. Our major competitors in the U.S. market include Teva Pharmaceutical Industries Limited, Mylan Inc., Watson Pharmaceuticals, Inc., Sandoz, a division of Novartis Pharma A.G., Ranbaxy Laboratories Limited and Caraco Pharmaceuticals Laboratories Limited.

Brand name manufacturers have devised numerous strategies to delay competition from lower cost generic versions of their products. One of these strategies is to change the dosage form or dosing regimen of the brand product prior to generic introduction, which may reduce the demand for the original dosage form as sought by a generic ANDA dossier applicant or create regulatory delays, sometimes significant, while the generic applicant, to the extent possible, amends its ANDA dossier to match the changes in the brand product. In many of these instances, the changes to the

brand product may be protected by patent or data exclusivities, further delaying generic introduction. Another strategy is the launch by the innovator or its licensee of an authorized generic during the 180-day generic exclusivity period, resulting in two generic products competing for the market rather than just the product that obtained the generic exclusivity. This may result in reduced revenues for the generic company which has been awarded the generic exclusivity period.

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Government regulations

U.S. Regulatory Environment

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

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

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

An ANDA applicant in the United States is required to review the patents of the innovator listed in the U.S. FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book, and make an appropriate certification. There are several different types of certifications that can be made. A Paragraph IV filing is made when the ANDA applicant believes its product or the use of its product does not infringe on the innovator s patents listed in the Orange Book or where the applicant believes that such patents are not valid or enforceable. The first generic company to file a Paragraph IV filing may be eligible to receive a six-month marketing exclusivity period from the date a court rules the patent is invalid or not infringed. A Paragraph III filing is made when the ANDA applicant does not intend to market its generic product until the patent expiration. A Paragraph II filing is made where the patent has already expired. A Paragraph I filing is made when the innovator has not submitted the required patent information for listing in the Orange Book. Another type of certification is made where a patent claims a method of use, and the ANDA applicant s proposed label does not claim that method of use. When an innovator has listed more than one patent in the Orange Book, the ANDA applicant must file separate certifications as to each patent. Generally, Paragraph IV and Paragraph III filings are made before the product goes off patent, and Paragraph II and Paragraph I filings are made after the patent has expired.

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

The timing of final U.S. FDA approval of an ANDA depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the brand-name manufacturer is entitled to one or more statutory exclusivity periods, during which the U.S. FDA may be prohibited from accepting applications for, or approving, generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, in certain circumstances the U.S. FDA may now extend the exclusivity of a product by six months past the date of patent expiration if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension.

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In June 2003, the U.S. FDA announced reforms in its generic drug review program with the goal of providing patients with greater and more predictable access to effective, low cost generic alternatives to brand name drugs.

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

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

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

United States Healthcare Reform Patient Protection and Affordable Care Act

In March 2010, the Patient Protection and Affordable Care Act , as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), was signed into law. The PPACA is one of the most significant healthcare reform measures in the United States in decades, and is expected to significantly impact the U.S. pharmaceutical industry. Among the provisions of the PPACA that may affect our business include the following:

- The PPACA is anticipated to expand healthcare coverage to tens of millions of U.S. citizens, mostly those employed in smaller companies and the unemployed. The PPACA also reduces certain co-payments for Medicaid, a joint federal and state health insurance program for the poor. These changes should provide opportunities for us to increase our pharmaceutical products sales volumes in the long term.
- The PPACA also imposes new rules regarding insurance regulation and access. For example, there will be new regulations governing the insurance industry that will prohibit the denial of coverage due to pre-existing diseases, and ban placing lifetime value limits on insurance policy coverages. Indirectly, these reforms should also provide opportunities for us to improve our pharmaceutical products sales volumes in the long term.

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In addition, the PPACA set forth new regulations relating to biological drugs. Among other things, the PPACA creates an abbreviated pathway to U.S. FDA approval of bio-similar biological products and allows the first interchangeable bio-similar product 18 months of exclusivity. These pro-generic provisions may provide increased opportunities for our bio-generics business, but also could increase competition in that field and thus adversely impact the selling prices, costs and/or profit margins for our bio-generics business. Conversely, the PPACA also has some anti-generic provisions, including provisions granting the innovator of a biological drug product 12 years of exclusive use before generic drugs can be approved based on being bio-similar.

The PPACA imposes on pharmaceutical manufacturers a variety of additional rebates, discounts and fees. Among other things, the PPACA includes annual, non-deductible fees that go into effect in 2011 for entities that manufacture or import certain prescription drugs and biologics. This fee will be calculated based upon each organization s percentage share of total branded prescription drug sales to U.S. government programs (such as Medicare, Medicaid and Veterans Affairs and Public Health Service discount programs), provided that the manufacturer must have at least $5 million in sales of branded prescription drugs (as defined in the PPACA) or biologics in order to be subject to the fee. Authorized generic products would generally be treated as branded products. The manufacturers fee for calendar year 2011 is based upon our sales of branded prescription drugs and biologics for the calendar year 2009, which were below the $5 million threshold, and thus we are not subject to the fee for calendar year 2011. In addition, the PPACA changes the computations used to determine Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program by redefining the average manufacturer s price (AMP), effective October 1, 2010, and by using 23.1% instead of 15% of AMP for most branded drugs and 13% instead of 11% of AMP for generic drugs, effective January 1, 2010. The impact of the Medicaid rebate changes has been accounted for in our consolidated financial statements, but it was not material to our U.S. revenues. The PPACA also increases the number of healthcare entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

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.

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

The full impact of the PPACA will be seen as it continues to be implemented, by promulgation of regulations and other administrative and judicial actions. We are continuing to evaluate the impact of the PPACA and how it may affect our business.

Canada Regulatory Environment

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

Europe

The European Union (the EU) presents significant opportunities for the sale of generic drugs. In the EU, the manufacture and sale of pharmaceutical products is regulated in a manner substantially similar to that in the United States. Legal requirements generally prohibit the handling, manufacture, marketing and importation of any pharmaceutical product unless it is properly registered in accordance with applicable law. The registration file relating to any particular product must contain medical data related to product efficacy and safety, including results of clinical testing and references to medical publications, as well as detailed information regarding production methods and quality control. Health ministries are authorized to cancel the registration of a product if it is found to be harmful or ineffective, or manufactured and marketed other than in accordance with registration conditions.

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Our sales of generic drugs in Europe for the year ended March 31, 2011 were 8,431 million, which accounted for 16% of our Global Generics segment s sales, and represented a decrease of 13% as compared to sales of generic drugs in Europe for the year ended March 31, 2010. This decrease was largely on account of our German operations, which were impacted by lower prices in the market resulting from competitive bidding tenders and other significant changes within the German generic pharmaceutical market, as further explained below. Within Europe, significant sales are generated by beta Holding GmbH (betapharm), our German subsidiary. In March 2006, we acquired 100% of betapharm from 3i Group plc, a European private equity firm. This acquisition allowed us to enter the German generics market.

Sales, Marketing and Distribution Network

Germany

In Germany, we sell a broad and diversified range of generic pharmaceutical products under the betapharm brand. Over the last four years, the German pharmaceutical market underwent a significant change. The new healthcare reform (the Statutory Health Insurance (SHI) Competition Strengthening Act or Wettbewerbsstärkungsgesetz (GKV WSG) (an act to strengthen the competition in public health insurance), which was effective as of April 1, 2007, has significantly increased the power of insurance companies and statutory health insurance funds (SHI funds) to influence dispensing of medicines.

Pursuant to the new law, pharmaceutical products covered by rebate contracts with insurance companies have to be prescribed by physicians and dispensed by pharmacies. This has increased the power of insurance funds. As a result, several SHI funds have entered into rebate contracts with pharmaceutical companies, causing pressure on margins. Pursuant to the rapid shift of the German generic pharmaceutical market towards a tender (i.e., competitive bidding) based supply model, further tenders were announced by several SHI funds during the year ended March 31, 2011. We participated in these tenders through our wholly-owned subsidiary, betapharm.

Traditionally, the SHI fund contracts had the elements of basic rebate and incremental rebates on additional prescriptions generated through persons insured by these SHI funds. Since the new healthcare reforms, the SHI funds have been aggressive in negotiating rebates for their contracts. Consequently, in recent years they have negotiated higher discounts.

With the above-mentioned discount contracts being effective, and further competitive bidding tenders announced by SHI funds, long term changes in the German market s structural framework are ongoing. The German generics market has experienced a shift to a tender based supply model from the previous prescription based model, where the key driver for generating sales had previously been doctors perceptions and pharmacists influence. In response to these market changes, betapharm has undergone a comprehensive restructuring of its sales force, with a reduction of more than 200 employees since we acquired it in March 2006.

United Kingdom and other Countries within Europe

We market our generic products in the United Kingdom and other EU countries through our U.K. subsidiary, Dr. Reddy s Laboratories (U.K.) Limited. This subsidiary was formed in the year ended March 31, 2003 after our acquisition of Meridian Healthcare Limited, a United Kingdom based generic pharmaceutical company. We currently market 29 generic products in such countries, representing 103 dosage strengths.

We also seek to expand our presence to other European countries, either directly or through strategic alliances. Other European countries where we have a physical presence and have been able to build our franchise include Romania and Italy. We have a wholly-owned subsidiary in Romania, and our sales in Romania during the year ended March 31, 2011 were 712 million.

We market our generic products in Italy through our Italian subsidiary, Dr. Reddy s SRL. This subsidiary was formed in the year ended March 31, 2009 in connection with our acquisition of Jet Generici SRL, a company engaged in sale of generic finished dosages in Italy.

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Competition

In Germany, we believe that the companies having rebate contracts with SHI funds are gaining market shares. Our key competitors within the German generics market include the Sandoz group of Novartis Pharma A.G. (including its Hexal, Sandoz and 1A Pharma subsidiaries), the Ratiopharm group of Teva Pharmaceutical Industries Ltd. (including its Ratiopharm and CT Arzneimittel subsidiaries) and the Stada group of Stada Arzneimittel AG (including its Stada and Aliud subsidiaries). With the discount contracts with SHI funds becoming effective, prices have become one of the most important competitive factors.

The United Kingdom is one of the largest markets for generic pharmaceuticals in Europe. It is also one of the most competitive markets, due to its very low barriers to entry. Significant vertical integration exists between wholesalers and retailers, ensuring low prices as long as there are several suppliers. The number of major pharmaceutical companies in the U.K. pharmaceutical market has decreased due to consolidation.

Government regulations

European Union Regulatory Environment

The activities of pharmaceutical companies within the European Union are governed by Directive 2001/83EC as amended. This Directive outlines the legislative framework, including the legal basis of approval, specific licensing procedures, and quality standards including manufacture, patient information and pharmaco-vigilance activities. Our U.K. facilities are licensed and periodically inspected by the U.K. Medicines and Health Care Products Regulatory Agencies (MHRA) Inspectorate, which has extensive enforcement powers over the activities of pharmaceutical manufacturers. Non-compliance can result in product recall and closure. In addition, the U.K. MHRA Inspectorate has approved and periodically inspected our manufacturing facility based in Andhra Pradesh, India for the manufacture of generic tablets and capsules for supply to Europe.

All pharmaceutical companies that manufacture and market products in Germany are subject to the rules and regulations defined by the German drug regulator, the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) and the Federal Drug Authorities. All the licensed facilities of pharmaceutical companies in Germany are periodically inspected by the Federal Drug Authorities, which has extensive enforcement powers over the activities of pharmaceutical companies. Non-compliance can result in closure of the facility. Prior approval of a Marketing Authorization is required to supply products within the European Union. Such Marketing Authorizations may be restricted to one member state then recognized in other member states or can cover the whole of the European Union, depending upon the form of registration elected. In Germany, Marketing Authorizations have to be submitted for approval to the BfArM.

Generic or abridged applications omit full non-clinical and clinical data but contain limited non-clinical and clinical data, depending upon the legal basis of the application or to address a specific issue. The majority of our generic applications are made on the basis of essential similarity although other criteria may be applied. In the case of an essentially similar application, the applicant is required to demonstrate that its generic product contains the same active pharmaceutical ingredients in the same dosage form for the same indication as the innovator product. Specific data is included in the application to demonstrate that the proposed generic product is essentially similar to the innovator product with respect to quality, safe usage and continued efficacy. European Union laws prevents regulatory authorities from accepting applications for approval of generics that rely on the safety and efficacy data of an innovator of a branded product until the expiration of the innovator s data exclusivity period (currently 6 or 10 years from the first marketing authorization in the European Union). The applicant is also required to demonstrate bio-equivalence with the reference product. Once all these criteria are met, a Marketing Authorization may be considered for grant.

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

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In Germany, the government continues to focus on reducing health care spending. During the year ended March 31, 2007, the German government passed the Economic Optimization of Pharmaceutical Care Act (or Arzneimittelversorgungs-Wirtschaftlichkeisgestz or AVWG) which became effective as of May 1, 2006, which was designed to contain increased pharmaceutical costs.

Another German law entitled the Statutory Health Insurance Competition Strengthening Act (or Wettbewerbsstärkungsgesetz or GKV WSG), which became effective as of April 1, 2007, has significantly increased the ability of insurance companies and SHI funds to influence dispensing of medicines. Pursuant to the GKV WSG law, pharmaceutical products covered by rebate contracts with insurance companies must be prescribed by physicians and dispensed by pharmacies. This has increased the role of insurance funds in the German pharmaceutical market.

During the fiscal year ended March 31, 2011, the German government introduced a new law entitled Act on the reorganization of the pharmaceutical market in the public health insurance (or *Arzneimittel Marktes Neuordnungs Gesetz* , commonly referred to as AMNOG), which affects reimbursement of drugs within the Germany s statutory health care system in order to further control the costs of medical care. The key elements of this law are as follows:

- Historically, the pharmaceutical companies had been free to set the initial asking price for drugs in the German public health system, subject to certain mandatory rebates. Under this new law, a pharmaceutical company will determine the price for a new drug or new therapeutic indication for the first year after launch, but must submit to the Joint Federal Committee (the Gemeinsamer Bundesausschuss or G-BA) a benefit assessment dossier on the drug at or prior to its launch. The G-BA will analyze whether the drug shows an additional clinical benefit in comparison to a corresponding established drug (the appropriate comparator therapy).
  - If an additional benefit is established, the pharmaceutical company must negotiate the price of the drug with the Federal Association of the health insurance funds. If no agreement is reached in the negotiation, then the price will be determined pursuant to an arbitration procedure. There must be a minimum term of one year.
  - If no additional benefit is established, the drug is immediately included into a group of drugs with comparable pharmaceutical and therapeutic characteristics, for which maximum reimbursement prices have already been set. If this is not possible due to the drug s novelty, then the pharmaceutical company must negotiate a reimbursement price with the Federal Association of the health insurance funds that may not exceed the costs of the appropriate comparator therapy.
  - The prices determined pursuant to the above procedures will also apply to private insurance agencies, privately insured persons and self-payers, although they may negotiate further discounts.
  - For drugs developed specifically to treat rare medical conditions that are designated as orphan drugs , the orphan drug will be presumed to have an additional benefit under certain circumstances.
- A new regulation for packaging size to be fully implemented by 2013. Standard sizes will be based upon the duration of therapies, instead of based on fixed quantity. Three different types of package sizes are now allowed: N1-packages for treatment periods of 10 days; N2-packages for treatment periods of 30 days; and N3-packages for treatment periods of 100 days. During the transition period, discrepancies of 20%, 10% and 5% will be respectively accepted for N1, N2 and N3 packages.
- The law increases the choice to patients by the use of co-payment as an option for patients opting for a non-rebated generic drug.

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Impairment

During the year ended March 31, 2009, there were significant changes in the German generic pharmaceutical market which impacted the operations of our German subsidiary betapharm. The biggest change was the shift to a tender based supply model within the German generic pharmaceutical market, as most prominently evidenced by the announcement of a large competitive bidding (or tender) process by the Allgemeine Ortskrankenkassen (AOK), the largest German statutory health insurance fund (SHI fund). In addition, there was a continuing decrease in prices of pharmaceutical products and an increased quantity of discount contracts being negotiated with other SHI funds.

In the AOK tender during the year ended March 31, 2009, we were awarded 8 products (with 33 contracts) covering AOK-insured persons in various regions within Germany, which represented 17% of the overall volume of the products covered by the AOK tender. betapharm was among the top three companies in terms of number of contracts awarded. While our future sales volumes are expected to increase for the products awarded to us under the AOK tender, we expected that our overall profit margins under the AOK tender arrangement were likely to be significantly lower due to decreased prices per unit of product. Also, the products awarded to us in the AOK tender did not include products which we consider to be our key products.

Due to these developments, as at March 31, 2009, we tested the carrying value of our product related intangibles and goodwill for impairment. The impairment test resulted in our recording an impairment loss on certain product related intangibles amounting to 3,167 million and impairment loss of 10,856 million on goodwill of the betapharm cash generating unit during the year ended March 31, 2009. Furthermore, due to the above adverse market developments and consequential impairment losses recorded by us in our betapharm cash generating unit, we also reviewed the useful life of our indefinite life intangible asset trademark/brand beta and revised it to 12 years.

During the year ended March 31, 2010, the adverse conditions continued in the German generics market, with increasing tender activity by a number of SHI funds (in addition to AOK). The SHI funds opted for tenders to a greater degree than we had anticipated during the year ended March 31, 2009. The final results of a majority of these tenders were announced, with a lower than anticipated success rate for betapharm.

Due to such market conditions, we reassessed the impact of these tenders on our future forecasted sales and profits during the year ended March 31, 2010. As a result of this re-evaluation, the carrying amounts of both the product related intangibles and the betapharm cash generating unit were determined to be higher than their respective recoverable amounts. Accordingly, an impairment loss of 2,112 million for the product related intangibles and 6,358 million for the betapharm cash generating unit was recognized in our income statement during the year ended March 31, 2010. Of the impairment loss pertaining to the betapharm cash generating unit, 5,147 million was allocated to the carrying value of goodwill during the year ended March 31, 2010, thereby impairing the entire carrying value. The remaining 1,211 million was allocated to the trademark/brand beta , which forms a significant portion of the intangible asset value of the betapharm cash generating unit, during the year ended March 31, 2010.

To offset the impact of reduced prices on betapharm s profitability, we increased the proportion of betapharm s products sourced from Indian manufacturing facilities, restructured betapharm s work force (terminating approximately 200 employees during the year ended March 31, 2010) and reduced betapharm s selling, general and administrative expenses to achieve a more sustainable structure in light of the current tender-based model and economic climate in Germany.

During the quarter ended December 31, 2010, AOK announced a new set of tenders. Our subsidiary betapharm was awarded the tenders for 12 products in 74 lots. The success rate for betapharm s bids for this tender was increased as compared to prior years, and our revenue is expected to increase for the products won by us in this tender. However, in view of competitive bidding, the selling prices offered are lower. Due to the inconsequential favorable impact on net margins, we concluded that no adjustment to previously recorded impairments losses were necessary.

Other markets of our Global Generics segment

In March 2009, we announced a realignment of our Global Generics segment s strategy for finished dosages to focus on certain key geographies, and that we would gradually exit from some of our very small, distributor driven markets. During the year ended March 31, 2010, we exited from all such small, distributor driven markets. The markets we exited accounted for less than 1% of our total company revenues.

The realignment resulting from this exit from small, distribution driven markets represents an important new focus in our Global Generics segment. Not only has this realignment resulted in consolidation and reduction in the complexity

of our operations, it will also enable us to significantly enhance our customer service and to increase our market share in the key geographies where we already have a considerable presence.

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Our revenues from other markets of this segment were 3,365 million in the year ended March 31, 2011, as compared to 2,869 million in the year ended March 31, 2010. The other key markets of our Global Generics segment include Venezuela, South Africa, New Zealand, Brazil, Jamaica, Sri Lanka and Vietnam.

Our revenues from Venezuela were 1,162 million in the year ended March 31, 2011, as compared to 1,105 million in the year ended March 31, 2010, with such increase primarily due to increases in both sales volumes and prices. The increase in prices was largely attributable to Venezuela s high inflation rates during these periods. The benefit of these price increases was partially offset by a devaluation in the exchange rate by the Venezuelan government effective as of January 1, 2011.

In South Africa, we operate through our wholly-owned subsidiary, Dr. Reddy s Laboratories (Proprietary) Limited. Previously we held a controlling interest of 60% and Calshelf Investments 214 (Proprietary) Limited held a non-controlling interest of 40% in this entity. During the year ended March 31, 2011, we acquired the 40% non-controlling interest, and the entity became our wholly-owned subsidiary. Our revenues from this country were 694 million in the year ended March 31, 2011, as compared to 444 million in the year ended March 31, 2010. This increase in revenues was primarily due to an increase in sales volumes of our key brand Omez, our brand of omeprazole, as well as the launch of two new products, moxifloxacin and desloratidine.

In Australia, during the year ended March 31, 2011 we received approvals for three new products, amlodipine, terbinafine and risperidone, and commenced selling the latter two products. In Australia, we operate through Dr. Reddy s Laboratories (Australia) Pty Ltd. which, in past years, was a joint venture in which we owned a 70% equity interest. During the year ended March 31, 2010, we acquired the remaining 30% stake in such joint venture from the minority equityholders, and it is now our wholly-owned subsidiary.

GSK Alliance

During the year ended March 31, 2010, we entered into a strategic partnership with GlaxoSmithKline plc (GSK) to develop and market select products across emerging markets outside India. This partnership will expand our reach in emerging economies, and leverage our product portfolio and process development strengths with GSK s market knowledge and presence in such markets. The products will be manufactured by us, and will be licensed and supplied to GSK in markets such as Latin America, Africa, the Middle East and Asia Pacific, excluding India. Considering the time required to file the dossiers in various markets, to obtain their approval from the respective authorities and to launch the products, this alliance is expected to make a meaningful contribution to our revenues only after a period of two to three years.

Global Generics Manufacturing and Raw Materials

Manufacturing for our Global Generics segment entails converting active pharmaceutical ingredients (API) into finished dosages. As of March 31, 2011, we had eight manufacturing facilities within this segment. Six of these facilities are located in India and two are located in the United States (Shreveport, Louisiana and Bristol, Tennessee). We also have one packaging facility in the United Kingdom. Two of the Indian facilities, one each at Hyderabad and Vizag, are also U.S. FDA compliant. During the year ended March 31, 2010, the two facilities in India and the one in Louisiana were inspected by the U.S. FDA and there were no major open audit observations. The manufacturing site in Vizag, India is a state of art facility for the manufacture of injectable form and potent products. The Vizag facility has satisfactorily passed inspection by the National Health Surveillance Agency (also known as ANVISA) of Brazil and by the German drug regulator Bundesinstitut für Arzneimittel und Medizinprodukte (also known as BfARM). These facilities are designed in accordance with Good Manufacturing Practice (GMP) requirements and are used for the manufacture of tablets and hard gelatin capsules, for sale in India as well as regulated and highly regulated markets.

We manufacture most of our finished products at these facilities and also use third-party manufacturing facilities as we determine necessary. We also purchase some products from approved third parties based on the necessity and requirement of our markets. For each of our products, we endeavor to identify alternate suppliers of our products and the processes applicable to our products.

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For the products intended to be sold in highly regulated markets, such as the United States, Europe, Australia, New Zealand, South Africa and Brazil, we are required to identify the suppliers of active raw materials for our products in the drug applications and dossiers. If raw materials for a particular product become unavailable from an approved source specified in a drug application, we are required to qualify a substitute supplier with the regulatory authorities, which could interrupt the manufacturing of the affected product. To the extent practicable, we attempt to identify more than one supplier in each drug application or make plans for alternate vendor development from time to time, considering the supplier s history and future product requirements. However, some raw materials are available only from a single source and, in some of our drug applications, only one supplier of raw materials has been identified, even in instances where multiple sources exist. In addition, we obtain a significant portion of our inactive pharmaceutical ingredients from foreign suppliers. Arrangements with international raw material suppliers are subject to, among other things, respective country regulations, various import duties and other government clearances.

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

In addition to our manufacturing facilities within India, we have manufacturing and packaging facilities outside India (such as our packaging facility at Beverley, United Kingdom, our manufacturing facilities at Shreveport, Louisiana, and Bristol, Tennessee, U.S.A.) and contract manufacturing sites. All these sites are approved by the respective regulatory bodies in the jurisdictions where they are located. In Germany, betapharm s products are mainly manufactured at our facilities in India and through some contract manufacturers at third party locations. We intend to continue shifting the manufacturing of betapharm products to our facilities in India. The logistics services for storage and distribution in Germany are outsourced to a third party service provider.

Manufacturing of finished dosages for less regulated markets is also subject to strict quality and contamination controls throughout the manufacturing process. We manufacture formulations in various dosage forms including tablets, capsules, injections, liquids and creams. These dosage forms are then packaged, quarantined and subject to stringent quality tests, to assure product quality before release into the market. We manufacture our key brands for our Indian markets at our facilities in Baddi, Himachal Pradesh and Yanam, Pondicherry, to take advantage of certain fiscal benefits offered by the Government of India, which include exemption from income tax and excise duty, in the case of Baddi, Himachal Pradesh, and exemption from income tax, in the case of Yanam, Pondicherry, for a specified period.

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

Product Transfers and Capacity Expansion

To meet growing demand in regulated markets, we are in the process of making one additional finished dosage facility currently serving branded markets U.S. FDA compliant. This will ease the pressure and optimize the capacities across our plants. Furthermore, we are also in the process of expanding our existing facilities and setting up new manufacturing facilities, including a plant which is part of a Special Economic Zone.

Shreveport Expansion

In July 2010, we entered into an agreement with the state of Louisiana, in the United States of America, to expand our Shreveport operations with tax incentives and support from the state and local governments. The project aims to retain over 161 jobs while adding approximately 73 new jobs, and represents a capital investment of up to U.S.$16.5 million.

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The plans to expand the scope and scale of our Shreveport facility are driven by a combination of several factors including, among other considerations, the strategic fit of the products and capabilities of the site with our corporate growth objectives, the work ethic of the people of North Louisiana, and the state and local tax incentives offered to us. The 300,000-square-foot Shreveport facility is the largest producer of silver sulfadiazine cream and the second-largest producer of ibuprofen for the North American (the United States and Canada) market. This planned expansion will allow us to support multiple new products at the site.

Pharmaceutical Services and Active Ingredients Segment (PSAI)

Our PSAI segment accounted for 26% of our total revenues for the year ended March 31, 2011. This segment includes active pharmaceutical ingredients and intermediates (API), also known as active pharmaceutical products or bulk drugs, which are the principal ingredients for finished pharmaceutical products. This segment also includes contract research services and the manufacture and sale of API and steroids in accordance with specific customer requirements. API become finished pharmaceutical products when the dosages are fixed in a form ready for human consumption (such as a tablet, capsule or liquid) using additional inactive ingredients. We produce and market more than 100 different APIs in numerous markets. We export API to emerging markets, as well as developed markets, covering more than 80 countries. Our principal markets in this business segment include North America (the United States and Canada) and Europe. Our PSAI segment s API business is operated independently from our Global Generics segment and, in addition to supplying API to our Global Generics segment, our PSAI segment sells API to third parties for use in creating generic products, subject to any patent rights of other third parties. Our PSAI segment s API business also manufactures and supplies all of the API requirements of our pharmaceutical services business. The research and development group within our API business contributes to our business by creating intellectual property (principally with respect to novel and non-infringing manufacturing processes and intermediates), providing research intended to reduce the cost of production of our products and developing approximately 15-20 new products every year.

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

Sales, Marketing and Distribution

Emerging Markets. India is an important emerging market, accounting for 13% of the PSAI segment s revenues in the year ended March 31, 2011. In India, we market our API products to Indian and multinational companies, many of whom are also our competitors in our Global Generics segment. In India, our top six products are ciprofloxacin, ranitidine, clopidogrel, ramipril, losartan potassium and ibuprofen. The market in India is highly competitive, with severe pricing pressure and competition from cheaper Chinese imports in several products.

In India, our sales team works closely with our sales agents to market our products. We market our products through these sales agents, commonly referred to as indenting agents, with a focus on regional sales and marketing. The sales are made directly from the factory.

Our sales to other emerging markets were 6,838 million for the year ended March 31, 2011. Our other key emerging markets include Israel, Turkey, Brazil, Mexico, South Korea, Japan, Bangladesh, Malaysia, Saudi Arabia, Argentina, Australia, Jordan, Egypt, Thailand, Chile, Singapore, China, Taiwan, Peru, Uruguay, Indonesia, Tunisia and Colombia. While we work through our agents in these markets, our zonal marketing managers also interact directly with our key customers in order to service their requirements. Our strategy is to build relationships with top customers in each of these markets and partner with them in product launches by providing timely technical and analytical support.

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Developed Markets. Our principal markets are North America (the United States and Canada) and Europe. In the United States and Europe, over the next two years, a large number of products are expected to lose patent protection, providing growth opportunities for our API business. We have been marketing API in the United States for over a decade. We market through our subsidiaries in the United States and Europe. These subsidiaries are engaged in all aspects of marketing activity and support our customers pursuit of regulatory approval for their products, focusing on building long-term relationships with the customers.

With respect to API, we filed 70 DMFs worldwide in the year ended March 31, 2011, 21 of which were filed in the United States, 3 in Canada, 16 in Europe and 30 in other countries. With these filings, we have a total of 173 U.S. DMFs filed as of March 31, 2011. Also, as of March 31, 2011, we had filed 102 DMFs in Europe and had 38 certificates of suitability granted by European authorities.

Including our Rest of the World markets (i.e., all markets other than North America, Europe, Russia and other countries of the former Soviet Union and India), as of March 31, 2011, we have made a total of 476 filings worldwide. For most of these, we are either already supplying commercial quantities or development quantities of API to various generic formulators.

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

Manufacturing and Raw Materials

The infrastructure for our PSAI segment consists of six U.S. FDA-inspected plants in India, a U.S. FDA-inspected plant in Mexico, a U.S. FDA-inspected plant in Mirfield, United Kingdom and three technology development centers, two of which are in Hyderabad, India and one of which is in Cambridge, United Kingdom.

India. All of the facilities in India are located in the state of Andhra Pradesh. With over 840 reactors of different sizes offering 2.6 million liters of reaction volume annually, we have the flexibility to produce quantities that range from a few kilograms to several metric tons. The manufacturing process consumes a wide variety of raw materials that we obtain from sources that comply with the requirements of regulatory authorities in the markets to which we supply our products. We procure raw materials on the basis of our requirement planning cycles. We utilize a broad base of suppliers in order to minimize risk arising from dependence on a single supplier. We also source several APIs from third party suppliers for the emerging markets to optimally utilize our in-house manufacturing capacities for the developed markets, which are more profitable relative to the emerging markets. During the year ended March 31, 2011, approximately 5% of our total revenues resulted from sales of API procured from third-party suppliers. We maintain stringent quality controls when procuring materials from third-party suppliers.

Our API outsourcing activities were improved during the year ended March 31, 2011 as a result of a new initiative to strengthen our relationships with our API vendors, who we view as our business partners, through a dedicated quality assurance team. This initiative has helped us maintain a strong and sustaining supply chain. In line with our philosophy of ensuring that our business partners grow with us, we have implemented a strong infrastructure to improve the performance of our partners, both in volume and quality. This includes a dedicated team of professionals from our technical, quality and commercial teams working with the partners, as well as a dedicated quality laboratory and a development laboratory. This has further helped us to mitigate risks due to single source and quality related issues.

The prices of our raw materials generally fluctuate in line with commodity cycles, though the prices of raw materials used in our active pharmaceutical ingredients business are generally more volatile. Raw material expense forms the largest portion of our operating expenses. We evaluate and manage our commodity price risk exposure through our operating procedures and sourcing policies.

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

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

The Dowpharma Small Molecules business, which we acquired from The Dow Chemical Company in April 2008, continues to offer niche capabilities, such as biocatalysis, chemocatalysis and hydroformulation, to provide cost effective solutions for chiral molecules. We are leveraging the acquired business and intangibles (including customer contracts, associated API products, process technology and know-how, technology licensing rights, trademarks and other intellectual property) to provide services and products to our existing customers, as well as new customers. The approximately 80 employees who joined us as a part of the acquisition have been integrated within our business. The non-exclusive license to Dow s Pfēnex Expression Technology for biocatalysis development, also acquired as part of the acquisition, continues to offer us opportunities to provide technology leveraged manufacturing services to innovators, including major global pharmaceutical companies. Our contract research and manufacturing business is uniquely positioned in the market where it utilizes assets (both in terms of physical assets and technical know-how) of a vertically integrated pharmaceutical company and combines this with the service model which we built over the last few years.

Competition

The global API market can broadly be divided into highly regulated and less regulated markets. The less regulated markets offer low entry barriers in terms of regulatory requirements and intellectual property rights. The highly regulated markets, like the United States and Europe, have high entry barriers in terms of intellectual property rights and regulatory requirements, including facility approvals. As a result, there is a premium for quality and regulatory compliance along with relatively greater stability for both volumes and prices. During the year ended March 31, 2011, the competitive environment for the API industry underwent significant changes. These changes included increased consolidation in the global generics industry and vertical integration of some key generic pharmaceutical companies. As an API supplier, we compete with a number of manufacturers within and outside India, which vary in size. Our main competitors in this segment are Hetero Drugs Limited, Divi s Laboratories Limited, Aurobindo Pharma Limited, Ranbaxy Laboratories Limited, Cipla Limited, Matrix Laboratories Limited, Sun Pharmaceutical Industries Limited and MSN Laboratories Limited, all based in India. In addition, we experience competition from European and Chinese manufacturers, as well as from Teva Pharmaceuticals Industries Limited, based in Israel.

With respect to our custom pharmaceuticals business, we believe that contract manufacturing is a significant opportunity for Indian pharmaceutical companies, based on their strengths of a skilled workforce and a low-cost manufacturing infrastructure. Key competitors in India include Divis s Laboratories Limited, Dishman Pharmaceuticals & Chemicals Limited, Jubilant Organosys Limited and Nicholas Piramal India Limited. Key competitors from outside India include Lonza Group, Koninklijke DSM N.V., Albany Molecular Research, Inc., Patheon, Inc. and Cardinal Health, Inc. We distinguish ourselves from our key competitors by offering a wider range of cost effective services spanning the entire pharmaceutical value chain. Growth in contract manufacturing is likely to be driven by increasing outsourcing of late-stage and off-patent molecules by large pharmaceutical companies to compete with generics. India is emerging as an alliance and outsourcing destination of choice for global pharmaceutical companies. Companies such as Roche, Bayer, Aventis, Novartis, Eli Lilly, Merck Sereno and GlaxoSmithKline are all executing plans to make India the regional hub for API and supply of bulk drugs.

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Government regulations

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

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

Our PSAI segment is subject to a number of government regulations with respect to pricing and patents as discussed below in our Global Generics segment.

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

Proprietary Products Segment

Our Proprietary Products segment involves the discovery of new chemical entities and differentiated formulations for subsequent commercialization and out-licensing. It also involves our specialty pharmaceuticals business which launched sales and marketing operations for in-licensed dermatology products in the year ended March 31, 2009.

During the year ended March 31, 2011, we leveraged our semi-virtual research and development model to expand our portfolio of drug discovery, differentiated and specialty formulations programs. This was achieved by efficiently collaborating with discovery biotechnology companies and service providers, and tapping their expertise in the niche areas of our interest. We also successfully progressed towards building a sustainable mix of proprietary, branded research and development portfolio with significantly reduced fixed costs.

Proprietary Products business

In our Proprietary Products segment, we actively pursue discovery and development of new molecules, sometimes referred to as New Chemical Entities (or NCEs) and differentiated formulations. Our research and development programs focus on the following therapeutic areas:

- metabolic disorders;
- cardiovascular disorders;
- bacterial infections;
- dermatological indications; and
- pain and inflammation.

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Our principal research laboratory is based in Hyderabad, India. As of March 31, 2011, we employed a total of 75 scientists, including approximately 11 scientists who held Ph.D. degrees, across all of this segment s locations. For NCEs, differentiated and specialty formulations, we pursue an integrated research strategy through a mix of translational, formulation and analytical research at our laboratories. Our research strategy focuses on discovery of new molecular targets, designing of screening assays to screen promising molecules and developing novel formulations of currently marketed drugs or combinations thereof to address unmet medical needs.

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

Alliances and Partnerships

In September 2005, we entered into a co-development and commercialization agreement with Denmark based Rheoscience A/S for the joint development and commercialization of Balaglitazone (DRF 2593), a partial PPAR-gamma agonist, for the treatment of type 2 diabetes. In the year ended March 31, 2009, we agreed with Rheoscience to amend the terms of this agreement. Under the terms of the amended agreement, we and Rheoscience will share costs for Phase III development according to certain pre-determined formulas. The parties will also share eventual revenues, whether from direct sales of products by either party or from third parties who may be responsible for marketing the product in certain countries. The agreement is valid for a period of ten years from the date of commercialization. We retain the right to supply clinical development and commercial quantities of the requisite active pharmaceutical ingredients on an arm s-length basis to all parties that commercialize DRF 2593. DRF 2593 commenced the first Phase III clinical trials in August 2007, which was completed in December 2009. The future strategy with respect to this molecule is currently being developed. In order to obtain approval from either the U.S. FDA or its European counterpart, the European Medicines Agency, many Phase III clinical trials will be required to be conducted over several years (the precise duration of which will be decided by the applicable regulatory authorities, after reviewing some of our Phase III clinical trials data).

In April 2010, we completed Phase I clinical studies for DRL 17822, a selective inhibitor of cholesterylester transfer protein (or CETP), for the treatment of dyslipidemia, atherosclerosis and associated cardiovascular diseases. The compound showed potent elevation in high-density lipoprotein (or HDL) cholesterol and reduction of atherosclerotic plaques in animals, and has a clean safety profile in preclinical studies. We also conducted Phase II enabling non-clinical studies during the year ended March 31, 2011, and filed a clinical trial application for conducting Phase II studies with the U.S. FDA.

During the year ended March 31, 2011, we entered into collaborations with discovery biotechnology companies to initiate new chemical entities (NCEs) and differentiated formulations programs in the therapeutic areas of our interest. During the year ended March 31, 2011, we initiated a Phase III clinical trial for DRL-NAB-P2 targeting onchomycosis and filed Investigational New Drug (IND) applications with the U.S. FDA for DFA-02 targeting bacterial infections, DRL-NAB-P5 targeting Psoriasis and DRL-NAB-P6 also targeting Psoriasis.

Our investments into research and development of NCEs, differentiated formulations and specialty formulations have been consistently focused towards developing promising therapeutics. The compounds currently under active development in our pipeline include:

Compound	Therapeutic Area	Status	Remarks
New Chemical Entities (NCEs)			
DRF 2593	Metabolic disorders	Phase III	In Phase III clinical testing for Type 2 diabetes partnered with Nordic Biosciences
DRL 17822	Metabolic disorders/ Cardiovascular disorders	Phase II	Targeting dyslipidemia / atherosclerosis
Differentiated and Specialty Formulations			
DRL-NAB-P2	Onchomycosis	Phase III	In Phase III clinical testing for Onchomycosis

DRL-NAB-P5	Psoriasis	Clinical	Targeting Psoriasis
DRL-NAB-P6	Psoriasis	Clinical	Targeting Psoriasis
DFA-02	Anti-Infectives	Clinical	Targeting bacterial infections
DFP-02	Migraine	Clinical	Targeting Migraines

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Patents. The status of our patents filed and issued as of March 31, 2011 is summarized below:

Category	USPTO(1) (Filed)	USPTO(1) (Granted)	PCT(2) (Filed)	India (Filed)	India (Granted)
Anti-diabetic	85	15	62	117	45
Anti-cancer	18	10	14	45	15
Anti-bacterial	8	6	10	22	4
Anti-inflammation/Cardiovascular	40	20	28	21	2
Anti-ulcerant	1	1		1	
Miscellaneous	4	1	3	23	8
Differentiated formulations	3 (provisional)		4	2 (provisional)	
TOTAL	**159**	**53**	**121**	**231**	**74**

(1) USPTO means the United States Patent and Trademark Office.

(2) PCT means the Patent Cooperation Treaty, an international treaty that facilitates foreign patent filings for residents of member countries when obtaining patents in other member countries.

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

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

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

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

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

Competition

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

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

Government regulations

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

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

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

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

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

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

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

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

Promius Pharma

Promius Pharma is our subsidiary in Bridgewater, New Jersey in the United States of America focusing on our U.S. Specialty Business i.e., development and sales of branded specialty products. It has a portfolio of in-licensed patented dermatology products and off-patent cardiovascular products. It also has an internal pipeline of dermatology products that are in different stages of development. Promius Pharma s current portfolio contains innovative products for the treatment of seborrheic dermatitis, onychomycosis, acne, psoriasis and androgenic alopecia. It has commercialized three products: EpiCeram®, which is a skin barrier emulsion for the treatment of atopic dermatitis; Scytera , which is foam for the treatment of psoriasis; and Promiseb , which is a cream for the treatment for seborrheic dermatitis. Over the last year, since the business has been launched, Promius Pharma has been able to enter into successful partnerships with companies such as Ceragenix, Foamix, Sinclair and Antares for in-licensing of products. It also leverages on our research, development and manufacturing facilities at Hyderabad, India. Promius Pharma also works with various third party research organizations in conducting product development, pre-clinical and clinical studies. Promius Pharma has approximately 50 sales representatives in the field. Its sales force targets physicians in the field of dermatology and is supported by a direct marketing team and a public relations program. In addition to its sales force, Promius Pharma s account managers also call on purchasing agents for drug wholesalers and chain drug stores.

The manufacturing of Promius Pharma s products has been outsourced to third party manufacturers based in the United States and Europe. The third party manufacturers are responsible for sourcing the raw materials required for manufacturing the products. However, in some cases we source the active pharmaceutical ingredients and supply them to the third party manufacturer. The logistics services for storage and distribution have also been outsourced to a third party service provider.

On March 31, 2011, through our wholly owned subsidiary Promius Pharma LLC, we entered into a collaboration agreement with Coria Laboratories Limited (a subsidiary of Valeant Pharmaceuticals International, Inc.) (Coria) for the right to manufacture, distribute and market its Cloderm® (clocortolone pivalate 0.1%) product in the United States. Cloderm® is a cream used for treating dermatological inflammation, and is an existing U.S. FDA approved product. In addition to acquiring all relevant U.S. FDA product regulatory approvals and intellectual property rights (other than trademarks) associated with Cloderm®, we also acquired an underlying raw material supply contract and an exclusive license to use the trademark Cloderm® for a period of 8 years. The rights and ownership of this trademark are to be transferred from Coria to us at the end of the 8th year, subject to our payment of all royalties under the contract. Consideration for these transactions includes an upfront payment of 1,605 million (U.S. $36 million) in cash and contingent consideration in the form of a royalty equal to 4% of our net sales of Cloderm® in the United States during the 8 year trademark license period.

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4.C. ***Organizational structure***

Dr. Reddy s Laboratories Limited is the parent company in our group. We had the following subsidiary companies where our direct and indirect ownership was more than 50% as of March 31, 2011:

Name of Subsidiary	Country of Incorporation	Percentage of Direct/ Indirect Ownership Interest
DRL Investments Limited	India	100%
Reddy Pharmaceuticals Hong Kong Limited	Hong Kong	100%
OOO JV Reddy Biomed Limited	Russia	100%
Reddy Antilles N.V.	Netherlands	100%
Reddy Netherlands B.V.	Netherlands	100%(1)
Reddy US Therapeutics, Inc.	U.S.A.	100%(1)
Dr. Reddy s Laboratories, Inc.	U.S.A.	100%(10)
Dr. Reddy s Farmaceutica do Brasil Ltda	Brazil	100%
Cheminor Investments Limited	India	100%
Aurigene Discovery Technologies Limited	India	100%
Aurigene Discovery Technologies, Inc.	U.S.A.	100%(3)
Kunshan Rotam Reddy Pharmaceutical Co. Limited	China	51.33%(4)
Dr. Reddy s Laboratories (EU) Limited	United Kingdom	100%(10)
Dr. Reddy s Laboratories (U.K.) Limited	United Kingdom	100%(5)
Dr. Reddy s Laboratories (Proprietary) Limited	South Africa	100%(12)
Reddy Cheminor S.A.	France	100%(2)
OOO Dr. Reddy s Laboratories Limited	Russia	100%
Dr. Reddy s Bio-sciences Limited	India	100%
Promius Pharma LLC (formerly Reddy Pharmaceuticals, LLC)	U.S.A.	100%(6)
Trigenesis Therapeutics, Inc.	U.S.A.	100%
Industrias Quimicas Falcon de Mexico, SA de CV	Mexico	100%
Reddy Holding GmbH	Germany	100%(7)
Lacock Holdings Limited	Cyprus	100%
betapharm Arzneimittel GmbH	Germany	100%(8)
beta Healthcare Solutions GmbH	Germany	100%(8)
beta institut fur sozialmedizinische Forschung und Entwicklung GmbH	Germany	100%(8)
Reddy Pharma Iberia SA	Spain	100%
Reddy Pharma Italia SPA	Italy	100%(7)
Dr. Reddy s Laboratories (Australia) Pty Ltd.	Australia	100%
Dr. Reddy s Laboratories SA	Switzerland	100%
Eurobridge Consulting B.V.	Netherlands	100%(1)
OOO DRS LLC	Russia	100%(9)
Aurigene Discovery Technologies(Malaysia) Sdn, Bhd	Malaysia	100%(3)
Dr. Reddy s New Zealand Limited (formerly Affordable Healthcare Limited)	New Zealand	100%(10)
Dr. Reddy s Laboratories Ilac Ticaret Limited	Turkey	100%
Dr. Reddy s SRL (formerly Jet Generici SRL)	Italy	100%(11)
Chirotech Technology Limited	United Kingdom	100%(5)
Dr. Reddy s Laboratories Louisiana LLC	U.S.A.	100%(6)

Dr. Reddy s Pharma SEZ Limited	India	100%
Dr. Reddy s Laboratories International SA	Switzerland	100%(8)
Idea2Enterprises (India) Pvt. Limited	India	100%
Dr. Reddy s Laboratories Romania SRL	Romania	100%(10)
I-Ven Pharma Capital Limited	India	100%(13)
Dr. Reddy s Venezuela, C.A	Venezula	100%(13)
Dr. Reddy s Laboratories Tennessee, LLC	U.S.A	100%(6)

(1) Indirectly owned through Reddy Antilles N.V.

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(2) Subsidiary under liquidation.

(3) Indirectly owned through Aurigene Discovery Technologies Limited.

(4) Kunshan Rotam Reddy Pharmaceutical Co. Limited is a subsidiary as we hold a 51.33% stake; However, we account for this investment by the equity method and do not consolidate it in our financial statements.

(5) Indirectly owned through Dr. Reddy s Laboratories (EU) Limited.

(6) Indirectly owned through Dr. Reddy s Laboratories, Inc.

(7) Indirectly owned through Lacock Holdings Limited.

(8) Indirectly owned through Reddy Holding GmbH.

(9) Indirectly owned through Eurobridge Consulting B.V.

(10) Indirectly owned through Dr. Reddy s Laboratories SA.

(11) Indirectly owned through Reddy Pharma Italia SPA.

(12) We acquired the 40% non-controlling interest in August 2010.

(13) Indirectly owned through DRL Investments Limited
Macred India Private Limited, India was our wholly-owned subsidiary until July 19, 2010, at which time we sold an 80% controlling interest in the entity and retained a 20% non-controlling interest.

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4.D. ***Property, plant and equipment***

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

Location	Approximate Area (Square feet)	Built up Area (Square feet)	Certifications	Installed Capacity	Actual Production
Pharmaceutical Services and Active Ingredients				3,831[8][11]	3,267[8][11]
Bollaram, Andhra Pradesh, India	734,013	369,008	U.S. FDA and EUGMP	See above[11]	See above[11]
Bollaram, Andhra Pradesh, India	648,173	383,542	U.S. FDA and EUGMP	See above[11]	See above[11]
Bollaram, Andhra Pradesh, India	715,610	217,515	U.S. FDA and EUGMP	See above[11]	See above[11]
Jeedimetla, Andhra Pradesh, India	228,033	102,464	U.S. FDA and EUGMP	See above[11]	See above[11]
Miryalaguda, Andhra Pradesh, India	3,402,907	447,693	U.S. FDA and EUGMP	See above[11]	See above[11]
Pydibheemavaram, Andhra Pradesh, India	2,668,465	1,007,643	U.S. FDA and EUGMP	See above[11]	See above[11]
Pydibheemavaram, Andhra Pradesh, India	792,786	54,338		See above[11]	See above[11]
Miyapur, Andhra Pradesh, India	113,256	85,736	ISO 27001: 2005 Information Security Management System	N/A	N/A
Jeedimetla, Andhra Pradesh, India	68,825	23,538	ISO 27001: 2005 Information Security Management System	N/A	N/A

Location	Approximate Area (Square feet)	Built up Area (Square feet)	Certifications	Installed Capacity	Actual Production
Cuernavaca, Mexico	2,774,378	1,345,488	[1]	3,500[8]	2,000[8]
Mirfield, United Kingdom	1,785,960	653,400	ISO 9001:2008, MHRA (UK) and U.S. FDA	[12]	[12]
Cambridge, United Kingdom[5]	9,383	9,383		N/A	N/A
Global Generics				5,581[6][7][13]	4,282[6][13]
Bollaram, Andhra Pradesh, India	217,729	103,894	[2]	See above[13]	See above[13]
Bachupally, Andhra Pradesh, India	1,306,372	425,554	[3]	See above[13]	See above[13]
Yanam, Pondicherry, India	457,000	34,526		See above[13]	See above[13]
Baddi, Himachal Pradesh, India	786,261	148,711		See above[13]	See above[13]
Bachupally, Andhra Pradesh, India	798,982	105,924	[2]	13,852[9]	6,951[9]

Bachupally, Andhra Pradesh, India	783,823	496,201	[4]	11,727[6][10]	6,656[6]
Duvvada, Andhra Pradesh, India	691,322	73,334		N/A	N/A
Visakhapatnam, Andhra Pradesh, India					
Beverley, East Yorkshire, United Kingdom	81,000	32,500	U.K. Medicine Control Agency, British Retail Consortium	N/A	N/A
Shreveport, Lousiana, United States	1,817,123	335,000	U.S. FDA	5,875[6][10]	2,078[6]
Bristol, TN, United States	1,742,400	390,000	U.S. FDA	2,460[6][10]	5[6]
Proprietary Products[10]					
Miyapur, Andhra Pradesh, India	445,401	153,577		N/A	N/A

(1) U.S. FDA; Therapeutic Goods Administration, Australia; Danish Medicines Agency, Denmark; U.S. Prescription Drug Marketing Act; Ministry of Health, Labour and Welfare, Japan; Secretaría de Salud y Asistencia, Mexico.

(2) Ministry of Health, Uganda; Brazilian National Agency of Sanitary Surveillance (ANVISA), Brazil; National Medicines Agency, Romania; Ministry of Health, Ukraine; Gulf Cooperation Council (GCC) group of countries.

(3) Medicine Control Council, Republic of South Africa; The State Company for Marketing Drugs and Medical Appliances, Ministry of Health, Iraq; Sultanate of Oman, Ministry of Health, Muscat; Ministry of Health, State of Bahrain; State Pharmaceutical Inspection, Republic of Latvia; Pharmaceutical and Herbal Medicines, Registration and Control Administrations, Ministry of Health, Kuwait.
National Medicines Agency, Romania; Ministry of Health, Ukraine; Ministry of Health, Indonesia; Health Authorities, Nigeria; Ministry of Health, Kirgystan; World Health Organization, cGMP; ANVISA, Brazil; Medicines and Health Care Products Regulatory Agencies (MHRA), U.K., British Retail Consortium; Danish Medicines Agency.

(4) U.S. FDA; Medicines and Healthcare Products Regulatory Agency, U.K.; Ministry of Health, UAE; Medicines Control Council, South Africa; ANVISA, Brazil; National Medicines Agency, Romania; Danish Medicines Agency, Environmental Management System ISO 14001; Occupational Health and Safety Management System OHSAS 18001; Quality Management System-ISO 9001:2000.

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(5) Leased facilities.

(6) Million units.

(7) On a single shift basis.

(8) Tons.

(9) Grams.

(10) Three shift basis

(11) Represents the aggregate capacity and production for the first seven facilities listed in this table under PSAI.

(12) Capacity and production at this facility is not separately tracked.

(13) Represents the aggregate capacity and production for the first four facilities listed in this table under Global Generics.

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

Global Generics

We are in the process of completing construction of another manufacturing plant at Baddi, Himachal Pradesh, India, in addition to a plant which already existed at this location. The new plant is intended for the manufacture of tablet and capsule finished dosages for our Global Generics segment. The project at Baddi is eligible for certain financial benefits, which include exemption from income tax for a specific period, offered by the Government of India to encourage industrial growth in the state of Himachal Pradesh, India.

We have completed construction of a facility at a Special Economic Zone located in Visakhapatnam, Andhra Pradesh, India for the manufacture of oral and injectable cytotoxic finished dosages for our Global Generics segment. In November 2009, the U.S. FDA audited this facility and declared that we had resolved all Form 483 open items, enabling us to initiate the manufacture and supply of products from this facility to the United States, subject to the approval of product specific ANDAs. During June 2010, we commenced operations at this facility by manufacturing and exporting anastrazole tablets.

We are in the process of constructing a manufacturing plant at Devunipalavalasa, Ranasthalam Mandal, Andhra Pradesh, India, where our property has been designated as a Special Economic Zone under the applicable laws of the Government of India. The new plant is intended for the manufacture of new molecules, and certain high volume products of our Global Generics segment.

Pharmaceutical Services and Active Ingredients

We are in the process of establishing a plant in a Special Economic Zone in Andhra Pradesh, India for the manufacture of APIs. The plant will be adjacent to an existing plant, in a newly acquired area of approximately 250 acres under a Pharmaceutical-Sector specific Special Economic Zone for fiscal benefits. The formal governmental approval for designating the property as a Special Economic Zone has been obtained. The project is proposed to be developed in a phased manner, subject to all regulatory approvals.

We have working capital facilities with banks and, in order to secure those facilities, we have created encumbrance charges on certain of our immovable and movable properties. We are subject to significant national and state environmental laws and regulations which govern the discharge, emission, storage, handling and disposal of a variety of substances that may be used in or result from our operations at the above facilities. Non-compliance with the applicable laws and regulations may subject us to penalties and may also result in the closure of our facilities.

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ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Overview

We are an emerging global pharmaceutical company with proven research capabilities. We derive our revenues from the sale of finished dosage forms, active pharmaceutical ingredients and intermediates, development and manufacturing services provided to innovator pharmaceutical and biotechnology companies, and license fees from our proprietary products segment.

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

Global Generics;
Pharmaceutical Services and Active Ingredients (PSAI); and
Proprietary Products.

Global Generics: This segment consists of finished pharmaceutical products ready for consumption by the patient, marketed under a brand name (branded formulations) or as generic finished dosages with therapeutic equivalence to branded formulations (generics). This reportable segment was formed through the combination and re-organization of our former Formulations and Generics segments in the year ended March 31, 2009.

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

Proprietary Products: This segment involves the discovery of new chemical entities for subsequent commercialization and out-licensing. It also involves our specialty pharmaceuticals business, which conducts sales and marketing operations for in-licensed and co-developed dermatology products.

The CODM reviews revenue and gross profit as the performance indicator. The measurement of each segment s revenues, expenses and assets is consistent with the accounting policies that are used in preparation of our consolidated financial statements.

Critical Accounting Policies

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

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Accounting estimates and judgments

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

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

Assessment of functional currency for foreign operations;
Financial instruments;
Measurement of recoverable amounts of cash-generating units;
Provisions and contingencies;
Sales returns, rebates and charge back provisions;
Evaluation of recoverability of deferred tax assets;
Business combinations; and
Contingencies.

Revenue

Sale of goods

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

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

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

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

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We have entered into marketing arrangements with certain marketing partners for sale of goods in certain overseas territories. Under such arrangements, we sell generic products to the marketing partners at a price agreed upon in the arrangement and are also entitled to a profit share which is over and above the agreed price, on the basis of the marketing partner s ultimate net sale proceeds.

Revenue under profit sharing arrangements is recognized when our business partners send us a valid confirmation of the amounts that are owed to us. Arrangements with our business partners typically require the business partner to provide confirmation on inventory status and net sales computations for the products covered under the arrangement, together with an indicative date for payment. Such confirmation from the business partners is typically received in the quarter following the quarter in which the actual underlying sales of the products were made by them. The collection of the profit share becomes probable, and a reliable measurement of the profit share becomes possible, only after the receipt of such confirmation. Accordingly, the timing of revenue recognition corresponds with the receipt of such confirmation. Due to the immateriality of any individual profit share payment, we generally verify the statements received from our business partners by performing overall confirmatory procedures, such as ensuring monthly availability of stock statements, and certain other analytical procedures. Additionally, as part of our arrangements, we typically reserve the right to have third parties conduct audits to verify the statements received from our business partners.

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

Set forth below are the main items that accounted for a reduction in our gross revenue for the year ended March 31, 2011. The following discussion refers to the operations of our U.S. Generics business. It is in our U.S. Generics business that this particular feature of the pharmaceutical industry (i.e., returns, chargebacks, rebates, discounts and Medicaid payments) is significant to our financial statements. The estimates of gross-to-net adjustments for our operations in India and other countries outside of the U.S. relate mainly to sales return allowances in all such operations and certain rebates to healthcare insurance providers specific to our German operations. The pattern of such sales return allowances is generally consistent with our gross sales. In Germany, the rebates to healthcare insurance providers mentioned above are contractually fixed in nature and do not involve significant estimations by us.

Chargebacks. Chargebacks are issued to wholesalers for the difference between our invoice price to the wholesaler and the contract price through which the product is resold in the retail part of the supply chain. The information that we consider for establishing a chargeback accrual includes the historical average chargeback rate over a period of time, current contract prices with wholesalers and other customers, and estimated inventory holding by the wholesaler. With this methodology, we believe that the results are more realistic and closest to the potential chargeback claims that may be received in the future period relating to inventory on which a claim is yet to be received as at the end of the reporting period. In addition, as part of our books closure process, a chargeback validation is performed in which we track and reconcile the volume of sold inventory for which we should carry an appropriate provision for chargeback. We procure the inventory holding statements and data through an electronic data interface with our wholesalers (representing approximately 90% of the total sales volumes on which chargebacks are applicable) as part of this reconciliation. On the basis of this volume reconciliation, chargeback accrual is validated. For the chargeback rate computation, we consider different contract prices for each product across our customer base. This chargeback rate is adjusted (if necessary) on a periodic basis for expected future price reductions.

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Rebates. Rebates (direct and indirect) are generally provided to customers as an incentive to stock and sell our products. Rebate amounts are based on a customer s purchases made during an applicable period. Rebates are paid to wholesalers, chain drug stores, health maintenance organizations or pharmacy buying groups under a contract with us. We determine our estimates of rebate accruals primarily based on the contracts entered into with our wholesalers and other direct customers and the information received from them for secondary sales made by them. For direct rebates, liability is accrued whenever we invoice to direct customers. For indirect rebates, the accruals are based on a representative weighted average percentage of the contracted rebate amount applied to inventory sold and delivered by us to wholesalers or other direct customers.

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

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

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

Shelf Stock Adjustments. Shelf stock adjustments, which are common in our industry, are given to compensate our customers for falling prices due to additional competitive products. These take the form of contractually agreed price protection or shelf stock adjustment clauses in our agreements with direct customers. Such shelf stock adjustments are accrued and paid when the prices of certain products decline as a result of increased competition upon the expiration of limited competition or exclusivity periods.

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

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We believe our estimation processes are reasonable methods of determining accruals for the gross-to-net adjustments. Chargeback accrual accounts for the highest element among the gross-to-net adjustments, and constituted approximately 82% of such gross-to-net adjustments for our U.S. Generics business for the year ended March 31, 2011. For the purpose of the following discussion, we are therefore restricting our explanations to this specific element. While chargeback accruals depend on multiple variables, the most pertinent variables are our estimates of inventories on which a chargeback claim is yet to be received and the unit price at which the chargeback will be processed. To determine the chargeback accrual applicable for a reporting period, we perform the following procedures to calculate these two variables:

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

(b) Unit pricing rate As at any point in time, inventory volumes on which we carry our chargeback accrual represents approximately 1.5 months of sales volumes. Therefore, the sensitivity of price changes on our chargeback accrual relates to only such volumes. Assuming that the chargebacks were processed within such period, we analyzed the impact of changes of prices for the periods beginning April 1, 2011, 2010 and 2009, respectively, and ended March 31, 2011, 2010 and 2009, respectively, on our estimated inventory levels computed based on the methodology mentioned above (see Chargebacks above). We noted that the impact on net sales on account of such price variation was negligible.

In view of this, we believe that the calculations are not subject to a level of uncertainty that warrants a probability-based approach. Accordingly, we believe that we have been reasonable in our estimates for future chargeback claims and that the amounts of reversals or adjustments made in the current period pertaining to the previous year s accruals are immaterial. Further, this data is not determinable except on occurrence of specific instances or events during a period, which warrant an adjustment to be made for such accruals. A roll-forward for each major accrual for our U.S. Generics operations is presented in Item 5.A. (Operating Results) below for our fiscal years ended March 31, 2009, 2010 and 2011, respectively.

Returns primarily relate to expired products which the customer has the right to return for a period of 12 months following the expiration date of such product. Such returned products are destroyed and credit notes are issued to the customer for the products returned. We account for sales returns accrual by recording an allowance for sales returns concurrent with the recognition of revenue at the time of a product sale. This allowance is based on our estimate of expected sales returns. We deal in various products and operate in various markets. Accordingly, our estimate of sales returns is determined primarily by our historical experience in the markets in which we operate. With respect to established products, we consider our historical experience of sales returns, levels of inventory in the distribution channel, estimated shelf life, product discontinuances, price changes of competitive