DR REDDYS LABORATORIES LTD
Form 20-F
June 15, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

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

OR

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

For the Fiscal Year Ended March 31, 2018

OR

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

OR

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

Commission File Number: 1-15182

DR. REDDY'S LABORATORIES LIMITED

(Exact name of Registrant as specified in its charter)

Not Applicable	**TELANGANA, INDIA**
(Translation of Registrant's name into English)	(Jurisdiction of incorporation or organization)

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

Hyderabad, Telangana 500 034, India

+91-40-49002900

(Address of principal executive offices)

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

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

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

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

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

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

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

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

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

165,910,907 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 ¨

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

Yes ¨ No 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 ¨

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

Yes ¨ No ¨

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

Large accelerated filer þ Accelerated filer ¨ Non-accelerated filer ¨ Emerging growth company ¨

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ¨

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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

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

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

Item 17 ¨ Item 18 ¨

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

Yes ¨ No þ

Currency of Presentation and Certain Defined Terms

In this annual report on Form 20-F, references to "$" or "U.S.$" or "dollars" or "U.S. dollars" are to the legal currency of the United States and references to "Rs." or "rupees" or "Indian rupees" are to the legal currency of India, references to "MXN" are to the legal currency of Mexico, and references to "EUR" or "euros" are to the legal currency of the European Union. Our financial statements are prepared in accordance with International Financial Reporting Standards, or "IFRS", as issued by the International Accounting Standards Board, or "IASB". These standards include International Accounting Standards, or "IAS", and their interpretations issued by the International Financial Reporting Interpretations Committee, or "IFRIC", or its predecessor, the Standing Interpretations Committee, or "SIC". References to a particular "fiscal" year are to our fiscal year ended March 31 of such year. References to our "ADSs" are to our American Depositary Shares.

References to "U.S. FDA" are to the United States Food and Drug Administration, to "NDAs" are to New Drug Applications, and to "ANDAs" are to Abbreviated New Drug Applications.

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", "DI "Dr. Reddy's" or the "Company" shall mean Dr. Reddy's Laboratories Limited and its subsidiaries. "Dr. Reddy's" is a registered trademark of Dr. Reddy's Laboratories Limited in India. Other trademarks or trade names used in this annual report on Form 20-F are trademarks registered in the name of Dr. Reddy's Laboratories Limited or are pending before the respective trademark registries, unless otherwise specified. Market share data is based on information provided by IMS Health Inc. and its affiliates ("IMS Health"), a provider of market research to the pharmaceutical industry, unless otherwise stated.

Our financial statements are presented in Indian rupees and translated into U.S. dollars for the convenience of the reader. Except as otherwise stated in this report, all convenience translations from Indian rupees to U.S. dollars are at the certified foreign exchange rate of U.S.$1 = Rs.65.11, as published by Federal Reserve Board of Governors on March 30, 2018. No representation is made that the Indian rupee amounts have been, could have been or could be converted into U.S. dollars at such a rate or any other rate.

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

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

Forward-Looking Statements

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”). In addition to statements which are forward-looking by reason of context, the words “may”, “will”, “should”, “expects”, “plans”, “intends”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, or similar expressions identify forward-looking statements. 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:

- in our generics medicines business: consolidation of our customer base and commercial alliances among our customers; the increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products; price erosion relating to our generic products, both from competing products and increased regulation; delays in launches of new generic products; efforts of pharmaceutical companies to limit the use of generics including through legislation and regulations; the difficulty and expense of obtaining licenses to proprietary technologies; returns, allowances and chargebacks; and investigations of the calculation of wholesale prices;

- in our specialty medicines business: competition for our specialty products; our ability to achieve expected results from investments in our product pipeline; competition from companies with greater resources and capabilities; and the effectiveness of our patents and other measures to protect our intellectual property rights;

- our business and operations in general, including: our ability to develop and commercialize additional pharmaceutical products; manufacturing or quality control problems, which may damage our reputation for quality production and require costly remediation; interruptions in our supply chain; disruptions of our or third party information technology systems or breaches of our data security; the failure to recruit or retain key personnel; challenges associated with conducting business globally, including adverse effects of political or economic instability, major hostilities or terrorism; significant sales to a limited number of customers in our U.S. market; our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions;

- compliance, regulatory and litigation matters, including: costs and delays resulting from the extensive governmental regulation to which we are subject; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; governmental investigations into selling and marketing practices; potential liability for patent infringement; product liability claims; increased government scrutiny of our patent settlement agreements; failure to comply with complex Medicare and Medicaid reporting and payment obligations; and environmental risks;

- other financial and economic risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; potential impairments of our intangible assets; potential significant increases in tax liabilities; and the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; and

- 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 and assumptions 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 with and/or furnished to 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," which are included elsewhere in this Annual Report on Form 20-F. The selected consolidated income statement data for the years ended March 31, 2018, 2017, 2016, 2015 and 2014 and the selected consolidated statement of financial position data as of March 31, 2018, 2017, 2016, 2015 and 2014 have been prepared and presented in accordance with IFRS as issued by the IASB, and have been derived from our audited consolidated financial statements and related notes included elsewhere herein. The selected consolidated financial data below has been presented for the five most recent fiscal years. Historical results are not necessarily indicative of future results.

Income Statement Data

	For the year ended March 31,				
2018	2018	2017	2016	2015	2014
(Rs. in millions, U.S.$ in millions, both except share and per share data)					
Convenience translation into U.S.$					

Revenues	**U.S.$** 2,181	**Rs.** 142,028	**Rs.** 140,809	**Rs.** 154,708	**Rs.** 148,189	**Rs.** 132,170
Cost of revenues	1,009	65,724	62,453	62,427	62,786	56,369
Gross profit	1,172	76,304	78,356	92,281	85,403	75,801
Selling, general and administrative expenses	720	46,910	46,372	45,702	42,585	38,783
Research and development expenses	281	18,265	19,551	17,834	17,449	12,402
Other (income)/expense, net	(12)	(788)	(1,065)	(874)	(917)	(1,416)
Results from operating activities	183	11,917	13,498	29,619	26,286	26,032
Finance (expense)/income, net	32	2,080	806	(2,708)	1,682	400
Share of profit of equity accounted investees, net of tax	5	344	349	229	195	174
Profit before tax	220	14,341	14,653	27,140	28,163	26,606
Tax expense	70	4,535	2,614	7,127	5,984	5,094
Profit for the year	**U.S.$** 151	**Rs.** 9,806	12,039	20,013	22,179	21,512
Attributable to:						
Equity holders of the Company	151	9,806	12,039	20,013	22,179	21,515
Non-controlling interests	-	-	-	-	-	(3)
Profit for the year	**U.S.$** 151	**Rs.** 9,806	**Rs.** 12,039	**Rs.** 20,013	**Rs.** 22,179	**Rs.** 21,512
Earnings per share						
Basic	U.S.$ 0.91	Rs. 59.13	Rs. 72.24	Rs. 117.34	Rs. 130.22	Rs. 126.52
Diluted	U.S.$ 0.91	Rs. 59.00	Rs. 72.09	Rs. 116.98	Rs. 129.75	Rs. 126.04
Weighted average number of equity shares used in computing earnings per equity share*						
Basic		165,845,408	166,648,943	170,547,643	170,314,506	170,044,518
Diluted		166,185,552	166,997,675	171,072,780	170,933,433	170,695,017
Cash dividend per equity share**	U.S.$ 0.31	Rs. 20	Rs. 20	Rs. 20	Rs. 18	Rs. 15

* Each ADR represents one equity share.

** Excludes corporate dividend tax.

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Statement of Financial Position Data

	As of March 31,					
	2018	2018	2017	2016	2015	2014
	(Rs. in millions, U.S.$ in millions, except share data)					
	Convenience translation into U.S.$					
Cash and cash equivalents	U.S.$41	Rs. 2,638	Rs. 3,866	Rs. 4,921	Rs. 5,394	Rs. 8,451
Other investments (current and non-current)	321	20,879	19,507	37,022	37,076	25,083
Total assets	3,465	225,604	219,821	207,650	194,762	170,223
Total long term debt, excluding current portion	385	25,089	5,449	10,685	14,307	20,740
Total equity	U.S.$1,942	Rs. 126,460	Rs. 124,044	Rs. 128,336	Rs. 111,302	Rs. 90,801
Number of shares outstanding		165,910,907	165,741,713	170,607,653	170,381,174	170,108,868

Convenience translation

For the convenience of the reader, our consolidated financial statements as of March 31, 2018 have been translated into U.S. dollars at the certified foreign exchange rate of U.S.$1 = Rs.65.11, as published by the Federal Reserve Board of Governors on March 30, 2018. 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.

For the year ended March 31,	Period End	Average	High	Low
2014	60.00	60.35	68.80	53.65
2015	62.31	61.34	63.67	58.30
2016	66.25	65.58	68.84	61.99
2017	64.85	66.96	68.86	64.85
2018	65.11	64.48	65.71	63.38

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 2017	65.48	64.70
November 2017	65.46	64.29
December 2017	64.57	63.83
January 2018	64.01	63.38
February 2018	65.20	63.93
March 2018	65.24	64.83

On June 8, 2018, the noon buying rate in the city of New York was Rs.67.56 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

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

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

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

Delays in the receipt of, or failure to obtain approvals for, future products, or new indications and uses, could result in delayed realization of product revenues, reduction in revenues and substantial additional costs. For example, in the

years ended March 31, 2017 and 2018, we experienced delays in obtaining approvals from the U.S. Food and Drug Administration ("U.S. FDA") for various generic and specialty products as anticipated, principally as a result of the warning letter referenced below.

Additionally, governmental authorities, including among others the U.S. FDA and the U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA"), heavily regulate the manufacturing of our products, including manufacturing quality standards. Periodic audits are conducted on our manufacturing sites, and if the regulatory and quality standards and systems are not found adequate, it could result in an audit observation (on Form 483, if from the U.S. FDA), or a subsequent investigative letter which may require further corrective actions. In recent years, a number of Indian generic pharmaceutical companies were issued import alerts and warning letters by the U.S. FDA. A significant proportion of our manufacturing base of active pharmaceutical ingredients and formulations plants servicing the United States and other markets of our Global Generics business is based out of India. There has been an increasing trend by the U.S. FDA and governmental regulators in other developed countries towards Indian manufacturing site audits. While our quality practices and quality management systems are conducted in a manner designed to satisfy these types of audits, we cannot guarantee that our efforts will prevent adverse outcomes such as audit observations, corrective action requests, warning letters or import bans.

For example, in November 2015, we received a warning letter from the U.S. FDA relating to cGMP deviations at three of our manufacturing facilities - two API manufacturing facilities and one injectable oncology formulations manufacturing facility in India. Refer to Item 4.A. "History and development of the company – Key business developments – Re-Audit of the warning letter impacted sites" for further details.

More generally, unless and until an issue raised in a warning letter from the U.S. FDA is resolved to the U.S. FDA's satisfaction, the U.S. FDA may withhold approvals of our new products and new drug applications, refuse admission of products manufactured at the facilities noted in the warning letter into the United States, and/or take additional regulatory or legal action against us. The delay in approvals due to moving to an alternate site or alternate vendor, or the cost incurred in connection with remedial actions, can have significant adverse impacts on our ongoing business, financial results and routine operations.

In recent years, there has been increasing regulatory scrutiny of pharmaceutical manufacturers, resulting in product recalls, plant shutdowns and other required remedial actions. We have been subject to increasing scrutiny of our manufacturing operations, and in previous years several of our facilities have been the subject of significant regulatory actions requiring substantial expenditures of resources to ensure compliance with more stringently applied production and quality control regulations. These regulatory actions also adversely affected our ability to supply various products worldwide and to obtain new product approvals at such facilities. If any regulatory body were to require one or more of our significant manufacturing facilities to cease or limit production, our business could be adversely affected. In addition, because regulatory approval to manufacture a drug is site-specific, the delay and cost of remedial actions, or of obtaining approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations.

Furthermore, we deal with numerous third party manufacturers and despite our oversight, any lapse in their quality practices and quality management systems could lead to similar adverse outcomes in the event of an audit.

If we or our third party suppliers fail to comply fully with applicable regulations or to take corrective actions that are mandated, then there could be a government-enforced shutdown of our production facilities or an import ban, which in turn could lead to product shortages that delay or prevent us from fulfilling our obligations to customers, or we could be subjected to government fines.

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

An increasing portion of our portfolio are “biologic” products. Unlike traditional “small-molecule” drugs, biologic drugs cannot be manufactured synthetically, but typically must be produced from living animal cells or micro-organisms. As a result, the production of biologic drugs that meet all quality and regulatory requirements is especially complex and is more susceptible to batch failures.

Typically, biological therapeutics face third party intellectual property rights, otherwise known as freedom to operate (“FTO”) issues, more than small molecule therapeutics because of the types of patents allowed by national patent offices. Further, our ability to successfully challenge third party patent rights is dependent on the laws of the applicable countries.

The regulatory requirements are still evolving in many markets where we sell or manufacture products, including our biosimilar products, and regulatory requirements may be unclear due to lack of precedents, among other reasons, which may lead to delays in product approvals or other sanctions. In the United States, the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created a statutory pathway and abbreviated approval processes for the approval of biosimilar versions of branded biological products. While the U.S. FDA has issued guidelines, the regulatory policies in this area are still evolving. Further, while a number of legal challenges concerning the requirements of the abbreviated biosimilar pathway, patent exchange and other provisions of BPCIA have been adjudicated in U.S. courts, legal challenges concerning FTO, patent exchange and trade matters, among others, continue.

We operate in a highly competitive and rapidly consolidating industry which may adversely affect our revenues and profits.

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

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

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

The number of significant new generic products for which Hatch-Waxman exclusivity is available, and the size of those product opportunities, has decreased in recent years and may decrease in future years in comparison to those available in the past. Patent challenges have become more difficult in recent years. Additionally, we increasingly share the 180-day exclusivity period with other generic competitors, which diminishes the commercial value of the exclusivity. Also, as generic competition has increased in recent years, there has been a corresponding increase in multiple generic applicants sharing available 180-day exclusivity periods as well as strict enforcement by the U.S. FDA in its enforcement of the requirements for a first applicant's eligibility for a 180-day exclusivity period, which reduces the economic benefit from being first-to-file for generic applications.

Further, in recent years the goals established under the Generic Drug User Fee Act, and increased funding of the U.S. FDA's Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition. The U.S. FDA has established new steps to enhance competition, promote access and lower drug prices and is approving record-breaking numbers of generic applications. While these improvements are expected to benefit our generic product pipeline, they will also benefit competitors that seek to launch products in established generic markets where we currently offer products.

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

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

greater use of a direct sales force than does our core generic business.

Our ability to realize significant revenues from direct marketing and sales activities depends on our ability to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. We may also need to enter into co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or sufficiently well-aligned to achieve maximum penetration in the market. Any failure to attract or retain qualified sales personnel or to enter into third-party arrangements on favorable terms could prevent us from successfully maintaining current sales levels or commercializing new innovative and specialty products.

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

In the United States, similar to other pharmaceutical companies, we sell our products through wholesale distributors and large retail chains in addition to hospitals, pharmacies and other groups. During the year ended March 31, 2018, our ten largest customers accounted for 77% of our North America Global Generics segment's revenues. We are exposed to a concentration of credit risk in respect of these customers. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation has resulted in these groups gaining additional purchasing leverage and, consequently, increasing the product pricing pressures facing our business. We expect this trend of increased pricing pressures to continue. Such pressures have reduced, and could continue to reduce, our revenue, margins and profitability.

Additionally, the emergence of large buying groups representing independent retail pharmacies, and the prevalence and influence of managed care organizations and similar institutions, creates competition among pharmaceutical companies to have their products included in the formulary of those groups and enables those groups to extract price discounts on our products.

The traditional model for distribution of pharmaceutical products is also undergoing disruption as a result of the entry or potential entry of new competitors and significant mergers among key industry participants. For example, Amazon Inc. has recently made initial moves to develop a pharmaceutical distribution business. Also, the consolidation resulting from the merger between CVS Health and Aetna, along with Cigna's proposed acquisition of Express Scripts, if consummated, is expected to create a vertically integrated organization with increased control over the physician and pharmacy networks and, ultimately, over which medicines are sold to patients. In addition, several major hospital systems in the United States and the U.S. Department of Veterans Affairs announced a plan to form a nonprofit company that will provide U.S. hospitals with a number of generic drugs. In January 2018, Amazon Inc., Berkshire Hathaway Inc. and JPMorgan Chase & Co., announced that they plan to join forces by forming an independent health care company for their combined one million U.S. employees. Initiatives like these are expected to further increase competition and enhance price erosion. These changes to the traditional supply chain could lead to our customers having increased negotiation leverage and to additional pricing pressure and price erosion.

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

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

- pursuing new patents for existing products that may be granted just before the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;
- introducing "next-generation" products prior to the expiration of market exclusivity for the generic product, which often materially reduces the demand for the generic product for which we seek regulatory approval;
- obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations;
- selling the brand product as an authorized generic, either by the brand company directly or through a marketing partner;
- using the Citizen Petition process to request amendments to U.S. FDA standards on testing bio-equivalence;
- seeking changes to U.S. Pharmacopeia, an organization that publishes industry recognized compendia of drug standards;

- attaching patent extension amendments to non-related federal legislation;

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

- seeking patents on methods of manufacturing certain active pharmaceutical ingredients;

- attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled; and

- entering into agreements with pharmacy benefit management companies that have the effect of blocking the dispensing of generic products.

Research and development efforts invested in our differentiated formulations pipeline may not achieve expected results.

In our Proprietary Products segment, our business model focuses on building a pipeline in the therapeutic areas of neurology and dermatology. We must invest increasingly significant resources to develop differentiated products, both through our own efforts and through collaborations, in-licensing and acquisition of products from or with third parties. The development of differentiated products involves processes and expertise different from those used in the development of generic drugs, which increases the risks of failure. During each stage, we may encounter obstacles that delay the development process and increase expenses, leading to significant risks that we will not achieve our goals and may be forced to abandon a potential product in which we have invested substantial amounts of time and money. These obstacles may include: preclinical failures; difficulty enrolling patients in clinical trials; delays in completing formulation and other work needed to support an application for registration; adverse reactions or other safety concerns arising during clinical testing; insufficient clinical trial data to support the safety or efficacy of the product candidate; and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured.

Because of the amount of capital required to be invested in augmenting our differentiated products pipeline, in some cases we are reliant on partnerships and joint ventures with third parties, and consequently face the risk that some of these third parties may fail to perform their obligations, or fail to reach the levels of success that we are relying on to meet our revenue and profit goals.

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 businesses are operating in an ever more challenging environment, with significant pressures on the pricing of our products and on our ability to obtain and maintain satisfactory rates of reimbursement for our products by governments, insurers and other payors. The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control healthcare spending even more tightly than in the past.

These pressures are particularly strong given the persistently weak economic and financial environment in many countries and the increasing demand for healthcare resulting from the aging of the global population and associated increases in non-communicable diseases. These pressures are further compounded by consolidation among distributors, retailers, private insurers, managed care organizations and other private payors, which can increase their negotiating power. In addition, these pressures are augmented by intense publicity regarding the pricing of pharmaceuticals by our competitors, as well as government investigations and legal proceedings regarding pharmaceutical pricing practices. In many countries in which we currently operate, including India, pharmaceutical prices are subject to regulation. Our products continue to be subject to increasing price and reimbursement pressure that can limit the revenues we earn from our products in many countries due to, among other things:

- the existence of government-imposed price controls, tender systems, mandatory discounts and rebates, and pricing transparency mandates;
- removal of drugs from government reimbursement schemes (for example products determined to be less cost-effective than alternatives);
- increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;
- increase in cost containment policies related to health expenses in the context of economic slowdown;
- more demanding evaluation criteria applied by Health Technology Assessment (“HTA”) agencies when considering whether to cover new drugs at a certain price level; and
- more governments using international reference pricing to set the price of drugs based on international comparisons.

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

In addition, there has been legislation and legislative proposals concerning drug prices and related issues, including the perceived need to bring more transparency to drug pricing, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

Opposition to free trade agreements and changes in trade policies of countries in which we operate could adversely affect the pricing and demand for our products.

Opposition to free trade agreements was an important component of the campaign platform of the new U.S. administration, and there are ongoing efforts to achieve that goal. For example, the United States recently withdrew from the Trans-Pacific Partnership (“TPP”) free trade agreement. Any such changes in free trade agreements could, among other things, interfere with free trade in goods, impose additional customs duties or tariffs, increase the costs and difficulties of international transactions and potentially disturb the international flow of goods and, in particular, trade between the United States and other countries, and thus may have a material adverse effect on our financial performance.

Any new tariffs or other changes in U.S. trade policy could trigger retaliatory actions by affected countries, potentially escalating and resulting in “trade wars”. For example, in March and April 2018, the U.S. government announced new tariffs on steel and aluminum from China, as well as more than 1,300 other Chinese exports. In response, the Chinese government announced that it would enact retaliatory tariffs on more than 100 American products. Trade policy changes or internal policy changes such as these can result in increased costs for goods, which may reduce customer demand for these products if the parties having to pay those tariffs increase their prices, or in increased costs to trading partners. If these consequences are realized, they may materially and adversely affect our sales and our business.

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

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

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Our research and development efforts are increasingly dependent on collaborating with third party partners and contract research organizations which have the capability to handle complex technologies and products. Lack of effective project management at our end, or any failure to manage collaboration arrangements among multiple partners, may pose significant risks to product development, to our ability to obtain requisite regulatory approvals in a timely manner, and to our ability to successfully and profitably produce and market such products.

Additionally, if we fail to adequately protect critical proprietary or confidential information or associated intellectual property rights or fail to manage third party partners and contract research organizations that our business depends on, it might have a material adverse impact on our product development execution.

From time to time we also acquire in-process research and development assets, which require significant resources and expenses to continue to develop, both through our own efforts and through collaborations. Because of the inherent risk associated with research and development efforts in our industry, including the high cost and uncertainty of conducting clinical trials (where required), such efforts may not result in the successful introduction of new pharmaceutical products approved by the relevant regulatory bodies.

For example, during the year ended March 31, 2017, we acquired eight Abbreviated New Drug Applications in the United States from Teva Pharmaceutical Industries Limited ("Teva") and an affiliate of Allergan plc. The consideration for such purchase was U.S.$350 million in cash at closing, which was funded through borrowings from certain institutional lenders. Our results of operations may suffer if these products are not timely developed, approved or successfully commercialized.

Failure to maintain supply of compliant, quality product.

We may experience difficulties, delays and interruptions in the manufacturing and supply of our products for various reasons, including among other reasons:

- demand significantly in excess of forecast demand, which may lead to supply shortages (this is particularly challenging before the launch of a new product);
- supply chain disruptions, including those due to natural or man-made disasters at one of our facilities or at a critical supplier or vendor;

- delays in construction of new facilities or the expansion of existing facilities, including those intended to support future demand for our products (the complexities associated with biologics facilities, especially for drug substance, increases the probability of delay);

- the inability to supply products due to a product quality failure or regulatory agency compliance action such as license withdrawal, product recall or product seizure; and

- other manufacturing or distribution problems, including changes in manufacturing production sites, limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, or physical limitations or other business interruptions that could impact continuous supply.

We also manufacture and sell a number of sterile products, including oncology products, which are technically complex to manufacture, and require sophisticated environmental controls. Because the production process for such products is so complex and sensitive, any production failures may lead to lengthy supply interruptions.

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

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

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

The use of tender systems and other forms of price control could reduce prices for our products or reduce our market opportunities.

A number of markets in which we operate have implemented or may implement tender systems in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender.

For example, this has resulted in more than 90% of generic products currently sold in German retail outlets being supplied through contracts procured in competitive bidding tenders, thereby causing significant pressure on product margins.

Certain other countries may consider the implementation of a tender system or other forms of price controls. Even if a tender system is ultimately not implemented, the anticipation of such a system could result in price reductions. Failing to win tenders, or the implementation of similar systems or other forms of price controls in other markets leading to further price declines, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

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

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

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

We may be susceptible to significant product liability claims that are not covered by insurance.

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 are introduced into the marketplace. Due to this fact, our customers and participants in clinical trials may bring lawsuits against us for alleged product defects. In other instances, third parties may perform analyses of published clinical trial results which raise questions regarding the safety of pharmaceutical products, and which may be publicized by the media. Even if such reports are inaccurate or misleading, in whole or in part, they may nonetheless result in claims against us for alleged product defects.

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

Following the United States Supreme Court’s June 2013 ruling in *Mutual Pharmaceutical Co. v. Bartlett* upholding such preemption and immunity of generic manufacturers, the U.S. FDA had proposed a new rule in November 2013 that would have allowed generic manufacturers to independently update product labeling through the CBE supplement process. If the U.S. FDA’s proposed new rule was adopted, it may have eliminated this preemption and increased our potential exposure to lawsuits relating to product safety, side effects and warnings on labels. This new potential exposure to lawsuits would also have increased the risk that, in the future, we would not be able to obtain the type and amount of insurance 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. After twice delaying publication of a final rule, the U.S. FDA withdrew its proposed rule during 2017.

The risk of exposure to lawsuits is likely to increase as we develop our own new patented products, or limited competition/complex products, such as injectable or biosimilar 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.

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. If improperly handled or subjected to the wrong conditions, these materials could hurt our employees, cause damage to our properties and harm the environment. Also, increases in business and operations in our plants, and the consequent hiring of new employees, can pose increased safety hazards. Such hazards need to be addressed through training, industrial hygiene assessments and other safety measures and, if not carried out, can lead to industrial accidents. Any of the foregoing could subject us to significant litigation or adversely impact our other litigation matters then outstanding, which could lower our profits in the event we were found liable, and could also adversely impact our reputation.

In a worst case scenario, this could also result in a government forced shutdown of our manufacturing plants, which in turn could lead to product shortages that delay or prevent us from fulfilling our obligations to customers and would adversely affect our business and results of operations.

Class action lawsuits could expose us to significant liabilities, result in negative publicity, harm our reputation and have a material adverse effect on the price of our ADSs.

Shareholders of a public company sometimes bring securities class action lawsuits against the company following periods of instability in the market price of that company's securities. As a public company grows in size, the risk of such litigations may increase. If we were to be sued in any such class action suit, irrespective of the merits of the underlying case, it could have adverse effects on us, including among other things: (a) a diversion of management's time and attention and other resources from our business and operations, which could harm our results of operations; (b) negative publicity, which could harm our reputation and restrict our ability to raise capital in the future; (c) require us to incur significant expenses to defend the suit; and (d) if a claim against us is successful, we may be required to pay significant damages and, in certain circumstances, to indemnify our directors and officers if they are named as defendants in the class action suit. Any of the foregoing could, individually or in the aggregate, have a material adverse effect on our financial condition and results of operations and/or the price of our ADSs.

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

We expect to derive an increasing portion of our sales from regions such as Latin America, Russia and other countries of the former Soviet Union, Central Europe, Eastern Europe and South Africa, all of which may be more susceptible to political and economic instability. For example, as a result of severe political instability and conflict in Ukraine, the United States and the European Union have imposed sanctions on certain individuals and companies in Ukraine and Russia, including sanctions targeted at the Crimea region of Ukraine which was annexed by Russia. Political instability in the region, combined with low worldwide oil prices, resulted in significant devaluation of the Russian rouble. In addition, the Ukrainian hryvnia experienced significant devaluation in 2014 and 2015 and the Venezuelan bolivar experienced significant devaluation beginning in 2013 and continuing through 2018.

Furthermore, the currencies of certain other markets in which we operate (such as South African rands, Brazilian reals, Colombian pesos and Kazakhstan tenges) have undergone significant currency volatility in 2015 and 2016. Some of these are new markets that we have recently entered, and we may decide to enter other new markets in the future and thus may face additional risks arising out of political and economic instability.

We monitor significant political, legal, regulatory 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, regulatory and economic developments, such as changes in capital and exchange controls; expropriation and other restrictive government actions; intellectual property protection and remedy laws; trade regulations; procedures and actions affecting approval, production, pricing and marketing of, reimbursement for and access to our products; and intergovernmental disputes, including embargoes and/or military hostilities.

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

On June 23, 2016, the United Kingdom ("U.K.") held a remain-or-leave referendum on its membership within the European Union ("EU"), the outcome of which was a decision for the U.K. to exit from the EU (the "Brexit") effective as of March 29, 2019. A process of negotiation will likely determine the future terms of the U.K.'s relationship with the EU, as well as whether the U.K. will be able to continue to benefit from the EU's free trade and similar arrangements. As pharmaceutical legislation in the U.K. is largely derived from the EU law and relies on mutual recognition of decision making, implementation of a number of practical steps is required before the U.K. exits the EU. Until the Brexit negotiation process is completed, it is difficult to anticipate the potential impact on our operations. As the process of Brexit evolves, we will continue to assess its impact on us.

In addition, following the Brexit vote in the U.K., the EU has decided to move the headquarters of the EU's health authority, the EMA, from the U.K. to the Netherlands by March 2019. It is expected that a significant percentage of the current employees of the EMA will decide not to make the move to the Netherlands. This raises the possibility that new drug approvals in the EU could be delayed as a result.

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

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

We operate in certain jurisdictions that experience governmental corruption to some degree or are found to be low on the Transparency International Corruption Perceptions Index and, in some circumstances, anti-bribery laws may conflict with some local customs and practices. In many less-developed markets, we work with third-party distributors and other agents for the marketing and distribution of our products. Although our policies prohibit these third parties from making improper payments or otherwise violating these anti-bribery laws, any lapses in complying with such anti-bribery laws by these third parties may adversely impact us. Business activities in many of these markets have historically been more susceptible to corruption.

If our efforts to screen third-party agents and detect cases of potential misconduct fail, we could be held responsible for the non-compliance of these third parties under applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act. Compliance with the U.S. Foreign Corrupt Practices Act and other anti-bribery laws has been subject to increasing focus and activity by regulatory authorities in recent years. We may be subject to injunctions or

limitations on future conduct, be required to modify our business practices and compliance programs and/or have a compliance monitor imposed on us, or suffer other criminal or civil penalties or adverse impacts, including lawsuits by private litigants or investigations and fines imposed by local authorities.

We need to constantly review and update our compliance program to keep it current and active. If we fail to do so, our vulnerabilities may increase and our controls may be found to be inadequate.

Actions by our employees, or third-party intermediaries acting on our behalf, in violation of such laws, whether carried out in the United States or elsewhere, may expose us to liability for violations of such anti-bribery laws and accordingly may have a material adverse effect on our reputation and our business, financial condition or results of operations.

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

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

Because of the discount pricing typically involved with generic pharmaceutical products, patented brand products generally realize a significantly higher profit margin than generic pharmaceutical products. In the case of a willful infringer, the definition of which is unclear, these damages may even be trebled.

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

For business reasons, we continue to examine such product opportunities (i.e., involving non-expired patents) going forward and this could result in patent litigation, the outcomes of which may have a material adverse effect on our results of operations, financial condition and cash flows.

Any failure to comply with the complex reporting and payment obligations under the Medicare and Medicaid programs or other laws regulating marketing practices may result in litigation or sanctions and adversely impact our business.

The U.S. laws and regulations regarding Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Some of the applicable laws may impose liability even in the absence of a specific intent to defraud. The subjective decisions and complex methodologies used in making calculations under these programs are subject to review and challenge, and it is possible that such reviews could result in material changes in the calculation outcomes. In addition, government authorities have significant leverage to persuade pharmaceutical companies to enter into corporate integrity agreements, which can be expensive and disruptive to operations.

If any of the above queries and/or investigations were to result in a lawsuit that was determined adversely to us or in a large cash settlement, it could require us to pay significant amounts and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

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

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

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

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

- We may not be able to retain the skilled employees and experienced management that may be necessary to operate the businesses we acquire. If we cannot retain such personnel, we may not be able to locate or hire new skilled employees and experienced management to replace them.

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

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

Our Proprietary Products segment, particularly our Specialty businesses in the United States, faces intense competition from companies that are more entrenched than we are or have greater resources than ours.

Our risk profile for our Proprietary Products segment is lower than the comparable risk profile of companies working with completely novel entities. Nevertheless, the risk that the businesses in this segment face is higher than that of the Generics business due to several factors outlined below.

Market penetration requires successful commercial positioning in relation not only to past therapies but also new competitors. All of the therapeutic areas in which we compete have many active competitors, each vying for market share in similar indications with products that may have some similar attributes. As such, success in our Proprietary Products segment requires the ability to strategically differentiate our offerings from those of our competitors, which often requires time and investment in additional clinical Health Economics and Outcomes Research (“HEOR”) studies and Real World Evidence (“RWE”) studies, and brings with it the typical uncertainty of outcome that faces many clinical studies. An additional emerging challenge is access to physicians, who can explicitly refuse to see our sales representatives, and new approaches need to be found to provide them with the information required in order to make informed and appropriate prescription decisions. Further, as payors demand more evidence of economic benefit via additional post-marketing studies, gaining favorable coverage is becoming a hurdle. While the impact of these challenges is currently limited, they could potentially become significant in the future.

Even if we are able to successfully differentiate our products, favorable unrestricted reimbursement from payors for our products is necessary in order to compete effectively. Typically, a managed care plan relies on a committee comprised of physicians and other decision makers and influencers to decide which drugs will appear on its formulary. The randomized clinical trial data generated to obtain U.S. FDA approval will no longer be sufficient to gain a favorable access decision. Without our products having a reasonable position on the formulary of managed care plans, patients will not be able to obtain access to our products and physicians become less likely to prescribe our products. Furthermore, even after we contract for access on managed care formularies, we often have to provide additional point-of-sale discounts to patients in order to make their out-of-pocket payments affordable. This has been exacerbated by the growing proliferation of high deductible health plans in the U.S., as employers transfer a greater share of healthcare costs to their employees. All of these are necessary in this business segment, in addition to the aggressive rebates, as all managed care plans attempt to aggressively direct their patients towards generic medicines due to their lack of belief in differentiation or overall cost improvement. Therefore, without heavy investments and new generation of addition clinical data, HEOR and RWE to address the skepticism of meaningful differentiation, our products will not obtain favorable coverage.

Additionally, because the Specialty business of our Proprietary Products segment works primarily with known active molecules, there remains a risk that these product are easier to engineer around than products possessing composition of matter patents. Although we strive to create a robust intellectual property ring fence around these assets, the products in our U.S. Specialty business portfolio may nonetheless enjoy fewer years of exclusivity than traditional innovative 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.

In recent years, significant questions have arisen regarding the safety, efficacy and potential for misuse of certain over-the-counter medicine products. Litigation, particularly in the United States, sometimes gives rise to these questions. As a result, health authorities around the world have begun to re-evaluate some important over-the-counter products, leading to restrictions on the sale of some of them and even the banning of certain products. If the U.S. FDA or another regulator were to review one or more of our over-the-counter products for such purposes, and if such review resulted in the U.S. FDA or another regulator charging us with violations applicable to such product, it could have a significant adverse effect on our sales of such over-the-counter products and, thus, our overall profitability.

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

A substantial portion of the value of our assets pertains to various intangible assets and goodwill. The proportion of the intangible assets and goodwill to our total assets could increase significantly as we pursue various growth

strategies. The value of these intangible assets and goodwill could be substantially impaired upon indications of impairment, with adverse effects on our financial condition and the value of our assets.

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

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

From time to time we enter new markets, and face risks arising out of our limited knowledge of the market and the customs, laws and regulatory systems that may apply.

From time to time we enter new markets in which we have limited knowledge of the market and the customs, laws, regulatory, political and social systems that may apply. Our success in these new markets is dependent upon the acceptability of our product and brand, the ease of doing business in such market and various other social and economic factors that may be specific to such market. Further, limitations by the local authorities of repatriation of generated funds may pose a risk to our success in these new markets. Our sales and profit margins may be adversely affected if we fail to provide competitive options in the market or our brands fail to gain acceptability in the market.

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

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

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

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

If we are unable to defend ourselves in patent challenges, we could be subject to injunctions preventing us from selling our products, or we could be subject to substantial liabilities that could adversely affect our profits. Further, our patent settlement agreements with the innovators may face government scrutiny, exposing us to significant damages.

There has been substantial patent related litigation in the pharmaceutical industry concerning the manufacture, use and sale of various products. In the normal course of business, we are regularly subject to lawsuits and the ultimate outcome of litigation could adversely affect our results of operations, financial condition and cash flow. Regardless of regulatory approval, lawsuits are periodically commenced against us with respect to alleged patent infringements by us, such suits often being triggered by our filing of an application for governmental approval, such as an ANDA or NDA. 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.

Further, we have been involved in various litigations involving challenges to the validity or enforceability of registered patents and therefore settling such patent litigations has been and is likely to continue to be an important part of our business.

Parties to patent litigation settlement agreements in the United States, including us, are required by law to file them with the Federal Trade Commission ("FTC") and the Antitrust Division of the Department of Justice for review. The FTC has publicly stated that, in its view, some of the brand-generic settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies that have entered into such agreements. Accordingly, such settlement agreements may expose us to antitrust violation claims.

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

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

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. In addition, there could be thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels.

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

A significant portion of our revenues are in currencies other than the Indian rupee, especially in the U.S. dollar, the Euro, the Russian rouble, and the U.K. pound sterling, while a significant portion of our costs are in Indian rupees. As a result, if the value of the Indian rupee appreciates relative to these other currencies, our revenues measured in Indian rupees may decrease and our financial performance may be adversely impacted. This also exposes us to additional risks in the event of devaluations, hyperinflation or restrictions on the conversion of foreign currencies, such as the devaluation of the Venezuelan bolivar beginning in 2013 and continuing through 2018.

Further, we may also be exposed to credit risks in some of the emerging markets from our customers on account of adverse economic conditions.

We use derivative financial instruments to manage some of our net exposure to currency exchange rate fluctuations in certain key foreign currencies. We do not use derivative financial instruments or other hedging techniques to cover all of our potential exposure.

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

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

Since a large part of our business centers around the United States, changes to the U.S. immigration laws could make it more difficult to obtain nonimmigrant work authorizations in the United States. There have been and will continue to be calls for extensive changes to U.S. immigration laws regarding the admission of highly-skilled temporary and

permanent workers.

There are some legislative proposals which, if passed and signed into law, could add further costs and/or restrictions to some of the high-skilled temporary worker categories and, in turn, our cost of doing business in the United States may increase. This could have a material and adverse effect on our business, revenues and operating results.

Significant disruptions of information technology systems, breaches of data security or other cyber-attacks could adversely affect our business.

Our business is dependent upon increasingly complex and interdependent information technology systems, including Internet-based systems, to support our business processes as well as internal and external communications. In addition, our businesses and operating models increasingly depend on outsourcing and collaboration, which requires exchanging data and information. The size and complexity and interconnectivity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion, computer viruses and other cyber-attacks. Although we have invested in measures to reduce these risks, we cannot be assured that these measures will be successful in preventing the compromise and/or disruption of our information technology systems and related data. Any such disruption may result in the loss, theft or unauthorized disclosure of key information and/or disruption of production and business processes, which could materially and adversely affect our business.

In addition, our systems are potentially vulnerable to data security breaches, whether by employees or others that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others. Such breaches of security could result in reputational damage and could otherwise have a material adverse effect on our business, financial condition and results of operations. Further, increasing use of information technology (“IT”) systems in manufacturing processes would require us to manage issues arising out of human error and/or sabotage.

In our pursuit of operational excellence, several change management initiatives across our organization are ongoing, including but not limited to information technology automation in the areas of manufacturing, research and development, supply chain and shared services. We have outsourced our IT hardware and applications in order to improve IT capability and performance. Any failure by such outsourced service providers to deliver timely and quality services and to co-operate with one another could create disruption, which could materially adversely affect our business or results of operations. Further, any failure by us to effectively manage such change initiatives or implement adequate controls in automation, security or availability of information technology systems could have a material adverse effects on our business.

Increased outsourcing or use of cloud services for conducting our business requires highly secure controls to ensure adequate security of information, considering potential for sabotage as well as availability. Data integrity, confidentiality and data privacy requirements are increasingly concerning regulators, and are incorporated into legal contracts. While we have invested heavily in the protection of data and information technology to reduce these risks, there can be no assurance that our efforts or those of our third-party service providers would be sufficient to protect against data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a security breach.

We are subject to data privacy and security laws and regulations in many different jurisdictions and countries where we do business, and our or our partners' failure to comply could result in fines, penalties, reputational damage, and could impact the way we operate our business.

We are subject to laws and regulations governing the collection, use and transmission of health information, including personal data. As the legislative and regulatory landscape for data privacy and protection continues to evolve around the world, there has been an increasing focus on privacy and data protection issues that may affect our business. For example, the European Union's General Data Protection Regulation ("GDPR") that became fully effective in May 2018, requires Companies to satisfy new requirements regarding the handling of personal and sensitive data and includes significant new penalties for non-compliance, with fines up to the higher of EUR 20 million or 4% of total annual worldwide revenue.

Other countries in which we do business have, or are developing, laws governing the collection, use and transmission of personal information as well that may affect our business or require us to adapt our technologies or practices. Some countries, including India, are considering legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements.

These and similar initiatives could increase the cost of developing, implementing or maintaining our IT systems and require us to allocate more resources to compliance initiatives thereby increasing our costs. In addition, a failure by us, or our third-party vendors, to comply with applicable data privacy and security laws could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on the way we operate our business, our 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 and mobile 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 and mobile tools 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 or third parties may make use of them in ways that may not be sanctioned by us, and that may give rise to liability, or that could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others. Such uses of social media could have a material adverse effect on our business, financial condition and results of operations. Social media posts could also contain information purported to be disclosed by us that is false or otherwise damaging, which could have a material adverse effect on our reputation and the price of our equity shares and ADSs.

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

Changing laws, regulations and standards relating to accounting, corporate governance and public disclosure, including the Sarbanes Oxley Act of 2002, new SEC regulations, New York Stock Exchange rules, provisions of India's Companies Act 2013, Securities and Exchange Board of India rules and Indian stock market listing regulations, create uncertainty for our company. These new or changed laws, regulations and standards may lack specificity and are subject to varying interpretations. Their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs of compliance as a result of ongoing revisions to such governance standards.

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

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

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

Changes in tax regulations of the countries we operate in may increase our tax liabilities and thus adversely affect our financial results.

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

For instance, presently under Indian tax laws, weighted deduction on research and development activities is available at 150% which will be reduced to 100% commencing April 1, 2020. Further, Special Economic Zone ("SEZ") units commencing manufacture or production of article and things after April 1, 2020 will not be eligible for SEZ tax deductions currently available.

India's Finance Act, 2016 amended the test of residence for foreign companies. While a non-resident company is generally taxed only on its Indian sourced income, a resident company is taxed on its global income. Under the amended rule, a company not formed under the laws of India would be considered a resident in India if its place of effective management in the previous year was in India. The term "place of effective management" (or "PoEM") has been defined to mean a place where key management and commercial decisions that are necessary for the conduct of the business of an entity as a whole are in substance made.

Effective July 1, 2017, a Goods and Services Tax ("GST") was introduced in India, replacing various taxes such as central excise duty, service tax, octroi, value added tax, sales tax and entry tax, thus avoiding the multiple layers of taxation that had previously existed in India. The GST rate applicable to finished dosages is generally 12%, whereas

API are subject to a GST rate of 18%. Taxing finished dosages at lower rates than API reduces the competitiveness of domestically manufactured finished dosages as compared to imported finished dosages - sometimes referred to as an "inverted duty structure". Relevant procedures have been prescribed in the GST legislation relating to tax credits allowing for refunds to offset the adverse impact of such inverted duty structure. Accumulation of tax credits is likely to persist at any point of time owing to the lag between the time the tax credit arises and the time that the refund is received.

Further, the effective rate of dividend distribution tax ("DDT") has been increased several times since 2013. Effective April 1, 2018, the effective rate of DDT increased from 20.3576% to 20.5553%.

In December 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "TCJA"). The TCJA makes broad and complex changes to the U.S. Internal Revenue Code, including, but not limited to, reducing the U.S. federal corporate income tax rate from 35% to 21% effective for tax years beginning after December 31, 2017. The TCJA also puts in place new tax laws that may impact our taxable income for tax years beginning after December 31, 2017, which include, but are not limited to (i) expanded limitations on the deductibility of interest, (ii) immediate expensing of capital expenditures, (iii) the migration from a "worldwide" system of taxation to a territorial system, (iv) the creation of an anti-base erosion minimum tax system; and (v) the modification or repeal of many business deductions and credits.

Changes in tax regimes in countries other than India, such as the TCJA, could result in a material impact on our cash tax liabilities and tax charges, resulting in either an increase or a reduction in financial results depending upon the nature of the change.

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

We are required to comply with various transfer pricing regulations in India and other countries. Failure to comply with such regulations may impact our effective tax rates and consequently affect our net margins. Additionally, we operate in numerous countries and our failure to comply with the local and municipal tax regimes may result in additional taxes, penalties and enforcement actions from such authorities. Although our intercompany arrangements are based on accepted tax standards, tax authorities in various jurisdictions may disagree with and subsequently challenge the amount of profits taxed in such jurisdictions, which may increase our tax liabilities and could have a material adverse effect on the results of our operations. Further, the base erosion and profit shifting ("BEPS") project undertaken by the Organization for Economic Cooperation and Development ("OECD") contemplates changes to numerous international tax principles. Various countries have incorporated such tax principles into their domestic legislations by way of enactment. These enactments are significant in nature and require compliance on a regular basis. Although we will continue to adhere to such compliance, significant uncertainties remain as to the outcome of these efforts.

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

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

In recent years, the global economy has experienced volatility and an unfavorable economic environment, and these trends may continue in the future. Reduced consumer spending, reduced funding for national social security systems or shifting concentrations of payors and their preferences, may force our competitors and us to reduce prices. The growth of our business may be negatively affected by high unemployment levels and increases in co-pays, which may lead some patients to delay treatments, skip doses or use less effective treatments to reduce their costs.

We have exposure to many different industries and counterparties, including our partners under our alliance, research and promotional services agreements, suppliers of raw materials, drug wholesalers and other customers, who may be unstable or may become unstable in the current economic environment. We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies.

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.

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

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

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

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

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

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

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

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 26.76% of our issued shares as at March 31, 2018. As a result, these people, acting in concert, are likely to have the ability to exercise significant control over most matters requiring approval by our shareholders, including the election and removal of directors and significant corporate transactions. This significant control by these directors and their family members could delay, defer or prevent a change in control, impede a merger, consolidation, takeover or other business combination involving us, or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. As a result, the value of the equity shares and/or ADSs of our minority shareholders may be adversely affected or our minority shareholders might be deprived of a potential opportunity to sell their equity shares and/or ADSs at a premium.

RISKS RELATING TO INVESTMENTS IN INDIAN COMPANIES

We are an Indian company. Our headquarters are located in India, a substantial part of our operations are conducted in India and a significant part of our infrastructure and other assets are located in India. In addition, a substantial portion of our total revenues for the year ended March 31, 2018 continued to be derived from sales in India. As a result, the following additional risk factors apply that are not specific to our company or industry.

We may be subjected to additional compliance and litigation risks as a result of introduction of the Companies Act, 2013 in India and the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

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

In addition, on September 2, 2015, the Securities and Exchange Board of India (“SEBI”) issued the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 (the “Listing Regulations”) that must be followed by all listed Indian public companies effective December 1, 2015. These Listing Regulations were intended to consolidate and streamline the provisions of the existing listing agreements for different segments of the capital markets (e.g., equity securities, debt securities, Indian depository receipts, etc.). The Listing Regulations have thus been structured to provide ease of reference by consolidating into one single document across various types of securities listed on the stock exchanges. Key features of the Listing Regulations include:

- A framework has been prescribed for disclosure of material events and information by listed entities to the Indian stock exchanges. Certain events mentioned in the regulations are deemed material and disclosure is mandatory. Certain events are to be disclosed based on application of the guidelines for materiality as prescribed. The Board of Directors is required to frame a policy for determination of materiality and disclose the same on the website of the company.

- Entities are required to frame policies on preservation of documents, determination of material subsidiaries, risk management, code of conduct, remuneration of directors, key managerial personnel and other employees, board diversity, materiality of related party transactions and dealing with related party transactions and criteria for evaluation of directors.

However, certain provisions of the Companies Act, 2013 and the new Listing Regulations provisions are subject to varying interpretations and their application in practice may evolve over time as additional guidance is provided by regulatory and governing bodies. Further, the Companies Act, 2013, the rules made thereunder and the new Listing Regulations are subject to various ongoing changes. In 2017, certain amendments to the Companies Act, 2013 were implemented through the Companies (Amendment) Act, 2017 in the areas of related party transactions, financial reporting, audit and auditors, board matters and others. Certain of such amendments are yet to be effective.

This may result in continuing uncertainty regarding compliance matters and higher costs of compliance as a result of ongoing revisions.

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

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

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

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

Due to various macro-economic factors, the rate of inflation has recently been volatile in India. If the inflation rises, we may not be able to pass these inflationary costs on to our customers by increasing the price we charge for our products.

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 may restrict our ability to have human resource policies that would allow us to react swiftly to the needs of our business. Approximately 4% of our employees belong to a number of different labor unions. If we experience problems with our labor unions, our production capacity and may adversely affect our results and operations.

Risks Relating to our ADSs THAT ARE NOT SPECIFIC TO OUR COMPANY OR INDUSTRY

The market price of our ADSs may be volatile, and the value of your investment could materially decline.

Investors who hold our ADSs may not be able to sell their ADSs at or above the price at which they purchased such ADSs. The price of our ADSs fluctuate from time to time, and we cannot predict the price of our ADSs at any given time. The risk factors described herein could cause the price of our ADSs to fluctuate materially. In addition, the stock market in general, including the market for generic and specialty pharmaceutical companies, has experienced price and volume fluctuations. These broad market and industry factors may materially harm the market price of our ADSs, regardless of our operating performance. In addition, the price of our ADSs may be affected by the valuations and recommendations of the analysts who cover us, and if our results do not meet the analysts' forecasts and expectations, the price of our ADSs could decline as a result of analysts lowering their valuations and recommendations or otherwise.

Negative media coverage and public scrutiny may adversely affect the prices of our equity shares and ADSs.

Media coverage, including social media coverage such as blogs, of us has increased dramatically over the past several years. Any negative media coverage, regardless of the accuracy of such reporting, may have an adverse impact on our reputation and investor confidence, resulting in a decline in the share price of our equity shares and our ADSs.

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

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

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

Indian legal restrictions may limit the supply of our ADSs. The only way to add to the supply of our ADSs will be through a primary issuance because the 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 equity shares as opposed to our ADSs.

The persistently weak global economic and financial environment in many other countries, particularly emerging market countries, and increasing political and social instability could have a material adverse effect on our business and the price and liquidity of our shares and our ADSs.

Many of the world's largest economies and financial institutions continue to be impacted by a weak ongoing global economic and financial environment, with some continuing to face financial difficulty, liquidity problems and limited availability of credit. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. In addition, these issues may be further impacted by the difficult conditions existing in parts of the Middle East, anti-immigrant activities, social unrest and fears of terrorism that have followed in many countries.

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

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

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

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

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

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

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

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

Sale of our equity shares may adversely affect the prices of our equity shares and ADSs.

The Government of India enacted the Depository Receipts Scheme, 2014, effective as of December 15, 2014. This law permits liberalized rules for sponsored and unsponsored secondary market issue of depository receipts, subject to the existing sectorial cap on foreign investment. Once the regulations are implemented, an Indian company's equity shares can be freely issued to a depository for the purpose of issuing depository receipts through any mode permissible for the issue of such securities to other investors. This would enable us to more readily issue shares to the depositary for our ADSs and conduct U.S. securities issuances of our ADSs, which would impact the share price and available float in Indian stock exchanges as well as the price and availability of our ADSs on the NYSE. Refer to Item 10.D. "Exchange controls – ADS guidelines" for further details.

ITEM 4. INFORMATION ON THE COMPANY

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

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

Key business developments:

Re-Audit of the Warning letter impacted sites

The U.S. FDA issued a warning letter dated November 5, 2015 (the "Warning Letter") relating to current Good Manufacturing Practice ("cGMP") deviations at our active pharmaceutical ingredient ("API") manufacturing facilities at Srikakulam, Andhra Pradesh and Miryalaguda, Telangana, as well as those at our oncology formulation manufacturing facility at Duvvada, Visakhapatnam, Andhra Pradesh. The contents of the Warning Letter emanated from Form 483 observations that followed inspections of these three sites by the U.S. FDA in November 2014, January 2015 and February-March 2015, respectively. Pending resolution of the issues identified in the Warning Letter, the U.S. FDA withheld approval of new products from these facilities.

Subsequent to the issuance of the Warning Letter, we promptly instituted corrective actions and preventive actions and submitted a comprehensive response to the Warning Letter to the U.S. FDA, followed by periodic written updates and in-person meetings with the U.S. FDA. Moreover, to minimize the business impact, we transferred certain key products to alternate manufacturing facilities.

The U.S. FDA subsequently re-inspected these facilities between February and April 2017. The outcome of these inspections were as follows:

- *API facility at Miryalaguda*: The U.S. FDA raised three observations in the areas of older methods of validation, improvements in instrument calibrations and adherence to United States Pharmacopeia ("USP") test methods. Subsequently, in June 2017, the U.S. FDA issued an Establishment Inspection Report ("EIR") indicating successful closure of audit of this facility.

- *API facility at Srikakulam*: The U.S. FDA raised two observations in the areas of high performance liquid chromatography ("HPLC") maintenance, and the management of soft copies of chromatograms. In February 2018, the U.S. FDA issued an EIR for this facility indicating that its inspection status remains unchanged.

- *Oncology formulation facility at Duvvada*: The U.S. FDA raised thirteen observations in the areas of investigations, batch production records, document controls, general computer systems and environmental monitoring. In November 2017, the U.S. FDA issued an EIR for this facility indicating that its inspection status remains unchanged.

Global corrective actions, as well as some specific actions, have already been implemented. Additionally, a detailed response was submitted to the U.S. FDA which included root cause, corrective actions and preventive actions and impact assessment. We remain fully committed to following high standards of quality and strive towards further strengthening of our quality management systems and processes for sustainability. Our plans to enhance our quality management systems and operations include improvements in rigor of investigations and document control systems, standardization of instrument calibrations, strengthening controls with respect to information technology, strengthening shop floor training programs, and simplifying and standardizing standard operating procedures and batch records at the shop floor.

Further, we have initiated additional operational improvements with respect to areas such as shop floor supervision and Gemba walks (also known as process walks) into the shop floor, engineering, implementation of electronic batch records to eliminate manual errors, and focus on robustness of processes.

Throughout the process of remediating issues raised in the Warning Letter, we have been continually engaged with the U.S. FDA in conveying the progress we have made. We are fully committed to produce safe and efficacious products for our patients.

Asset purchase agreement with Teva Pharmaceutical Industries Ltd

Refer to Note 33 of our consolidated financial statements.

Principal capital expenditures:

During the years ended March 31, 2018, 2017 and 2016, we invested Rs.8,894 million, Rs.12,234 million and Rs.11,933 million (net of sales of capital assets), respectively, in capital expenditures for manufacturing, research and development facilities and other assets. We believe that these investments will create the capacity to support our strategic growth agenda. As of March 31, 2018, we also had contractual commitments of Rs.3,788 million for capital expenditures. These commitments included Rs.3,516 million to be spent in India and Rs.272 million in other countries. We currently intend to finance our additional capital expansion plans entirely through our operating cash flows and through cash and other investments.

4.B. *Business overview*

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

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

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

Pharmaceutical Services and Active Ingredients. This segment includes our business of manufacturing and marketing active pharmaceutical ingredients and intermediates, also known as "API" 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 our contract research services business and our manufacture and sale of active pharmaceutical ingredients and steroids in accordance with the specific customer requirements.

Proprietary Products. This segment consists of our business that focuses on the research, development, and manufacture of differentiated formulations. These novel products fall within the dermatology and neurology therapeutic areas and are marketed and sold through Promius® Pharma, LLC.

Others. This includes the operations of our wholly-owned subsidiary, Aurigene Discovery Technologies Limited, a discovery stage biotechnology company developing novel and best-in-class therapies in the fields of oncology and inflammation and which works with established pharmaceutical and biotechnology companies in early-stage collaborations, bringing drug candidates from hit generation to pre-clinical development.

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

OUR STRATEGY

Our strategy is guided by our core purpose of accelerating access to affordable and innovative medicines, because "Good Health Can't Wait".

Spiraling health care costs across the world have put many medicines out of the reach of millions of people who desperately need them. As a global pharmaceutical company, we take very seriously our responsibility to offer affordable alternatives to expensive medicines and help patients manage their disease better.

We deliver on our purpose through a set of promises we make to our customers and partners:

- to bring expensive medicines within reach;
- to address unmet patient needs;
- to help patients manage disease better;
- to work with partners to help them succeed; and
- to enable and help our partners ensure that our products are always available where needed.

Our business strategy and operating priorities strive to fulfill these promises. They are carefully chosen to enable us to deliver the maximum positive impact on the lives of patients around the world. The key elements of our business strategy for achieving these promises include the following:

Strengths in science and technology

Our strengths in science and technology range from synthetic organic chemistry, formulation development, biologics development to small molecule based drug discovery. Such expertise enables us to deliver first-to-market, difficult-to-make products with an industry leading intellectual property and technology leveraged product portfolio.

Product Offerings

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

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

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

- *Biologics*: Our biologics business seeks to accelerate access to biosimilar products globally through process development and relevant clinical research. We were the first company to launch a biosimilar version of rituximab in 2007, and have launched 4 biosimilar products in India and other key markets.

Our vertical integration and process innovation helps to ensure that quality products are available to patients in need at all times.

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

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

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

Proprietary Products: Our Proprietary Products segment is comprised of our differentiated formulations business in the therapeutic areas of dermatology and neurology. In this segment, we work to improve patient outcomes by identifying unmet and under-met medical needs and addressing them through innovative products and services that are affordable and accessible. We also have an internal pipeline of differentiated products in dermatology and neurology products in various stages of development. In addition, we have a commercial portfolio of in-licensed dermatology products.

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Operating priorities

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

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

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

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

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

OUR PRINCIPAL AREAS OF OPERATIONS

The following table shows our revenues and the percentage of total revenues of our business segments for the years ended March 31, 2018, 2017 and 2016, respectively:

Segment	For the year ended March 31, 2018 (Rs. in millions, U.S.$ in millions)			2017			2016		
Global Generics	U.S.$1,751	Rs. 114,014	80 %	Rs. 115,409	82 %		Rs. 128,062	83 %	
PSAI	338	21,992	16 %	21,277	15 %		22,379	14 %	
Proprietary Products	65	4,245	3 %	2,363	2 %		2,659	2 %	
Others	27	1,777	1 %	1,760	1 %		1,608	1 %	
Total Revenue	**U.S.$**2,181	**Rs.** 142,028	100%	**Rs.** 140,809	100%		**Rs.** 154,708	100%	

Revenues by country and by therapeutic area for the years ended March 31, 2018, 2017 and 2016 are discussed in Note 5 to our consolidated financial statements.

Global Generics Segment

Our Global Generics segment's revenues were Rs.114,014 million for the year ended March 31, 2018, as compared to Rs.115,409 million for the year ended March 31, 2017. The decline is largely attributable to this segment's operations in the United States, where price erosion of certain of our existing products has reduced our revenues.

The production processes for finished dosages of generics are similar, to a certain extent, regardless of whether the finished dosages are to be marketed to highly regulated or less regulated markets. In many cases, the processes share common and interchangeable facilities and employee bases, and use similar raw materials. However, differences remain between highly regulated and less regulated markets in terms of manufacturing, packaging and labeling requirements and the intensity of regulatory oversight, as well as the complexity of patent regimes.

While the degree of regulation in certain markets may impact product development, we are observing increasing convergence of development needs throughout both highly regulated and less regulated markets. As a result, when we begin the development of a product, we may not necessarily target it at a particular market, but will instead target the product towards a cluster of markets that will include both highly regulated and less regulated markets.

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

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

India

During the year ended March 31, 2018, India accounted for 20% of our total Global Generics segment sales. In India, our key therapeutic categories include gastro-intestinal, cardiovascular and anti-diabetic, pain management and oncology. We are also increasing our presence in the niche areas of dermatology, urology and nephrology.

As of March 31, 2018, we had a total of 292 branded products in India. Our top ten branded products together accounted for 28% of our revenues in India in the year ended March 31, 2018. According to IMS Health, a provider of market research to the pharmaceutical industry, in its moving annual total report for the twelve month period ended March 31, 2018, our secondary sales in India grew by 1.8%. In comparison, the Indian pharmaceutical market experienced growth of 6.3% during such period. Strategic Marketing Solutions and Research Center Private Limited ("SMSRC"), a prescription market research firm, in its report measuring pharmaceutical prescriptions in India for the period from January 2018 to February 2018, ranked us 11th in terms of the number of prescriptions generated in India during such period.

Sales, marketing and distribution network

We generate demand for our products through our 5,680 sales representatives (which include representatives engaged by us on a contract basis through a service provider) and front line managers, who frequently visit doctors to detail our related product portfolio. They also visit various pharmacies to ensure that our brands are adequately stocked.

We sell our products primarily through clearing and forwarding agents to approximately 3,000 wholesalers who decide which brands to buy based on demand. The wholesalers pay for our products in an agreed credit period and in turn sell these products to retailers. Our clearing and forwarding agents are responsible for transporting our products to the wholesalers. We pay our clearing and forwarding agents on a commission basis. We have insurance policies that cover our products during shipment and storage at clearing and forwarding locations.

Competition

We compete with different companies in the Indian formulations market, depending upon therapeutic and product categories and, within each category, upon dosage strengths and drug delivery. On the basis of sales, we were the 16th largest pharmaceutical company in India, with a market share of 2.2%, according to IMS Health in its moving annual total report for the twelve month period ended March 31, 2018.

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

Government regulations

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

- The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945;
- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954;
- The Narcotic Drugs and Psychotropic Substances Act, 1985;
- The Drugs (Price Control) Order, 1995 and 2013, read in conjunction with the Essential Commodities Act, 1955; and
- The National Pharmaceuticals Pricing Policy, 2012.

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

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

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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.

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

Under the present drug policy of the Government of India, certain drugs have been specified under the Drugs (Prices Control) Order, 2013 (the "DPCO") as subject to price control. The Government of India established the National Pharmaceutical Pricing Authority, 2012 ("NPPA"), to control pharmaceutical prices. Under the DPCO, the NPPA has the authority to fix the maximum selling price for specified products.

During the year ended March 31, 2013, the Department of Pharmaceuticals under the ministry of Chemicals and Fertilizers of the Government of India proposed the National Pharmaceuticals Pricing Policy, 2012, a revised national Pharmaceutical Pricing policy to apply price controls to 348 drugs listed in National List of Essential Medicines. Some of our formulation products were subject to these price controls. The National List of Essential Medicines, as revised in 2016, now contains 376 drugs.

On June 30, 2017, the NPPA announced revisions of the maximum prices for various products scheduled in the National List of Essential Medicines on account of the GST implementation in India. This was followed by an announcement on April 2, 2018 of an increase in the maximum prices of various drugs, as a result of positive inflation as measured by India's Wholesale Price Index.

On March 12, 2016, the Department of Health and Family Welfare under the Ministry of Health and Family Welfare of the Government of India banned 344 fixed dose combination drugs (i.e., two or more active drugs combined in a fixed ratio into a single dosage). A number of pharmaceutical companies, including us, filed a writ petition before the Delhi High Court challenging the ban. The Delhi High Court initially granted an interim stay on the ban notification and on December 1, 2016, it overturned the government imposed ban on the 344 fixed dosage combinations. Subsequently, the Government of India filed an appeal of the decision in the Supreme Court of India. In December 2017, the Supreme Court of India referred the issue to the government's expert body, the Drugs Technical Advisory Board ("DTAB"), for a fresh review of safety, efficacy and therapeutic justification of the drugs before recommending

action. Currently, the DTAB is in the process of examination. In the event that this ban becomes effective, it could adversely impact our revenues.

Such ongoing price control changes, product bans and other changes can disrupt the Indian branded pharmaceutical market and negatively impact the revenues and profitability of our Indian business and our company.

Russia and other Countries of the former Soviet Union

Russia

Russia accounted for 11% of our Global Generics segment's revenues in the year ended March 31, 2018. IMS Health ranked us 18th in sales in Russia, with a market share of 1.5% for the twelve months ended March 31, 2018.

According to IMS Health, as per its moving annual total report for the twelve months ended March 31, 2018, our sales value growth was 3.0% and our sales volume decreased by 1.5% for such period, as compared to the Russian pharmaceutical market value growth of 3.3% and sales volume decrease of 2.1% for such period. We were the top ranked Indian pharmaceutical company in Russia for such period.

Our top five brands, Nise, Omez, Ketorol, Ibuclin and Cetrine, accounted for 56% of our Global Generics segment's revenues in Russia for the year ended March 31, 2018. Omez (an anti-ulcerant product), Nise and Ketorol (both pain management products), Cetrine (a respiratory product) and Ibuclin (pain management product) were ranked as the 59th, 21st, 160th, 189th and 230th best-selling formulation brands, respectively, in the Russian market by IMS Health in its moving retail segment report for the twelve months ended March 31, 2018.

Our strategy in Russia is to focus on the gastro-intestinal, pain management, anti-infectives, respiratory, oncology and cardiovascular therapeutic areas. Our focus is on building leading brands in these therapeutic areas in prescription, over-the-counter and hospital sales. Nise, Omez, Ketorol, Cetrine, Ibuclin, Novigan, Plagril, Razo, Levolet and Ciprolet continue to be brand leaders in their respective categories, as reported by IMS Health in its moving report for the twelve months ended March 31, 2018.

Our Global Generics segment's revenues in Russia increased by 4% (in Russian rouble absolute currency terms) during the year ended March 31, 2018, which was driven by increased marketing and pharmacy chain activities for over-the-counter medicines. Such revenues, measured in Indian rupees, increased by 9% as compared to the year ended March 31, 2017.

Other Countries of the former Soviet Union and Romania

We operate in other countries of the former Soviet Union, including Ukraine, Kazakhstan, Belarus, Uzbekistan and Romania. For the year ended March 31, 2018, revenues from these countries accounted for 4% of our total Global Generics segment's revenues.

Sales, marketing and distribution network

Our marketing and promotion efforts in our Russian prescription division is driven by a team of 308 medical representatives and 42 managers to detail our products to doctors in 77 cities in Russia.

Our Russian over-the-counter ("OTC") division has 212 medical representatives and 30 managers and is focused on establishing a network of relationships with key pharmacy chains and individual pharmacies. Our Russian hospital division has 40 hospital specialists and 18 key account managers, and is focused on expanding our presence in hospitals and institutes.

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

Competition

Our principal competitors in the Russian market include Gedeon Richter RUS (an affiliate of Gedeon Ritcher PLC), Krka Pharma Limited, Teva, Lek-Sandoz Pharmaceuticals (an affiliate of Novartis Pharma A.G.), Zao Ranbaxy (an affiliate of Ranbaxy Laboratories Limited), Nycomed International Management GmbH and Zentiva N.V. (an affiliate of Sanofi-Aventis S.A.).

Government regulations

Healthcare system development in Russia

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.

The Russian government approved the State Program for Healthcare System Development on December 26, 2017. The objectives of this program are increasing life expectancy at birth, reducing mortality of the working-age population, reducing mortality from circulatory diseases and tumors (including malignant ones) and raising medical care quality satisfaction.

Reference pricing regime

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

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

In 2017, a draft of “Rules for State registration and re-registration of the maximum ex-works manufacturer prices of medicines included in EDL” was published by the Russian Ministry of Health. However, there remains ambiguity on the final form of the document or implementation period and we are in the process of evaluating the impact of these changes on our operations even as we await further clarity on this draft law.

State Regulation of Prices for Vital and Essential Medicines

Russia's Federal Law No. 34-FZ dated March 8, 2015 amended the Federal Law 61-FZ "On Circulation of Medicines". The amendments created new rules for the registration, manufacture and quality control of medicines, including new rules for the calculation and registration of the maximum retail prices of vital and essential medicines established by the ZhNVLS (the "EDL").

Calculation of the maximum sale price for medicines included in the EDL list is determined by the Government of the Russian Federation taking into account a variety of economic and/or social criteria. The updated EDL lists for 2018, approved by the Decree of the Government No. 2323-p dated October 23, 2017, became effective from January 1, 2018. These lists include the list of drugs for provision to specific groups of citizens, medicines prescribed by a decision of a medical commission of medical organizations, medical supplies from the 7 Nosologies program list (which covers expensive treatments for patients with certain severe chronic diseases), as well as the minimum range of medicines required for medical aid.

Restrictions on access of foreign drugs

In 2015, the Russian Government enacted the Priority Action Plan for sustainable economic and social stability development and regulation No. 128. This plan and regulation affects medicines included in the EDL, and some of their key terms that have impacted the pharmaceutical industry are (i) supporting import substitution; (ii) optimizing budget costs and reducing inefficient expenses; and (iii) restrictions on access of foreign drugs to state procurement tenders, if two or more locally manufactured drugs participate in the relevant tender.

Interactions between healthcare professionals and medical product companies

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

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

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

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

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

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

Liability for non-compliance with such restrictions extends to both the healthcare professional and the medical product representative. Except for requiring the disclosure of information on conflicts of interest, no specific liability has been currently prescribed for medical product companies.

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

Russia signed the agreement on a common market for medicines within the Eurasian Economic Union

The Eurasian Economic Union ("EEU"), whose member states are Russia, Belarus, Kazakhstan, Armenia, and Kyrgyzstan, officially started functioning on January 1, 2015. Among other things, the member states of the EEU signed an international agreement establishing common principles and rules of functioning of the market for medicines within the EEU. According to the agreement, the market authorization for a particular medicine received in one EEU member state will be valid throughout the whole EEU territory. On May 6, 2017, the agreement was ratified by the EEU countries. Manufacturers of the EEU countries will be able to apply for re-registration of medicines under common procedures and reduce administrative costs. All medicines registered under the national regulations of the individual EEU member states on or before to December 31, 2020 shall be re-registered under the regulations of the EEU common market on or before December 31, 2025.

Russian GMP required for medicines registration

Effective January 1, 2016, foreign medicinal products (i.e., manufactured outside of Russia) became subject to the following requirements:

- for the initial state registration of a foreign medicinal product, it is required to present a statement of conformity of the manufacture thereof to Russian GMP standards issued by a Russian authority; and

- for re-registration of a foreign medicinal product, it was sufficient to present a certificate of GMP compliance (obtained in the country of origin) to the applicable GMP standards in the country of origin, issued by the relevant foreign authority with a certified Russian translation. However, effective January 1, 2017, re-registrations of a foreign medicinal product also are subject to the requirement to present a document regarding conformity to Russian GMP standards issued by a Russian authority.

Monitoring System of Movement of Medicines from the Producer to the Final Consumer

The Ministry of Health in Russia has proposed a full serialization system to track and trace the passage of pharmaceuticals through the entire supply chain, from the manufacturers to the end users. The proposed federal repository and tracking system would provide the manufacturers, supply chain and end users of pharmaceuticals many functionalities. Listed below are some of the functions that would be available in addition to the usual authentication and track and trace services:

- the system would provide price controls on products designated as vital and essential medicines;

- consumers would be able to compare the price of the drug to its official price limit, find which pharmacies do have the drug available, and get the product information.;

- manufacturers would be able to get real time data on the logistics and storage of their products in the market;

- pharmacists could get information related to the price, and monitor expiration dates;

- health care institutions would be able to track registration and prices; and

- federal agencies would have capability to monitor all medicinal products on the market to facilitate price controls as well as report on and analyze the industry.

Marketing application holders for medicinal products are required to file registration information for the track-and-trace system with the Russian governing body by January 1, 2019. The provisions on manufacturers' obligations to label the package with the identification marks, to submit the data to the monitoring system as well as the terms governing liability for non-compliance will become effective starting January 1, 2020.

Medicines promo and sales

In December 2017, the Russian State Duma Committee on Health approved the draft law on "On Amendments to Certain Legislative Acts of the Russian Federation regarding Remote Retail Trade of Pharmaceuticals", which regulates online retail sales of pharmaceuticals. Under the draft, a pharmacy (including a veterinarian pharmacy) may sell via the internet only OTC pharmaceuticals and only if a valid pharmaceutical license is held. Online sales of prescription drugs is prohibited, and websites breaching this requirement shall be banned.

Further, the Russian Ministry of Industry and Trade posted the draft law "On Amendments to Certain Legislative Acts of the Russian Federation regarding Sale of Medicines by Retail Trade Organizations" for public discussion. As per the draft, retailers will have to obtain a pharmaceutical license to be able to sell OTC drugs in stores and supermarkets.

Political Instability

There has been severe political instability in Ukraine following civilian riots and political unrest which began in November 2013, destabilization of the Ukrainian President's office in February 2014, and subsequent military action in the destabilized country operating under a temporary government.

As a result of ongoing conflict in the region, the United States and the European Union have imposed sanctions on certain designated individuals and companies in Ukraine and Russia. These sanctions were targeted at persons threatening the peace and security of Ukraine, senior officials of the Government of the Russian Federation and the energy, defense and financial services sectors of Russia, but they have had macroeconomic consequences beyond those persons and industries. In December 2014, the United States imposed further sanctions aimed at blocking new investments in the Crimea region of Ukraine which was annexed by Russia, and blocking trade between the United States or U.S. persons and Crimea. These sanctions also authorized the United States government to impose sanctions on any U.S. persons determined to be operating in the Crimea region of Ukraine, subject to certain authorizations for the export and re-export of certain agricultural commodities, medicine, medical supplies, and replacement parts to Crimea.

Political instability in the region has led to significant devaluation of the Russian rouble. In addition, the Ukrainian hryvnia experienced significant devaluation in 2014 and 2015. The possibility of additional sanctions implemented by the United States and/or the European Union against Russia or vice versa, continued political instability, civil strife, deteriorating macroeconomic conditions and actual or threatened military action in the region may result in serious economic challenges in Ukraine, Russia and the surrounding areas.

Among our operations, we are engaged in sales, distribution and marketing of pharmaceutical products in Russia and Ukraine, including the Crimea region, all through non-U.S. entities that sell to distributors. Our sales in Russia and Ukraine are not to any of the individuals, companies or sectors designated by the current sanctions, and our sales in the Crimea region accounted for approximately 0.1% of our total revenues for the year ended March 31, 2018. We do not believe that our business in Russia, Ukraine or the Crimea region violates any of the current sanctions. However, relevant regulators could take a view that is different from ours on this issue. We continue to monitor our subsidiaries' activities in light of the restrictions imposed by these and any future sanctions.

North America (the United States and Canada)

During the year ended March 31, 2018, North America (the United States and Canada) accounted for 53% of our total Global Generics segment sales. In the United States, we sell generic drugs that are the chemical and therapeutic

equivalents of reference branded drugs, typically sold under their generic chemical names at prices below those of their brand drug equivalents. Generic drugs are finished pharmaceutical products ready for consumption by the patient. These drugs are required to meet the U.S. FDA or Health Canada, as applicable, 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 companies sometimes conduct “at-risk launches”, in which sales of the product are launched prior to resolution of a patent challenge.

Generic pharmaceutical sales increased significantly in the last decade, primarily due to an increased awareness and acceptance among consumers, physicians and pharmacists that generic drugs are the equivalent of brand name drugs, substantial cost savings and an encouragement by governments through passage of legislation permitting generic drug alternatives. However, in the last two years an increase in competition and consolidation of distributors has resulted in a decline in the growth of the generic companies in North America. We intend to continue building our presence in the region by leveraging our product development capabilities and alliance management, manufacturing capacities inspected by various international regulatory agencies and access to our own APIs, which offer significant supply chain efficiencies.

Key acquisitions in North America:

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

Further, in March 2011, we acquired from GlaxoSmithKline plc and Glaxo Group Limited (collectively, “GSK”) a penicillin-based antibiotics manufacturing site in Bristol, Tennessee, U.S.A. and certain related antibiotic product rights. The acquisition enabled us to enter the U.S. oral antibiotics market with a comprehensive product filing and a dedicated manufacturing site.

During the years ended March 31, 2018, and 2017, we continued our efforts to grow the Habitrol® business (an over-the-counter Nicotine Replacement Therapy transdermal patch) that we acquired from Novartis Consumer Healthcare Inc. during the year ended March 31, 2015, having fully integrated the business. The Habitrol® business has shown healthy growth as a result of our expansion of distribution into new channels and our product innovations. We believe that there are significant growth opportunities in the smoking cessation category in the United States, and intend to continue growing the business through our focus on expansion in availability and portfolio augmentation.

Additionally, during the year ended March 31, 2017 we acquired from Ducere Pharma the rights to six over-the-counter brand products within the cough-and-cold, pain, and dermatology therapeutic areas, including Doan's, Bufferin and Nupercainal.

Through 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, 2018, we made 19 new ANDA filings with the U.S. FDA. As of March 31, 2018 our cumulative filings were 284, which includes 4 NDA filings under section 505(b)(2) and 280 ANDA filings. These 280 ANDA filings include 8 ANDAs that we acquired from Teva and an affiliate of Allergan plc. As of March 31, 2018, we had 110 filings pending approval with the U.S. FDA (107 ANDAs and 3 NDAs under 505(b)(2) route including 14 tentative approvals). Of the 107 ANDAs which are pending approval, 63 are Paragraph IV filings, and we believe that we are the first to file with respect to 30 of these filings. Further, these 107 ANDAs which are pending for approval include 6 ANDAs acquired from Teva and Allergan plc's affiliate, of which 5 are Paragraph IV filings.

Our Canada business generated revenues of Rs.545 million during the year ended March 31, 2018. This business includes revenues from certain profit sharing arrangements with distributors who market certain of our generic products. As of March 31, 2018 we have filed a cumulative total of 30 Abbreviated New Drug Submissions ("ANDS") in Canada, out of which, 20 were approved, 6 are pending approval, and 4 were withdrawn or rejected.

Sales, Marketing and Distribution Network

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

The majority of revenue from our North America generics business is derived from sales of oral solids, as well as sales of various products (both oral solids and others) to retail chains. This portion of the business represents nearly three quarters of this segment's gross revenues for this region. The product portfolio includes a wide range of therapeutic areas. During the year ended March 31, 2017, we acquired from Teva and an affiliate of Allergan plc a portfolio of eight ANDAs for our North American Generics business. The transaction, valued at $350 million, represents the largest assets acquisition in our history.

Our over-the-counter ("OTC") division primarily markets and distributes store brand OTC products, but expanded into the branded OTC segment in May 2016, developing a new channel for our growth. This division has successfully launched over 10 products. OTC products include store brand generic equivalents of products that originally have prescription drug status and are switched to OTC drug status by the innovator upon U.S. FDA approval (sometimes called "Rx-to-OTC switch" products). Our entry into the OTC branded division in May 2016 was through the acquisition from Ducere Pharma of the rights to six OTC brand products, including Doan's, Bufferin and Nupercainal. Our OTC division services a broad range of customers, including drug retailers, mass merchandisers, food chains, drug wholesalers and distributors, and GPOs. For the year ended March 31, 2018, our OTC division generated Rs.10,332 million in revenues.

A portion of our revenue is derived from the sale of injectable products in the therapeutic areas of oncology and critical care. Our injectable product portfolio in the United States primarily consists of products such as azacitidine, decitabine, zoledronic acid, doxorubicin liposomal and bivalrudin. We have also expanded our presence from drug wholesalers to specialty distributors, integrated distribution networks ("IDNs"), clinics, and hospitals to market these products. We also supply products for private label customers for injectable prescription products.

Competition

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

Continued consolidation of customer purchasing power through acquisitions, alliances and joint ventures continues to intensify the competition and drive down prices. Consolidation of manufacturers is also continuing and, at the same time, new manufacturers continue to enter the generic market in the United States, which may further lower our pricing power and adversely affect our revenues in that market.

Brand name manufacturers have devised numerous strategies to delay competition by introducing 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 exclusivities, further delaying generic introduction. Another strategy is the launch by the innovator or its licensee of an "authorized generic" during the 180-day generic exclusivity period, resulting in two generic products competing in the market rather than just the product that obtained the generic exclusivity. This may result in reduced revenues for the generic company which has been awarded the generic exclusivity period.

The U.S. market for OTC pharmaceutical products is highly competitive. Competition is based on a variety of factors, including price, quality, product mix, customer service, marketing support, and the reliability and flexibility of the supply chain for products. Our competition in store brand and innovator branded products in the United States consists of several publicly traded and privately owned companies, including large brand-name pharmaceutical companies. The competition is highly fragmented in terms of both geographic market coverage and product categories, such that a competitor generally does not compete across all product lines. In the store brand market, we compete directly with companies, such as Perrigo, Apotex, Aurobindo Pharma that sell store brand OTC products. In the branded market, we compete directly with companies, such as Bayer and Pfizer, which sell branded OTC products.

With the acquisition of Habitrol®, we now not only compete with store brands but also with large branded companies such as GlaxoSmithKline Consumer Care, which is an industry leader in the nicotine replacement therapy category. In addition, since a majority of our products are generic equivalents of innovator brands, we also compete against large brand-name pharmaceutical companies.

The competitive landscape and market dynamics of the OTC market are rapidly evolving. Large brand-name pharmaceutical companies have begun to more aggressively pursue Rx-to-OTC switches in new categories, which could present opportunities for us and other companies that sell store brand products. At the same time, pricing pressures continue to increase with the entry of new competitors in the market. On key select molecules, the expectation is that competition in this area will continue to grow as newer categories experience Rx-to-OTC switches.

Government regulations

U.S. Regulatory Environment

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

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

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

An ANDA applicant in the United States is required to review the patents of the innovator listed in the U.S. FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book," and make an appropriate certification. There are several different types of certifications that can be made. A Paragraph IV filing is made when the ANDA applicant believes its product or its manufacture, use or sales thereof does not infringe on the innovator's patents listed in the Orange Book or where the applicant believes that such patents are not valid or enforceable. The first generic company to file a Paragraph IV filing may be eligible to receive a six-month marketing exclusivity period starting from either the first commercial marketing of the drug by any of the first applicants or a decision of a court holding the patent that is the subject of the paragraph IV certification to be invalid or not infringed. A Paragraph III filing is made when the ANDA applicant does not intend to market its generic product until the patent expiration. A Paragraph II filing is made where the patent has already expired. A Paragraph I filing is made when there are no patents listed in the Orange Book. Another type of certification is made where a patent claims a method of use, and the ANDA applicant's proposed label does not claim that method of use. When an innovator has listed more than one patent in the Orange Book, the ANDA applicant must file separate certifications as to each patent.

Before approving a product, the U.S. 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 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.

The "pediatric exclusivity" program under The Best Pharmaceuticals for Children Act provides a six-month period of extended exclusivity, applicable to certain listed patents and to other regulatory exclusivities for all formulations of an active ingredient, if the sponsor performs and submits pediatric studies requested by the FDA within specified timeframes. An effect of this program has been to delay the launch of numerous generic products by an additional six months.

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 where the first Paragraph IV certification was submitted on or after December 8, 2003.

Under the revised 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. The180-day exclusivity period begins on the date of first commercial marketing of the drug by any of the first applicants or a decision of a court holding the patent that is the subject of the paragraph IV certification to be invalid or not infringed.

However, a first applicant may forfeit its exclusivity in a variety of ways, including, but not limited to (a) failure to obtain tentative approval within 30 months after the application is filed or (b) failure to market its drug by the later of two dates calculated as follows: (x) 75 days after approval or 30 months after submission of the ANDA, whichever comes first, or (y) 75 days after each patent for which the first applicant is qualified for 180-day exclusivity is either (1) the subject of a final court decision holding that the patent is invalid, not infringed, or unenforceable or (2) withdrawn from listing with the U.S. FDA (court decisions qualify if either the first applicant or any applicant with a tentative approval is a party; a final court decision is a decision by a court of appeals or a decision by a district court that is not appealed). The foregoing is an abbreviated summary of certain provisions of the Medicare Act of 2003, and accordingly such act 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.

The federal Controlled Substances Act (the “CSA”) and its implementing regulations establish a closed system of controlled substance distribution for legitimate handlers. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements upon legitimate handlers under the oversight of the U.S. Drug Enforcement Administration (the “DEA”). The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV, or V — with varying qualifications for listing in each schedule. Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA inspects manufacturing facilities to review security, record keeping and reporting and handling prior to issuing a controlled substance registration. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action, such as civil penalties, refusal to renew necessary registrations, or the initiation of proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Food and Drug Administration Safety and Innovation Act, Generic Drug User Fee Act, Biosimilar User Fee Act and Food and Drug Administration Reauthorization Act

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

FDASIA also includes the Generic Drug User Fee Act ("GDUFA") and Biosimilar User Fee Act ("BuFA"), programs to provide the U.S. FDA with additional funds through user fees imposed on generic and biosimilar products. Under GDUFA, total fees are derived primarily from facility fees paid by finished dosage form manufacturers and active pharmaceutical ingredient facilities listed or referenced in a pending or approved generic drug application. A significant portion is also derived from application fees, including generic drug application fees, prior approval supplement fees and drug master file fees.

The FDA Reauthorization Act of 2017 ("FDARA") and the GDUFA Amendments ("GDUFA II"), signed into law on August 18, 2017, extended the user fee program for a period of another five years through September, 2022. Under the provisions of these acts, an additional generic drug applicant program fee will be established, which will be based on the number of ANDAs the applicant holds and the prior approval supplement fees will be eliminated. Of the total GDUFA user fee revenue, 35% will be generated from this ANDA-based fee. Further, the GDUFA II commitment letter describes a consolidated review goals scheme for all cohorts of ANDAs, prior approval supplements and amendments. This includes shorter review goals for generic drug submissions that are public health priorities.

The establishment of dedicated biosimilar fees was also intended to help ensure that the U.S. FDA has appropriate resources for managing the introduction of biosimilar products on the U.S. market. Under the FDARA, for the first time, an independent fee structure for biosimilars will be implemented, including an initial biosimilar development fee which will be assessed the first year a manufacturer begins clinical trials. Further, an annual biosimilar development fee for subsequent years of the development process, a biosimilar program fee for approved biosimilars, and an application fee for new biosimilar applications will be introduced. The legislation also reauthorizes several programs that are designed to simplify and expedite the regulatory process for the development of drugs and devices that aid patients with rare diseases.

In addition, under the FDARA, a drug is eligible for designation as a "Competitive Generic Therapy" if the U.S. FDA determines that there is inadequate generic competition i.e., with respect to a drug, there is not more than one approved drug on the list of drugs described in section 505(j)(7)(A) (not including drugs on the discontinued section of such list) that is (a) the reference listed drug; or (b) a generic drug with the same reference listed drug as the drug for which designation as a competitive generic therapy is sought.

As part of GDUFA II, in order to accelerate access to generic version of complex products, GDUFA II pre-ANDA program product development meetings can be initiated by the U.S. FDA for an ongoing ANDA development program for complex products. These meetings will encourage applicants for product development meetings, pre-submission meetings and mid-review cycle meetings to clarify regulatory expectations early in product development. Furthermore, in November 2017, the Manual of Policy and Procedures ("MAPP") 5240.3, "Review Order of Original ANDAs, Amendments, and Supplements" was revised to MAPP 5240.4, "Prioritization of the Review of Original ANDAs, Amendments and Supplements" under which a priority review may be granted by the U.S. FDA if an original ANDA, amendment, or supplement meets one of the prioritization factors set forth in the MAPP, and may receive either a shorter goal date or an expedited review, as defined in the MAPP.

Withdrawal of U.S. FDA Proposed Labeling Rule

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

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

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

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

If the U.S. FDA's proposed new rule was adopted, it may have eliminated this pre-emption and increased our potential exposure to lawsuits relating to product safety, side effects and warnings on labels. This new potential exposure to lawsuits may also have increased the risk that, in the future, we would not have been able to obtain the type and amount of insurance coverage we desire at an acceptable price and self-insurance may have become the sole commercially reasonable means available for managing the product liability risks of our business. After twice delaying publication of a final rule, the U.S. FDA withdrew its proposed rule during 2017.

Prescription Drug Marketing Act and Laws Regulating Payments to Healthcare Professionals

The FDA also enforces the requirements of the Prescription Drug Marketing Act, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians. Sales, marketing and scientific/educational grant programs must comply with the federal anti-kickback statute, the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. We are also subject to Section 6002 of the Patient Protection and Affordable Care Act, commonly known as the Physician Payment Sunshine Act which regulates disclosure of payments to certain healthcare professionals and providers.

Patient Protection and Affordable Care Act and Medicaid Drug Rebate Program

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 significantly impacts the U.S. pharmaceutical industry. The PPACA imposes additional rebates, discounts and fees, mandates certain reporting and contains various other requirements that affect our business. The PPACA made several important changes to the federal anti-kickback statute, false claims laws, and health care fraud statutes that made it easier for the government or whistleblowers to pursue such fraud and abuse violations. In addition, the PPACA increased penalties for fraud and abuse violations. 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.

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"). In November 2015, the Bipartisan Budget Act of 2015 (the "BBA") amended the Medicaid Drug Rebate Program to impose a penalty rebate on generic drugs whose price increases exceed the inflation rate. Initially, the penalty rebate had only applied to brand drugs and authorized generics, but other generic drugs were subject to a fixed base rebate of 13% of AMP. The BBA imposed a price increase penalty rebate on generic drugs similar to that of the price increase penalty on brand drugs and authorized generics. The additional penalty rebate for generic drugs applies to rebate periods beginning with the first quarter of 2017. The additional penalty rebate due for generic drugs is equal to the AMP for the current quarter minus the baseline AMP adjusted for inflation based upon the Consumer Price Index for Urban Consumers.

The PPACA also increased the number of healthcare organizations eligible to participate in the Public Health Service pharmaceutical pricing program, which provides for government controlled prices that result in substantial discounts for participants. To further facilitate the government's efforts to coordinate and develop comparative clinical effectiveness research, the PPACA established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in such research. The manner in which the comparative research results would be used by third-party payors is uncertain.

The PPACA has created an abbreviated pathway to U.S. FDA approval of "biosimilar" biological products and allows the first interchangeable biosimilar biological product 18 months of exclusivity, which could increase competition for our biosimilars business. The PPACA also has some anti-generic provisions that could adversely affect our biosimilars 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.

On February 1, 2016, the CMS published in the Federal Register a Final Regulation with comment period to implement the Medicaid Drug Rebate Program. The Final Regulation was to clarify ambiguities in the ACA amendments. The key provisions covered under the Final Regulation included, without limitation, the following: (i) the adoption of a final definition of "retail community pharmacy" ("RCP"), (ii) the adoption of a rule permitting inhalation, infusion, instilled, implanted, or injectable drugs ("5i drugs") to be deemed not to be "generally dispensed" through a RCP, and thus excluded from the calculation of their AMP, if 70% or more of its sales were to entities other than RCPs or wholesalers for drugs distributed to RCPs (the prior threshold was 90%), (iii) the inclusion of authorized generics in calculations of AMP and best price, (iv) narrowing the regulatory definition for "best price", (v) requiring additional Medicaid rebate payments for generic drugs, effective as of April 1, 2017, and (vi) clarification of the definition of "bona fide service fees" based on a four part test. We are still awaiting guidance from CMS on two aspects of the rule that were deferred for later implementation. These include a definition of what constitutes a product "line extension" and a delay in the participation of the U.S. territories in the Medicaid Drug Rebate Program until April 1, 2020. We will evaluate the financial impact of these two elements when they become effective.

In 2017, the new U.S. Presidential administration, which had promised to repeal and replace the PPACA, took office in the United States. Although legislative proposals in 2017 to repeal and replace the PPACA in 2017 were never enacted, there are ongoing efforts to achieve that goal. For example, in October 2017, the U.S. President signed an Executive Order directing federal agencies to modify how the PPACA is implemented, ending the subsidies to health care insurance companies that sell insurance to low income consumers through state health insurance marketplaces. Further, the Tax Cuts and Jobs Act enacted in December 2017 effectively repealed the PPACA's individual mandate by removing the penalties imposed for failure to purchase healthcare insurance. This may have the impact of reducing the number of insured as well as coverage for pharmaceutical products. We cannot predict the ultimate effect of the reform on our business, and additional policy changes disruptive to the PPACA exchange markets could arise.

Drug Quality and Security Act

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

prescriptions. During 2017, the U.S. FDA delayed the enforcement of serialization requirements for manufacturers until November 2018 to provide manufacturers with additional time to comply and avoid supply disruptions. We are working to meet these requirements on a timely basis.

Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

On October 6, 2016, the U.S. FDA issued a final rule to implement new regulations that govern the approval of 505(b)(2) applications and ANDAs. This rule revises and clarifies U.S. FDA regulations as to matters such as: the procedures and requirements for providing notice to each patent owner and the NDA holder of certain patent certifications made by applicants submitting 505(b)(2) applications or ANDAs; the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved; submission of amendments and supplements to 505(b)(2) applications and ANDAs; and the types of bioavailability and bioequivalence data that can be used to support these applications. This rule was effective December 5, 2016.

Biologics Pathway

The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) created a statutory pathway and abbreviated approval processes for the approval of biosimilar versions of branded biological products. Under the BPCIA, a biosimilar must be highly similar with no clinically meaningful differences compared to the reference medicine. Approval of a biosimilar in the United States requires the submission of a Biologics License Application (“BLA”) to the U.S. FDA, including an assessment of immunogenicity, and pharmacokinetics or pharmacodynamics. The BLA for a biosimilar can be submitted as soon as four years after the initial approval of the reference biologic, but can only be approved 12 years after the initial approval of the reference biologic. This pathway is still relatively new and some aspects remain untried, controversial and subject to ongoing litigation. Though the U.S. FDA has issued and updated various technical guidance documents addressing quality considerations, scientific considerations and questions and answers regarding commonly posed issues to assist the biopharmaceutical industry in developing biosimilar products in compliance with the BPCIA, there remains some uncertainty regarding the abbreviated biosimilar pathway.

21st Century Cures Act

On December 13, 2016, the 21st Century Cures Act was enacted into law in the United States, and is intended to promote biomedical innovation and personalized medicines. The 21st Century Cures Act includes increased funding for the National Institutes of Health and the U.S. FDA and provides for the implementation of, among other reforms, enhanced pathways for medical product approval and the modernization and harmonization of clinical trial procedures over a period of several years.

Blueprint to Lower Drug Prices

In May 2018, U.S. President Trump released "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," which outlines actions that his administration proposes to take to lower prescription drug prices, including certain actions that can be taken immediately by the U.S. Department of Health and Human Services ("HHS") and issues on which HHS will solicit public feedback before determining any additional reform proposals. This blueprint seeks to increase competition, improve negotiation, incentivize lower list prices and lower out-of-pocket costs. It calls for, among other things, greater transparency of drug prices, better informing consumers about prescription drugs, increased promotion of generic drugs and experimenting with value-based payment. We are currently evaluating the impact of this blueprint on our business, and we cannot yet be certain what the effect will be.

Other matters

Civil Investigative Demand from the Office of the Attorney General, State of Texas

On or about November 10, 2014, Dr. Reddy's Laboratories, Inc., one of our subsidiaries in the United States, received a Civil Investigative Demand ("CID") from the Office of the Attorney General, State of Texas (the "Texas AG") requesting certain information, documents and data regarding sales and price reporting in the U.S. marketplace of certain products for the period of time between January 1, 1995 and the date of the CID. We have responded to all of the Texas AG's requests to date, and we understand that the investigation is continuing.

Subpeona duces tecum from the Office of the Attorney General, California

On November 3, 2014, Dr. Reddy's Laboratories, Inc. received a subpoena duces tecum to appear before the Office of the Attorney General, California (the "California AG") and produce records and documents relating to the pricing of certain products. A set of five interrogatories related to pricing practices was served as well. On July 18, 2016, the California AG sent a letter to inform Dr. Reddy's Laboratories, Inc. that, in light of the information which had been provided, no further information would be requested at such time in response to this subpoena.

Subpoenas from the Division of the U.S. Department of Justice ("DOJ") and the office of the Attorney General for the State of Connecticut

On July 6, 2016 and August 7, 2016, Dr. Reddy's Laboratories, Inc. received subpoenas from the DOJ and the office of the Attorney General for the State of Connecticut, respectively, seeking information relating to the marketing, pricing and sale of certain of our generic products and any communications with competitors about such products. We have been cooperating, and intend to continue to fully cooperate, with these inquiries.

State Attorneys General Civil Actions in the United States

On December 18, 2016, the Attorneys General for 19 states filed claims in the United States District Court for the District of Connecticut against a number of pharmaceutical companies alleging conspiracies to fix prices and to allocate bids and customers from 2013 through at least 2016, with respect to two generic drugs for which our company and our U.S. subsidiaries were not named as defendants.

In April 2017, a total of 45 states, plus the District of Columbia and the Commonwealth of Puerto Rico, joined as plaintiffs in this case (the "State AG Action"). In August 2017, the State AG Action was transferred and consolidated with the private plaintiff class actions pending in the multi-district litigation (MDL-2724) in the United States District Court for the Eastern District of Pennsylvania. On October 31, 2017, the Attorneys General for the 45 States, plus the District of Columbia and the Commonwealth of Puerto Rico, filed an Amended Complaint in the State AG Action in MDL-2724 which has added our U.S. subsidiary as a defendant. The State AG Action alleges that our subsidiary and other named defendants engaged in a conspiracy to fix prices and to allocate bids and customers in the sale of generic zoledronic acid and meprobamate in the United States, and alleges an over-arching conspiracy with the defendants on the other 13 drugs named in the State AG Amended Complaint. The State AG Amended Complaint alleges violations of Section 1 of the Sherman Act, 15 U.S.C. §1, and the consumer and antitrust laws of 45 states, the District of Columbia and the Commonwealth of Puerto Rico, seeking injunctive relief, recovery of treble damages, attorney's fees and other costs. We deny any wrongdoing and intend to vigorously defend against these claims.

Civil Investigative Demand from the Division of the U.S DOJ

On May 15, 2018, Dr. Reddy's Laboratories, Inc. received a Civil Investigative Demand from the Civil Division of the U.S. DOJ, enquiring whether there have been any violations of the U.S. False Claims Act, arising from allegations that generic pharmaceutical manufacturers, including us, have engaged in market allocation or price fixing agreements, or paid illegal remuneration, and caused false claims to be submitted in violation of the said Act. We intend to fully cooperate with the DOJ in responding to the demand and cooperate with the investigation.

Canada Regulatory Environment

In Canada, we are required to file product dossiers with the Health Canada for permission to market a generic pharmaceutical product. The regulatory authorities may inspect our manufacturing facility before approval of the dossier. As of March 31, 2018, we had filed a total of 30 Abbreviated New Drug Submissions ("ANDS") in Canada, out of which 20 were approved, 6 are pending approval, and 4 were withdrawn or rejected.

Europe

Our sales of generic medicines in Europe for the year ended March 31, 2018 were Rs.8,217 million, which accounted for 7% of our Global Generics segment's sales. Our principal markets in Europe are Germany and the United Kingdom. We have also established our presence in other markets, including Italy, France and Spain.

Sales, Marketing and Distribution Network

Germany

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

Over the last decade, the German pharmaceutical market has significantly changed. Health care reforms by the government have significantly increased the power of insurance companies and statutory health insurance funds ("SHI

funds") to influence dispensing of medicines. Pursuant to the reforms, those pharmaceutical products which are covered by rebate contracts with insurance companies and SHI funds will be prescribed by physicians and dispensed by pharmacies with priority. As a result, many SHI funds have enacted tender (i.e., competitive bidding) processes to determine which pharmaceutical companies they will enter into rebate contracts with. This has resulted in more than 90% of generic products currently sold in German retail outlets being supplied through contracts procured in competitive bidding tenders, thereby causing significant pressure on product margins.

United Kingdom and other Countries within Europe

We market our generic products in the United Kingdom and other European Union ("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 sell more than 50 products in the United Kingdom, covering both International Nonproprietary Name ("INN") generics and branded generics. INN generics are sold via wholesale and retail channels, and hospitals. In the U.K., we work closely with the Clinical Commissioning Groups (i.e., groups that commission healthcare services for their local communities and include all of the general practitioner groups in their geographical area) to promote our range of branded generics. Whilst the retail business covers a broad range of therapeutic areas, the hospital business focuses mainly on oncology, anti-infectives and HIV.

In 2016, we established a commercial structure in Italy, Spain and France to expand our direct footprint in the western European region. Our initial focus has been to supply products through hospitals and to institutional clients. Our product mix in these markets focuses on a limited number of key therapy areas such as oncology, anti-infectives and HIV, leveraging our portfolio. This market's business is predominantly tender-driven, without the need for a large sales force.

Competition

The German market is highly competitive as a result of a large number of generic players and the predominance of a tender system which drives competition. Our key competitors within the German generics market include Sandoz International GmbH, Teva Pharmaceutical Industries Limited ("Teva"), Winthrop Arzneimittel GmbH and Stada Arzneimittel AG.

According to the British Generic Manufacturers Association, the United Kingdom is one of the largest markets for generic pharmaceuticals in Europe, with generic penetration of around 84%, and is also one of the most price competitive markets due to a high degree of vertical integration and consolidation of buyers, as more than 65% of the retail pharmacies are owned by wholesalers or are part of retail chains, and has low barriers of entry. The market is dominated by global pharmaceutical companies such as Teva, the Sandoz group of Novartis Pharma A.G. and Mylan Inc.

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In Italy, Spain and France, we compete with companies such as Hospira (an affilate of Pfizer Limited), Fresenius SE & Co. KGaA, Teva and Accord Healthcare Limited (an affilate of Intas Pharmaceuticals Ltd.), each of which has a well-established presence in the hospital segment of these countries.

Government regulations

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 and manufactured in accordance with applicable law. The registration file relating to any particular product must contain scientific data related to product efficacy and safety, including results of clinical testing and references to medical publications, as well as detailed information regarding production methods and quality control. Regulatory authorities are authorized to suspend, restrict or cancel the registration of a product if it is found to be harmful or ineffective, or manufactured and marketed other than in accordance with registration conditions.

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

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

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

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

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

All pharmaceutical companies that manufacture and market human medicinal products in Germany are subject to the applicable rules and regulations executed by the Federal Institute for Drugs and Medical devices ("BfArM") or the Paul-Ehrlich-Institut ("PEI") and the supervisory authorities of the respective federal state in Germany. All pharmaceutical companies in Germany are periodically inspected by the Regierung von Oberbayern (the district government of Upper Bavaria in Germany), which has extensive enforcement powers over the activities of pharmaceutical companies. Non-compliance can result in closure of the facility. The Regierung von Oberbayern has also inspected our plants in Hyderabad and Visakhapatnam.

In Germany, the government has in the past decade enacted a number of laws designed to limit pharmaceutical cost increases. During the fiscal year ended March 31, 2011, the German government introduced a new law entitled "Act on the reorganization of the pharmaceutical market in the public health insurance" (or *"Arzneimittelmarktneuordnungsgesetz",* commonly referred to as "AMNOG"), which affects reimbursement of drugs within Germany's statutory health care system in order to further control the costs of medical care. The key elements of this law are as follows:

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

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

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

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

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

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

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

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

The German Social Code's price freeze imposed on reimbursable drugs, which was due to expire at the end of 2017, was extended until December 31, 2022 for all patent free drugs launched before August 1, 2010, although the continued price freeze will not apply to medicines subject to internal reference pricing.

New European pharmacovigilance legislation (Regulation (EU) No 1235/2010 and Directive 2010/84/EU) was enacted in July 2012. These new requirements have not yet been fully implemented. Implementation of the final

stages, specifically new obligations for safety signal management, will increase our administrative burdens and therefore our costs. In 2015, the European Commission introduced pharmacovigilance service fees that our industry pays for the simplification and maintenance of the European pharmacovigilance system, as well as fees for the assessment of aggregate safety reports and protocols and study reports mandated following a safety referral. The service fees payable for these reports are unpredictable, as the Pharmacovigilance Risk Assessment Committee ("PRAC") of the European Medicine Agency ("EMA") can initiate a safety referral for any medicine or class of medicines with a significant new safety concern at any time. The costs of such a referral and the consequent costs of any recommendation, such as restrictions on use, cannot be predicted.

The International Standards for Identification of Medicinal Products ("IDMP"), comprised of five International Organization for Standardization ("ISO") standards, were approved in 2012. These standards are designed to allow unambiguous identification of medicinal products across companies and regions in order to support and improve pharmacovigilance and other activities. Full implementation of these standards in the EU has been deferred, but will be implemented in a phased approach for medicinal product information starting in mid-2018.

The submission of medicinal product data to support pharmacovigilance has been required since 2012 in the EU. The original European database for data regarding medicinal products, the Eudravigilance Medicinal Product Dictionary ("EVMPD"), was launched by the EMA at the end of 2001. It was designed to standardize the collection, reporting, coding, and evaluation of authorized and investigational medicinal product information. In 2012 it became mandatory for marketing-authorization holders to supply information to the extended version of the EVMPD (xEVMPD or Article 57 database). However, this currently contains only a fraction of the data that eventually will have to be submitted to the IDMP-compliant database for each authorized product in the EU. In order for us to support the maintenance of medicinal product data in the IDMP-compliant database, we are investing in new systems and will have to make significant changes to our processes and procedures.

In order to prevent counterfeit medicines entering into the supply chain, in October 2015, as part of the Falsified Medicines Directive, the European Commission adopted regulations providing detailed rules for the safety features appearing on the packaging of medicinal products for human use. Accordingly, all medicinal products generally subject to prescription must bear safety features that facilitate specifically the identification of individual packs and the verification of their authenticity. Effective as of February 9, 2019, only those prescription drugs which have a unique serial number on the pack, and where the integrity of the pack can be seen, may be marketed in all EU countries. Manufacturers shall be required to put a unique identifier code, in human readable form and in an encrypted two-dimensional matrix, on all secondary packages and shall also be required to include an ”anti-tampering device” safety feature on packages to enable the verification of whether the packaging of a medicinal product has been tampered with. Marketing authorization holders shall upload the serial numbers, along with other product information, to a “EU Hub” operated by the European Medicines Verification Organisation (“EMVO”). End users (e.g., pharmacies and wholesalers) shall be required to verify and decommission the identifier code before handing over the package to the patient. We have invested significantly in machinery, technology and know-how, and are cooperating with relevant international partners, to ensure our timely readiness for implementation without impacting the supply of our products.

The impact of the decision for the United Kingdom to exit from the EU (the “Brexit”) on pharmacovigilance operations is unclear at this stage. The U.K. pharmaceutical industry and the U.K. MHRA have expressed their desire to continue as full participants in the harmonized pharmacovigilance activities of the EU and the EMA. However, which activities and procedures will remain accessible to the U.K. marketing authorization holders (“MAHs”) post Brexit are only likely to become clear as the negotiations between the U.K. government and the European Commission near their conclusion. If full access to the pharmacovigilance activities of the EU and the EMA is not available to U.K. MAHs post Brexit, the U.K. MHRA may have to introduce parallel processes in the U.K. which might result in increased costs to the MAHs.

Following the Brexit vote, the EU has decided to move the headquarters of the EMA from the U.K. to the Netherlands by March 2019. It is expected that a significant percentage of the current employees of the EMA will decide not to make the move to the Netherlands. This raises the possibility that new drug approvals in the EU could be delayed as a result.

“Rest of the World” markets of our Global Generics segment

We refer to all markets of our Global Generics segment other than North America, Europe, Russia and other countries of the former Soviet Union and Romania and India as our “Rest of the World” markets. Our significant Rest of the World markets include South Africa, Australia, Brazil, Colombia and Myanmar. Our revenues from our “Rest of the World” markets were Rs.6,126 million in the year ended March 31, 2018, an increase of 5% as compared to the year ended March 31, 2017. This increase in sales was primarily attributable to our entry in new markets during the year.

Collaboration agreement with Merck Serono

On June 6, 2012, we entered into a collaboration agreement with the biosimilars division of Merck KGaA, Darmstadt, Germany, formerly known as Merck Serono (hereinafter, "Merck KGaA"), to co-develop a portfolio of biosimilar compounds in oncology, primarily focused on monoclonal antibodies. The arrangement covers co-development, manufacturing and commercialization of the compounds around the globe, with some specific country exceptions.

During the year ended March 31, 2016, the collaboration agreement was amended to rearrange and realign the development of compounds, territory rights and royalty payments. Both parties undertook commercialization based on their respective regional rights as defined in the agreement. We lead and support early product development towards or including Phase 1 development. Merck KGaA carries out manufacturing of the compounds and leads further development for its territories. In our exclusive and co-exclusive territories, we carry out our own development, wherever applicable, for commercialization. We will continue to receive royalty payments upon commercialization by Merck KGaA in its territories.

During the year ended March 31, 2016, we received from Merck KGaA certain amounts relating to its share of development costs and other amounts linked to the achievement of milestones for the development of compounds under the collaboration agreement, as amended. Furthermore, during the year ended March 31, 2017, we received from Merck KGaA payments of U.S.$1 million towards achievement of a milestone for the development of a compound under the collaboration agreement.

On September 1, 2017, Fresenius Kabi acquired the biosimilars business of Merck KgaA. Since then, our collaboration has continued as planned with Fresenius Kabi.

Global Generics Manufacturing and Raw Materials

Manufacturing for our Global Generics segment entails converting API into finished dosages. As of March 31, 2018, we had twelve manufacturing facilities within this segment. Ten of these facilities are located in India and two are located in the United States (Shreveport, Louisiana; and Bristol, Tennessee). In addition, we also have one packaging facility in the United Kingdom. All of the facilities are designed in accordance with and are compliant with current cGMP requirements and are used for the manufacture of tablets, hard gelatin capsules, injections, liquids and creams for sale in India as well as other markets. All of our manufacturing sites' laboratories and facilities are designed and maintained to meet increasingly stringent requirements of safety and quality. All of our sites outside of India are approved by the respective regulatory bodies in the jurisdictions where they are located.

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

part of risk mitigation and continual improvement.

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

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

The logistics services for storage and distribution in the United States, the European Union, Russia, South Africa, Australia and other emerging markets are outsourced to a third party service provider.

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

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

In November 2015, we received a warning letter from the U.S. FDA relating to violations at our injectible oncology formulation manufacturing facility at Duvvada, Visakhapatnam, Andhra Pradesh. Refer to Item 4.A. "History and development of the company – Key business developments – Re-Audit of the warning letter impacted sites" for further details.

Pharmaceutical Services and Active Ingredients ("PSAI") segment

Our PSAI segment includes our business of manufacturing and marketing active pharmaceutical ingredients and intermediates, also known as “API” 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 our contract research services business and our manufacture and sale of steroids in accordance with specific customer requirements.

Our PSAI segment’s revenues for the year ended March 31, 2018 were Rs.21,992 million, an increase of 3% as compared to the year ended March 31, 2017. Our PSAI segment accounted for 16% of our total revenues for the year ended March 31, 2018.

During the year ended March 31, 2018, we filed 73 Drug Master Files (“DMFs”) worldwide, of which 12 were filed in the United States, 3 were filed in Europe and 58 were filed in other countries. Cumulatively, our total DMFs filed worldwide as of March 31, 2018 were 882, including 207 DMFs filed in the United States.

We produce and market more than 100 different APIs for numerous markets. Our API business is operated independently from our Global Generics segment and, in addition to supplying API to our Global Generics segment, our PSAI segment sells API to third parties for use in manufacturing generic products, subject to any patent rights of other third parties. We export API to more than 80 countries, and our principal overseas markets in this business segment include North America (the United States and Canada) and Europe. 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 polymorphs), providing research intended to reduce the cost of production of our products and developing new products.

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 Innovator pharmaceutical and fine chemicals industry. 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 quickly and more efficiently. The focus is to leverage our skills in process development, analytical development, formulation development and Current Good Manufacturing Practice (“cGMP”) to serve various needs of innovator pharmaceutical companies. We have positioned our PSAI segment’s Custom Pharmaceutical Services business to be the partner of choice for large and emerging innovator companies across the globe, with service offerings spanning the entire value chain of pharmaceutical services.

Sales, Marketing and Distribution

Developed Markets. Our PSAI segment's principal overseas markets are the United States and Europe. Our PSAI segment's sales to these markets were Rs.11,274 million for the year ended March 31, 2018, and accounted for 51% of our PSAI segment's revenues for the year ended March 31, 2018. In the United States and Europe, the patent protection for a large number of high value branded pharmaceutical products expired in years ended March 31, 2011, 2012 and 2013 and this opened the market to generic products that sourced their API from our PSAI segment. However, during the years ended March 31, 2014 through March 31, 2018, such expirations were much less frequent, which resulted in a decrease in new opportunities in these markets for the customers of our PSAI segment. We market our products through our subsidiaries in the United States and Europe. These subsidiaries are engaged in all aspects of marketing activity and support our customers' pursuit of regulatory approval for their products, focusing on building long-term relationships with the customers.

Other Key Markets. India is an important market for our PSAI segment, with total sales of Rs.1,858 million, and it accounted for 9% of the PSAI segment's revenues in the year ended March 31, 2018. In India, we market our API products to Indian and multinational companies, many of whom are also our competitors in our Global Generics segment. The market in India is highly competitive, with severe pricing pressure and competition from lower cost foreign imports in several products.

Our PSAI segment's sales to all of the other markets (excluding the United States, Europe and India) was Rs.8,860 million for the year ended March 31, 2018 and accounted for 40% of our PSAI segment's revenues for the year. Our PSAI segment's other key markets include Brazil, Mexico, China and Japan. While we work through our agents in these markets, our zonal marketing managers also interact directly with our key customers in order to service their requirements.

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.

Going forward, we expect our PSAI segment to show growth on account of our investments in newer technologies and platforms. We are also pursuing a partnership model to enable our customers to reach more markets faster and efficiently by leveraging our cost leadership and presence across the globe.

PSAI Manufacturing

The infrastructure for our PSAI segment consists of nine U.S. FDA-inspected plants (seven in India, including one in a Special Economic Zone, one in Mexico, and one in Mirfield, United Kingdom) and three technology development centers (two in Hyderabad, India and one in Cambridge, United Kingdom).

India. All of our facilities in India are located in the states of Andhra Pradesh and Telangana. We have the flexibility to produce quantities that range from a few kilograms to several metric tons. 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.

In November 2015, we received a warning letter from the U.S. FDA relating to cGMP deviations at our API manufacturing facilities at Miryalguda, Telangana and Srikakulam, Andhra Pradesh. Refer to item 4.A. “History and development of the company – Key business developments – Re-Audit of the warning letter impacted sites” for further details.

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

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

For our contract research services, we have well-resourced synthetic organic chemistry laboratories, analytical laboratories and kilo laboratories at our technology development centers at Miyapur and Jeedimetla in Hyderabad, India. Our chemists and engineers understand cGMP manufacturing and regulatory requirements for synthesis, manufacture and formulation of a NCE from the pre-clinical stage to commercialization. To complete the full value chain in development services, we also provide formulation development services. We 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. We also offer end to end project management support for effective deliveries.

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.

Raw Materials

Raw material expense forms the largest portion of our cost of revenues. Raw materials consist of fine chemicals, bulk chemicals, solvents, catalysts, and basic and advanced intermediates. The prices of these raw materials generally fluctuate in line with commodity cycles, demand supply situations and changes to government policies. We evaluate and manage our commodity price risk exposure through periodical supply contracts as well as agile and responsive sourcing procedures.

Competition

The global API market can broadly be divided into regulated and less regulated markets. The less regulated markets offer low entry barriers in terms of regulatory requirements and intellectual property rights. The regulated markets, like the United States and Europe, have high entry barriers in terms of intellectual property rights and regulatory requirements, including facility approvals. As a result, there is a premium for quality and regulatory compliance along with relatively greater stability for both volumes and prices. As an API supplier, we compete with a number of manufacturers within and outside India, which vary in size. Our main competitors in this segment are Divis Laboratories Limited, Aurobindo Pharma Limited, Cipla Limited, Mylan Laboratories Limited, Sun Pharmaceutical Industries Limited and MSN Laboratories Limited, all based or operating in India. In addition, we experience competition from European and Chinese manufacturers, as well as from Teva Pharmaceuticals Industries Limited, based in Israel.

With respect to our custom pharmaceuticals business, we believe that contract research and manufacturing is a significant opportunity for Indian pharmaceutical companies, based on their strengths of a skilled workforce and low-cost manufacturing infrastructure. Key competitors in India include Divis Laboratories Limited, Dishman Pharmaceuticals & Chemicals Limited and Piramal Enterprises Ltd. Key competitors from outside India include Lonza Group, AMRI Inc., Patheon Inc., Catalent Inc., Cambrex Inc., and WuXi PharmaTech. We distinguish ourselves from Indian competitors by offering a wider range of services spanning the entire pharmaceutical value chain. The inspection of our CPS facility in Hyderabad, India was completed by the U.S. FDA on September 21, 2017 with zero observations, and the U.S. FDA issued an establishment inspection report in December 2017. This facility also follows rigorous Safety and Information Security practices and is certified against ISO 27001:2013 standards for information security. For competitors from outside India, we distinguish ourselves through cost effectiveness. Keeping on par with the advancements in technology and changing needs of the innovator and mid-sized pharmaceutical companies, we are positioning ourselves in niche technologies. With growth in contract research and manufacturing services likely to be driven by increased outsourcing by medium size pharmaceutical companies, particularly those focused on biotechnology and therapy, we expect India to emerge as an alliance and outsourcing destination of choice due to speed, skill and cost advantage.

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, recordkeeping, safety, approval, advertising, promotion, sale and distribution of pharmaceutical products.

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

We submit a DMF for active pharmaceutical ingredients to be commercialized in the United States. Any drug product for which an ANDA is being filed must have a DMF in place with respect to a particular supplier supplying the underlying API. The manufacturing facilities are inspected by the U.S. FDA to assess compliance with cGMP. The manufacturing facilities and production procedures must meet U.S. FDA standards.

All of our manufacturing facilities are inspected and approved by the U.S. FDA. For European markets, we submit a European DMF and, wherever applicable, obtain a certificate of suitability from European Directorate for the Quality of Medicines.

Proprietary Products Segment

Our Proprietary Products segment focuses on the research, development, and manufacture of differentiated formulations. These novel products fall within the dermatology and neurology therapeutic areas and are marketed and sold through Promius® Pharma, LLC.

We continue to leverage our semi-virtual research and development model to expand our portfolio of specialty formulation products. Our efforts primarily focus on repurposing or improving the clinical properties of already approved and well-characterized API for application in the dermatologic and neurologic disease areas. We achieve this by utilizing internal resources as well as efficiently collaborating with leading technology and platform based companies and service providers, tapping into their expertise areas across different phases of the development process. We continue to progress towards building a diversified portfolio with a sustainable mix of branded proprietary formulations generated through research and development with significantly reduced fixed costs.

Our research and development efforts have a unique “medicines-to-molecules” approach to product development. In this approach, we identify areas of medical need and then leverage in an integrated manner the disciplines of biology, chemistry, drug delivery, clinical development, regulatory and commercial positioning to develop differentiated formulations.

Our research and development model is both in-house and virtual (i.e., operations are outsourced, subject to our supervision of strategic and project management functions), and follows these core principles:

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

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

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leverage knowledge and presence in emerging markets (India and other developing countries) to maximize cost advantages.

Our principal research laboratory is based in Hyderabad, India. As of March 31, 2018, we employed a total of 171 scientists, including 35 scientists who hold Ph.D. degrees and six with M.D. degrees. We pursue an integrated research strategy through a mix of translational, formulation and analytical research at our laboratories. We focus on discovery of new molecular targets, design of assays to screen promising molecules and development of novel formulations of currently marketed drugs or combinations thereof to address unmet medical needs.

While we develop novel agents ourselves, we continue to seek licensing and development opportunities with third parties to further expand our product pipeline. Our goal is to balance the development of our own product candidates with in-licensing of promising compounds that complement our product offering. We also pursue licensing and joint development of some of our lead compounds with companies looking to enhance their own product portfolio.

Pipeline Status

As of March 31, 2018, we had 13 active product development programs in our pipeline. In January and February 2016, we received U.S. FDA approval of our New Drug Applications (each, a "NDA") for two products – our dermatology product Sernivo® and our neurology product Zembrace®. Both products were launched in the U.S. market during the year ended March 31, 2017. In May and November 2017, we received U.S. FDA approval for two dermatology products – DFD-10 (minocycline hydrochloride) and DFD-06 (Impoyz™ (clobetasol propionate)) cream. DFD-06 is out-licensed to Encore Dermatology Inc.

The details of our products in Phase 3 and the products for which an NDA has been filed with the U.S FDA as of March 31, 2018 are as follows:

Compound	**DFN-02 (Sumatriptan intranasal spray)**	**DFD-11 (Xeglyze™)**
Therapeutic Area	Neuroscience	Pediatrics
Indication	Acute treatment of migraines, with or without aura in adults.	Treatment of head lice in patients 6 months of age or older.
Significant developments during the period	Pivotal bioequivalence studies were completed. Patient safety studies and efficacy studies have been completed.	The NDA was initially filed by Hatchtech in September 2015; ownership was transferred to us in December 2015.
Significant patents associated with the compound	Patents (including those granted to the development partner) expiring as follows: · U.S.A. - 2031; · All other countries - 2030 Further, patent applications are pending in certain other countries along with the U.S.A.	Three patents were granted in the U.S.A., with estimated expiration in 2026. Patents were also granted in Australia, Canada, India, and New Zealand. Some other patent applications are pending in certain countries, including the U.S.A.
Current status/ expected NDA filing*	NDA was submitted in March 2018.	NDA was submitted in September 2015 and we received a complete response letter ("CRL") from the U.S. FDA in August 2016. We are in the process of submitting our response to the CRL.

[Continued from prior table, first column repeated]

Compound	**PPC-06 (Tepilamide Fumarate)**	**E7777**
Therapeutic Area	Dermatology	Hematology-Oncology
Indication	Treatment of plaque psoriasis in patients 18 years of age or older.	Treatment of Cutaneous T Cell Lymphoma.
Significant developments during the period	This is a NCE program in-licensed from Xenoport Inc. (which was subsequently acquired by Arbor Pharmaceuticals). Phase 2 is completed. Five patents were granted, with estimated expiration of the last such patents in 2029. In addition, one notice of allowance has been received.	This is an anti-cancer biologic agent in-licensed from EISAI limited.
Significant patents associated with the compound	Patents were also granted in multiple other countries such as Australia, China, Europe, Japan and Russia, with estimated expiration in 2029. There are also other patent applications pending in the U.S.A. and some other countries.	None.
Current status/ expected NDA filing*	Phase 2b studies are being executed.	Phase 3 is in process. Submission of a biologics license application to the U.S. FDA is planned for 2019.

[Continued from prior table, first column repeated]

Compound	**DFD-03 (Tazarotene Lotion)**	**DFN-15 (Celecoxib Oral Solution)**
Therapeutic Area	Dermatology	Neurology
Indication	Treatment of acne vulgaris.	Treatment of migraines in adults with or without aura.
Significant developments during the period	Phase 3 and other supporting studies were under progress during the year.	Phase 3 clinical studies were completed and analysis was under progress.
Significant patents associated with the compound	Two patent were granted in the U.S.	Three patents were granted in the U.S.
Current status/ expected NDA filing*	NDA is expected to be filed in 2019.	NDA expected to be filed in 2018/19.

* The timelines for expected filing may change due to various factors, including outcome of Phase 3 studies, completion of Integrated Summary of Safety/Integrated Summary of Effectiveness (“ISS/ISE”), outcome of stability data and internal reprioritization of portfolio.

Patents. Our Proprietary Products segment had the following patent applications filed and patents granted as of March 31, 2018:

Category	**USPTO[1] (# Filed)**	**USPTO[1] (# Granted)**	**PCT[2] (# Filed)**	**India (# Filed)**	**India (# Granted)**
Anti-diabetic	85	17	62	117	45
Anti-cancer	18	11	14	45	15
Anti-bacterial	8	7	10	22	4
Anti-inflammation/cardiovascular	47	27	35	26	3
Anti-ulcerant	1	1	-	1	-
Miscellaneous	20	18	4	27	8
Differentiated formulations	53	29	24	49	1
Total	232	110	149	287	76

(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.

Competition

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

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

Government regulations

Virtually all pharmaceutical and biologics products that we or our collaborative partners develop will require regulatory approval by governmental agencies prior to commercialization. The nature and extent to which these regulations apply varies depending on the nature of the products and also vary from country to country. In particular, human pharmaceutical products are subject to rigorous nonclinical 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 order to market a drug in the United States, we or our partners are 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.

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**
Nonclinical	Animal studies and laboratory tests to evaluate safety and efficacy, demonstrate activity of a product candidate and identify its chemical and physical properties.
Phase 1	Clinical studies to test safety and pharmacokinetic profile of a drug in normal human subjects.
Phase 2	Clinical studies conducted with groups of patients to determine preliminary efficacy, dosage and expanded evidence of safety.
Phase 3	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. Nonclinical tests assess the potential safety and efficacy of a product candidate in animal models. The results of these studies must be submitted to the U.S. FDA as part of an Investigational New Drug (“IND”) application before human testing may proceed.

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

The clinical trial process can take five to ten years or more to complete, and there can be no assurance that the data collected 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 (“IRBs”) or Ethics Committees (“ECs”), 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.

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 are required to file a 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 are 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 LLC

Promius Pharma LLC (“Promius Pharma”), our subsidiary based in Princeton, New Jersey in the United States, conducts our U.S. Specialty business, which is engaged in the promotion and sale of branded specialty products in the therapeutic areas of dermatology and neurology.

In addition to its existing portfolio of proprietary and licensed dermatology and neurology products, Promius Pharma also has a pipeline of dermatology and neurology products that are in different stages of development. Promius Pharma’s current portfolio contains innovative products for the treatment of seborrheic dermatitis, psoriasis, acne and steroid responsive dermatoses. The following are the products commercialized by Promius Pharma:

Product	**For treatment of**
Promiseb®	Seborrheic dermatitis
Cloderm® (clocortolone pivalate 0.1%)	Corticosteroid-responsive dermatoses
Trianex®	Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
Zembrace® SymTouch® (subcutaneous sumatriptan 3mg)	Autoinjector for treatment of migraine headaches
Sernivo® (betamethasone propionate, 0.05%)	Mild to moderate plaque psoriasis

Promius Pharma leverages our research, development and manufacturing facilities in Hyderabad, India. Promius Pharma also works with various third party research organizations in conducting product development, non-clinical and clinical studies. Manufacturing is also outsourced to reputable contract manufacturing organizations in the United States and Europe. Both of Promius Pharma’s commercial groups - dermatology and neurology have the support of teams spanning marketing, sales operations, market access and medical affairs. The dermatology and neurology teams are comprised of 133 marketing, sales, and market access and operations professionals.

4.C. *Organizational structure*

Dr. Reddy’s Laboratories Limited is the parent company in our group. Refer to Note 43 of our consolidated financial statements for a list of our subsidiaries and joint ventures.

4.D. *Property, plant and equipment*

Our principal executive offices are located in Hyderabad, Telangana, India. Our business operates through a number of subsidiaries having offices, research facilities and production sites throughout the world. The following table sets forth current information relating to our principal facilities:

Sl No.	Name/Location	**Approximate Area (Square feet)**	Segments Which Primarily Use
	Within India		
1	API Hyderabad Plant 1, Telangana, India	645,995	Global Generics and PSAI
2	API Hyderabad Plant 2, Telangana, India	781,379	Global Generics and PSAI
3	API Hyderabad Plant 3, Telangana, India	644,805	Global Generics and PSAI
4	API Hyderabad Plant 4, Telangana, India	189,343	Global Generics and PSAI
5	API Nalgonda Plant, Telangana, India	3,397,680	Global Generics and PSAI
6	API Srikakulam Plant, Andhra Pradesh, India	4,027,688	Global Generics and PSAI
7	API Srikakulam Plant (SEZ), Andhra Pradesh, India	9,917,739	Global Generics and PSAI
8	Technology Development Centre Hyderabad 1, Telangana, India	113,256	Global Generics and PSAI
9	Technology Development Centre Hyderabad 2, Telangana, India	68,825	Global Generics and PSAI
10	Formulations Hyderabad Plant 1, Telangana, India	271,379	Global Generics
11	Formulations Hyderabad Plant 2, Telangana, India	3,207,826	Global Generics
12	Formulations Baddi Plant 1, Himachal Pradesh, India	728,234	Global Generics
13	Formulations Baddi Plant 2, Himachal Pradesh, India	381,342	Global Generics
14	Biologics Hyderabad, Telangana, India	795,841	Global Generics
15	Formulations Hyderabad Plant 3, Telangana, India	1,539,089	Global Generics
16	Formulations Srikakulam Plant 1 (SEZ), Andhra Pradesh, India	879,041	Global Generics
17	Formulations Srikakulam Plant 2 (SEZ), Andhra Pradesh, India	334,105	Global Generics
18	Formulations Srikakulam Plant 11, Andhra Pradesh, India	8,611	Global Generics
19	Formulations Visakhapatnam Plant 1 (SEZ), Andhra Pradesh, India	582,206	Global Generics
20	Formulations Visakhapatnam Plant 2 (SEZ), Andhra Pradesh, India	544,322	Global Generics
21	ADTL Hyderabad, Telangana, India	187,308	Others
22	ADTL Bengaluru, Karnataka, India	689,216	Others
23	Integrated Product Development Center, Bengaluru, India	29,500	Others
24	Integrated Product Development Center, Telangana, India	103,350	Global Generics, PSAI and Proprietary

	Outside India		
25	API Cuernavaca Plant, Mexico	2,361,840	Global Generics and PSAI
26	API Mirfield Plant, United Kingdom	1,785,960	Global Generics and PSAI
27	API Middleburgh Plant, New York, United States	292,000	Global Generics
28	Technology Development Centre, Cambridge, United Kingdom	32,966	Global Generics and PSAI
29	Technology Development Centre, OctoPlus N.V., Leiden, the Netherlands	56,500	Global Generics and PSAI
30	Formulations Beverley Plant, East Yorkshire, United Kingdom	81,000	Global Generics
31	Formulations Shreveport Plant, Louisiana, United States	2,349,251	Global Generics
32	Formulations Bristol Plant, Tennessee, United States	1,742,400	Global Generics
33	Aurigene Discovery Technologies, Malaysia	5,672	Others

During the three months ended March 31, 2018, we disposed of our Formulations Yanam plant in Puducherry, India.

We generally own our facilities. However, some of our sites (primarily office space) are leased. All properties identified above, including leased properties, are either used for manufacturing and packaging of pharmaceutical products or for research and development activities. In addition to the above, we have sales, marketing and administrative offices, some of which are owned and some others are leased properties. We believe that our facilities are optimally utilized.

Global Generics

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

During the year ended March 31, 2014, we set up a new manufacturing facility, Formulations Visakhapatnam Plant 2 (SEZ), Andhra Pradesh, India for the manufacture of parenteral (injectable form) products. This facility helps us meet the demand for such products in some of our key markets, including the United States.

During the year ended March 31, 2015, we obtained approvals from the U.S. FDA for products to be manufactured from a recently commissioned oral solid dosage form facility, Formulations Srikakulam Plant 1 (SEZ), Andhra Pradesh, India. This plant, which began operations during the year ended March 31, 2016, manufactures new molecules and certain high volume products of our Global Generics segment. Further, during the year March 31, 2016, we began manufacturing products from this plant.

Pharmaceutical Services and Active Ingredients

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

Material plans to construct, expand and improve facilities

As of March 31, 2018, we had capital work-in-progress of Rs.7,928 million and capital commitments of Rs.3,788 million for expansion of our manufacturing and research facilities, primarily relating to facilities located in India, the United States and Mexico. Our current capital work-in-progress and capital commitments primarily include projects towards capacity enhancement of our biologics facility in Hyderabad, strengthening packaging capability of our formulations manufacturing facilities at Visakhapatnam, building infrastructure for implementing the serialization regulation in our facilities at Hyderabad and Visakhapatnam and a corporate learning and research centre in Visakhapatnam. We currently intend to finance our additional expansion plans entirely through our operating cash

flows and through cash and other investments. A majority of these projects are expected to be completed during the fiscal years ending March 31, 2019 and March 31, 2020.

Environmental laws and regulations

We are subject to significant national and state environmental laws and regulations which govern the discharge, emission, storage, handling and disposal of a variety of substances that may be used in or result from our operations at the above facilities. Non-compliance with the applicable laws and regulations may subject us to penalties and may also result in the closure of our facilities.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Overview

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

The Chief Operating Decision Maker ("CODM") evaluates our performance and allocates resources based on an analysis of various performance indicators by reportable segments. The CODM reviews revenue and gross profit as the performance indicator for all of the operating segments, and does not review the total assets and liabilities of an operating segment. Our Chief Executive Officer is the CODM of our company.

Our reportable operating segments are as follows:

- Global Generics;
- Pharmaceutical Services and Active Ingredients; and
- Proprietary Products.

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

Pharmaceutical Services and Active Ingredients. This segment includes our business of manufacturing and marketing active pharmaceutical ingredients and intermediates, also known as "API" 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 our contract research services business and our manufacture and sale of active pharmaceutical ingredients and steroids in accordance with the specific customer requirements.

Proprietary Products. This segment consists of our business that focuses on the research, development, and manufacture of differentiated formulations. These novel products fall within the dermatology and neurology therapeutic areas and are marketed and sold through Promius® Pharma, LLC.

Others. This includes the operations of our wholly-owned subsidiary, Aurigene Discovery Technologies Limited, a discovery stage biotechnology company developing novel and best-in-class therapies in the fields of oncology and inflammation and which works with established pharmaceutical and biotechnology companies in early-stage collaborations, bringing drug candidates from hit generation to pre-clinical development.

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

Accounting estimates and judgments

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

Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. In particular, 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:

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- Evaluation of joint arrangements;
- Assessment of functional currency;
- Financial instruments;
- Business combinations;
- Useful lives of property, plant and equipment and intangible assets;
- Valuation of inventories;
- Measurement of recoverable amounts of cash-generating units;
- Assets and obligations relating to employee benefits;
- Provisions and other accruals;
- Sales returns, rebates and chargeback provisions;
- Evaluation of recoverability of deferred tax assets; 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 is measured at the fair value of the consideration received or receivable, net of returns, sales tax and applicable trade discounts and allowances. Revenue includes shipping and handling costs billed to the customer.

Revenue from sales of generic products in India is recognized upon delivery of products to distributors by our clearing and forwarding agents. 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. Revenue from sales of API and intermediates in India is recognized on delivery of products to customers (generally formulation manufacturers) from

our factories. Revenue from export sales and other sales outside of India 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.

Profit share revenues

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

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

Milestone payments and out licensing arrangements

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

Provision for chargeback, rebates, sales returns and discounts

In our U.S. Generics business, our gross revenues are significantly reduced by chargebacks, rebates, sales returns, discounts, shelf stock adjustments, Medicaid payments and similar "gross-to-net" adjustments. Each of such adjustments are discussed in detail below.

- *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 book closure process, a chargeback validation is performed in which we track and reconcile the volume of inventory sold 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 95% of the total value of chargebacks outstanding at every year end reporting date) as part of this reconciliation. On the basis of this volume reconciliation, chargeback accrual is validated. For the chargeback rate computation, we consider different contract prices for each product across our customer base. This chargeback rate is adjusted (if necessary) on a periodic basis for expected future price reductions.

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

- *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. Our estimate of sales returns is determined primarily by our historical experience. 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.

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

We believe our estimation processes are reasonable methods of determining accruals for the "gross-to-net" adjustments. Chargeback accrual accounts for the highest element among the "gross-to-net" adjustments, and constituted approximately 68% of such "gross-to-net" adjustments for our U.S. Generics business for the year ended March 31, 2018. 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*— At any point in time, inventory volumes on which we carry our chargeback accrual represents approximately 1 month of sales volumes. Therefore, the sensitivity of price changes on our chargeback accrual only relates to such volumes. Assuming that the chargebacks were processed within such period, we analyzed the impact of changes of prices for the periods beginning April 1, 2017, 2016 and 2015, respectively, and ended March 31, 2018, 2017 and 2016, respectively, on our estimated inventory levels computed based on the methodology described above (see "Chargebacks" above). We note that the impact on net sales on account of such price variation was negligible.

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

A roll-forward for each major accrual for our U.S. Generics operations is presented below for our fiscal years ended March 31, 2016, 2017 and 2018:

Particulars	Chargebacks	Rebates	Medicaid	Sales Returns
	(All values in U.S.$ millions)			
Beginning Balance: April 1, 2015	194	222	17	40
Current provisions relating to sales during the year[1]	2,208	767	23	32
Provisions and adjustments relating to sales in prior years	*	-	-	-
Credits and payments**	(2,193)	(732)	(26)	(27)
Ending Balance: March 31, 2016	209	257	14	45
Beginning Balance: April 1, 2016	209	257	14	45
Current provisions relating to sales during the year [2]	1,963	700	22	28
Provisions and adjustments relating to sales in prior years	*	-	-	-
Credits and payments**	(1,981)	(771)	(23)	(37)
Ending Balance: March 31, 2017	191	186	13	36
Beginning Balance: April 1, 2017	191	186	13	36
Current provisions relating to sales during the year [3]	1,750	630	18	22
Provisions and adjustments relating to sales in prior years	*	-	-	-
Credits and payments**	(1,771)	(655)	(19)	(30)
Ending Balance: March 31, 2018	170	161	12	28

* Currently, we do not separately track provisions and adjustments, in each case to the extent relating to prior years for chargebacks. However, the adjustments are expected to be non-material. The volumes used to calculate the closing balance of chargebacks represent approximately 1.1 months equivalent of sales, which corresponds to the pending chargeback claims yet to be processed.

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

(1) Chargebacks and rebates provisions for the year ended March 31, 2016 and payments for the year ended March 31, 2016 were each higher as compared to the year ended March 31, 2015, primarily as a result of product mix changes and the addition of new products.

(2) Chargebacks and rebates provisions for the year ended March 31, 2017 and payments for the year ended March 31, 2017 were each lower as compared to the year ended March 31, 2016, primarily as a result of lower sales, product mix changes and relatively low value of new products.

(3) Chargebacks and rebates provisions for the year ended March 31, 2018 and payments for the year ended March 31, 2018 were each lower as compared to the year ended March 31, 2017, primarily as a result of lower pricing rates per unit for chargebacks, due to a reduction in the invoice price to wholesalers for certain of our products, and due to certain product mix changes.

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

Our overall provision for sales returns as at March 31, 2018 was Rs.3,210 million, as compared to a provision of Rs.3,784 million as at March 31, 2017. This decrease in our provision was primarily attributable to a lower allowance for returns provision created for the year ended March 31, 2018 due to lower sales recorded for the year ended March 31, 2018 based on our historical experience and recent trends in actual sales returns, in the markets in which we operate. For further information regarding our sales return provisions, refer to Note 20 to our consolidated financial statements.

Services

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

License fees

In the ordinary course of business, we periodically enter into certain dossier sales, licensing and supply arrangements with various parties. Income from licensing arrangements is generally recognized over the term of the contract. Some of these arrangements include certain performance obligations by us. Revenue from such arrangements is recognized in the period in which we complete all of our performance obligations.

Financial instruments

Non-derivative financial instruments

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

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

Cash and cash equivalents

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

Held-to-maturity investments

Held-to-maturity investments consist of investments in bonds with fixed or determinable payments and fixed maturity that we have the positive intention and the ability to hold to maturity. Such investments are initially measured at fair value with subsequent measurements made at amortized cost using the effective interest rate method.

Other investments

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

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

Trade payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade payables are classified as current liabilities if payment is expected within one year or within the normal operating cycle of the business. After initial recognition, trade payables are recognized at amortized cost using effective interest rate method.

Trade receivables

Trade receivables are amounts due from customers for merchandise sold or services performed in the ordinary course of business. Trade receivables are classified as current assets if the collection is expected within one year or within the normal operating cycle of the business. After initial recognition, trade receivables are recognized at amortized cost using effective interest rate method.

Debt instruments and other financial liabilities

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

initial recognition, these financial liabilities are measured at amortized cost using the effective interest method.

Other non-derivative financial instruments

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

De-recognition of financial assets and liabilities

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

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

Offsetting financial assets and liabilities

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

Derivative financial instruments

We are exposed to exchange rate risks which arise from our foreign exchange revenues, expenses and borrowings primarily in U.S. dollars, U.K. pounds sterling, Russian roubles, Brazilian reals, South African rands (“ZAR”), Romanian new leus and Euros, and foreign currency debt in U.S. dollars, Russian roubles, Ukranian hryvnia and Euros.

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

Hedges of highly probable forecast transactions

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

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

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

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

Hedges of recognized assets and liabilities

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

Hedges of changes in the interest rates

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

Foreign currency

Functional currency

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

In respect of certain non-Indian subsidiaries that operate as marketing arms of our parent company in their respective countries/regions, the functional currency has been determined to be the functional currency of our parent company (i.e., the Indian rupee). The operations of these subsidiaries are largely restricted to importing of finished goods from our parent company in India, sales of these products in the foreign country and making of import payments to our parent company. The cash flows realized from sales of goods are available for making import payments to our parent company and cash is paid to our parent company on a regular basis. The costs incurred by these subsidiaries are primarily the cost of goods imported from our parent company. The financing of these subsidiaries is done directly or indirectly by our parent company. In respect of subsidiaries whose operations are self-contained and integrated within their respective countries/regions, the functional currency has been generally determined to be the local currency of those countries/regions, unless use of a different currency is considered appropriate.

Foreign currency transactions and foreign operations

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

However, foreign currency differences arising from the translation of the following items are recognized in other comprehensive income ("OCI"):

- available-for-sale financial assets (except on impairment, in which case foreign currency differences that have been recognized in OCI are reclassified to the consolidated income statement);

- a financial liability designated as a hedge of the net investment in a foreign operation to the extent that the hedge is effective; and

- qualifying cash flow hedges, to the extent that the hedges are effective.

When several exchange rates are available, the rate used is that at which the future cash flows represented by the transaction or balance could have been settled if those cash flows had occurred at the measurement date.

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

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

Business combinations

We use the acquisition method of accounting to account for any business combination that occurred on or after April 1, 2009. The acquisition date is the date on which control is transferred to the acquirer. Judgment is applied in determining the acquisition date and determining whether control is transferred from one party to another. Control exists when we are exposed to, or have rights to variable returns from our involvement with the entity and have the ability to affect those returns through power over the entity. In assessing control, potential voting rights are considered only if the rights are substantive. We measure goodwill as of the applicable acquisition date at the fair value of the consideration transferred, including the recognized amount of any non-controlling interest in the acquiree, less the net

recognized amount of the identifiable assets acquired and liabilities assumed. When the fair value of the net identifiable assets acquired and liabilities assumed exceeds the consideration transferred, a bargain purchase gain is recognized immediately in the consolidated income statement. Consideration transferred includes the fair values of the assets transferred, liabilities incurred by us to the previous owners of the acquiree, and equity interests issued by us. Consideration transferred also includes the fair value of any contingent consideration. Consideration transferred does not include amounts related to the settlement of pre-existing relationships. Any goodwill that arises on account of such business combination is tested annually for impairment.

Any contingent consideration is measured at fair value at the date of acquisition. If an obligation to pay contingent consideration that meets the definition of a financial instrument is classified as equity, then it is not re-measured and the settlement is accounted for within equity. Otherwise, other contingent consideration is re-measured at fair value at each reporting date and subsequent changes in the fair value of the contingent consideration are recorded in the consolidated income statement.

A contingent liability of the acquiree is assumed in a business combination only if such a liability represents a present obligation and arises from a past event, and its fair value can be measured reliably.

On an acquisition-by-acquisition basis, we recognize any non-controlling interest in the acquiree either at fair value or at the non-controlling interest's proportionate share of the acquiree's identifiable net assets. Transaction costs that we incur in connection with a business combination, such as finder's fees, legal fees, due diligence fees and other professional and consulting fees, are expensed as incurred.

Property, plant and equipment

Recognition and measurement

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses, if any. Cost includes expenditures that are directly attributable to the acquisition of the asset. The cost of self-constructed assets includes the cost of materials and other costs directly attributable to bringing the asset to a working condition for its intended use. Borrowing costs that are directly attributable to the construction or production of a qualifying asset are capitalized as part of the cost of that asset.

When parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment.

Gains and losses upon disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognized net within "other (income)/expense, net" in the consolidated income statement.

The cost of replacing part of an item of property, plant and equipment is recognized in the carrying amount of the item if it is probable that the future economic benefits embodied within the part will flow to us and its cost can be measured reliably. The costs of repairs and maintenance are recognized in the consolidated income statement as incurred.

Items of property, plant and equipment acquired through exchange of non-monetary assets are measured at fair value, unless the exchange transaction lacks commercial substance or the fair value of either the asset received or asset given up is not reliably measurable, in which case the asset exchanged is recorded at the carrying amount of the asset given up.

Depreciation

Depreciation is recognized in the consolidated income statement on a straight line basis over the estimated useful lives of property, plant and equipment. Leased assets are depreciated over the shorter of the lease term and their useful lives. The depreciation expense is included in the costs of the functions using the asset. Land is not depreciated.

Leasehold improvements are depreciated over period of the lease agreement or the useful life, whichever is shorter.

Depreciation methods, useful lives and residual values are reviewed at each reporting date. The estimated useful lives are as follows:

Buildings	
- Factory and administrative buildings	20 - 50 years
- Ancillary structures	3 - 15 years
Plant and equipment	3 - 15 years
Furniture, fixtures and office equipment	4 - 10 years
Vehicles	4 - 5 years
Computer equipment	3 - 5 years

Software for internal use, which is primarily acquired from third-party vendors and which is an integral part of a tangible asset, including consultancy charges for implementing the software, is capitalized as part of the related tangible asset. Subsequent costs associated with maintaining such software are recognized as expense as incurred. The capitalized costs are amortized over the estimated useful life of the software or the remaining useful life of the tangible fixed asset, whichever is lower.

Advances paid towards the acquisition of property, plant and equipment outstanding at each reporting date and the cost of property, plant and equipment not ready to use before such date are disclosed under capital work-in-progress. Assets not ready for use are not depreciated.

Goodwill and other intangible assets

Recognition and measurement

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

Goodwill

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

Other intangible assets

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

Research and development

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

Development activities involve a plan or design for the production of new or substantially improved products and processes. Development expenditures are capitalized only if:

- development costs can be measured reliably;
- the product or process is technically and commercially feasible;

· future economic benefits are probable; and

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

Separate acquisition of intangible assets

The expenditures to be capitalized include the cost of materials and other costs directly attributable to preparing the asset for its intended use. Other development expenditures are recognized in the consolidated income statement as incurred.
Payments to third parties that generally take the form of up-front payments and milestones for in-licensed products, compounds and intellectual property are capitalized. Our criteria for capitalization of such assets is consistent with the guidance given in paragraph 25 of International Accounting Standard 38 ("IAS 38") (i.e., the receipt of economic benefits embodied in each intangible asset separately purchased or licensed in the transaction is considered to be probable).

In-Process Research and Development assets ("IPR&D")

Acquired research and development intangible assets that are under development are recognized as In-Process Research and Development assets ("IPR&D"). IPR&D assets are not amortized, but evaluated for potential impairment on an annual basis or when there are indications that the carrying value may not be recoverable. Any impairment charge on such IPR&D assets is recorded in the consolidated income statement under "Research and Development expenses".

Subsequent expenditure

Other intangible assets

Subsequent expenditures are capitalized only when they increase the future economic benefits embodied in the specific asset to which they relate. All other expenditures, including expenditures on internally generated goodwill and brands, is recognized in the consolidated income statement as incurred.
Subsequent expenditure on an IPR&D project acquired separately or in a business combination and recognized as an intangible asset is:

IPR&D assets

· recognized as an expense when incurred, if it is research expenditure;

· recognized as an expense when incurred, if it is development expenditure that does not satisfy the criteria for recognition as an intangible asset in paragraph 57 of IAS 38; and

· added to the carrying amount of the acquired in-process research or development project, if it is development expenditure that satisfies the recognition criteria in paragraph 57 of IAS 38.

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

As of March 31, 2018, no internal drug development expenditure amounts have met the recognition criteria. The expenditures to be capitalized include the cost of materials and other costs directly attributable to preparing the asset for its intended use. Other development expenditures are recognized in the consolidated income statements as incurred.

A substantial portion of our current research and development activities relates to the development of bio-equivalent products, which do not require full scale clinical trials to be conducted prior to the filing by us of applications with regulatory authorities to allow the marketing and sale of such products. Our total research and development costs for the year ended March 31, 2018 were Rs.18,265 million, which was approximately 13% of our total revenue for the year. The amounts spent on research and development related to our bio-equivalent products for the years ended March 31, 2018, 2017 and 2016 represented approximately 64%, 61%, and 65%, respectively, of our total research and development expenditures.

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

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

Amortization

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

In determining the useful life we consider the following factors:

- technical, technological, commercial or other types of obsolescence;

- expected actions by competitors or potential competitors;

- typical product life cycles for the asset and public information on estimates of useful lives of similar assets that are used in a similar way; and

- the period of control over the asset and legal or similar limits on the use of the asset.

The estimated useful lives are as follows:

Trademarks	3 - 12 years
Product related intangibles	5 - 15 years
Customer-related intangibles	1 - 11 years
Technology related intangibles	3 - 13 years
Other intangibles	3 - 15 years

Impairment

Financial assets

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

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

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

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

Non-financial assets

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

The recoverable amount of an asset or cash-generating unit (as defined below) is the greater of its value in use and its fair value less costs to sell. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks

specific to the asset or the cash-generating unit. For the purpose of impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of the cash inflows of other assets or groups of assets (the “cash-generating unit”).

In the circumstances where the asset specific discount rate is not directly available from the market, we use surrogates to estimate the discount rate. For this purpose, we take into consideration the following rates:

- the weighted average cost of capital determined using techniques such as the Capital Asset Pricing Model;

- our incremental borrowing rate; and

- other market borrowing rates.

However, these rates are adjusted:

- to reflect the way that the market would assess the specific risks associated with the asset’s estimated cash flows; and

- to exclude the risks that are not relevant to the asset’s estimated cash flows or for which the estimated cash flows have been adjusted.

Consideration is given to risks such as country risk, currency risk and price risk.

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

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

An impairment loss in respect of goodwill is not reversed. In respect of other assets, impairment losses recognized in prior periods are assessed at each reporting date for any indications that the loss has decreased or no longer exists. An impairment loss for an asset other than goodwill is reversed if there has been a change in the estimates used to determine the recoverable amount. An impairment loss for an asset other than goodwill is reversed only to the extent

that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortization, if no impairment loss had been recognized. Goodwill that forms part of the carrying amount of an investment in an associate is not recognized separately, and therefore is not tested for impairment separately. Instead, the entire amount of the investment in an associate is tested for impairment as a single asset when there is objective evidence that the investment in an associate may be impaired.

Income tax

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

Deferred tax is recognized using the balance sheet method, providing for temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognized for the following temporary differences:

- temporary differences on the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit;

- temporary differences relating to investments in subsidiaries and jointly controlled entities to the extent that it is probable that they will not reverse in the foreseeable future; and

- taxable temporary differences arising upon the initial recognition of goodwill.

Deferred tax is measured at the tax rates that are expected to be applied to the temporary differences when they reverse, based on the laws that have been enacted or substantively enacted by the reporting date. Deferred tax assets and liabilities are offset if there is a legally enforceable right to offset current tax liabilities and assets, and they relate to income taxes levied by the same tax authority on the same taxable entity, or on different tax entities, but they intend to settle current tax liabilities and assets on a net basis or their tax assets and liabilities will be realized simultaneously.

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

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

Inventories

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

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

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

Litigations

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

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

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

Other provisions

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

Restructuring

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

Onerous contracts

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

Reimbursement rights

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

Contingent liabilities and contingent assets

A disclosure for a contingent liability is made when there is a possible obligation or a present obligation that may, but probably will not, require an outflow of resources. Where there is a possible obligation or a present obligation in respect of which the likelihood of outflow of resources is remote, no provision or disclosure is made.

Contingent assets are not recognized in the financial statements. However, contingent assets are assessed continually and, if it is virtually certain that an inflow of economic benefits will arise, the asset and related income are recognized in the period in which the change occurs.

Recent Accounting Pronouncements

Refer to Note 3(s) to our consolidated financial statements.

5.A. *Operating results*

Income Statement Data

	For the year ended March 31,			
	2018	2018	2017	2016
	(Rs. in millions, U.S.$ in millions)			
	Convenience translation into U.S.$			
Revenues	U.S.$2,181	Rs. 142,028	Rs. 140,809	Rs. 154,708
Cost of revenues	1,009	65,724	62,453	62,427
Gross profit	1,172	76,304	78,356	92,281
Selling, general and administrative expenses	720	46,910	46,372	45,702
Research and development expenses	281	18,265	19,551	17,834
Other (income)/expense, net	(12)	(788)	(1,065)	(874)
Results from operating activities	183	11,917	13,498	29,619
Finance (expense)/income, net	32	2,080	806	(2,708)
Share of profit of equity accounted investees, net of tax	5	344	349	229
Profit before tax	220	14,341	14,653	27,140
Tax expense	70	4,535	2,614	7,127
Profit for the year	**U.S.$**151	**Rs.** 9,806	**Rs.** 12,039	**Rs.** 20,013

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

	Percentage of Sales For the year ended March 31,			Percentage Increase/(Decrease)	
	2018	2017	2016	**2017 to 2018**	**2016 to 2017**
Revenues	100.0 %	100.0 %	100.0 %	0.9 %	(9.0 %)
Gross profit	53.7 %	55.6 %	59.6 %	(2.6 %)	(15.1 %)
Selling, general, and administrative expenses	33.0 %	32.9 %	29.5 %	1.2 %	1.5 %
Research and development expenses	12.9 %	13.9 %	11.5 %	(6.6 %)	9.6 %
Other (income)/expense, net	(0.6 %)	(0.8 %)	(0.6 %)	(26.0 %)	21.8 %
Results from operating activities	8.4 %	9.6 %	19.1 %	(11.7 %)	(54.4 %)
Finance (expense)/income, net	1.5 %	0.6 %	(1.8 %)	158.1 %	(129.8 %)

Share of profit of equity accounted investees, net of tax	0.2	%	0.2	%	0.1	%	(1.4 | %)	52.5	%
Profit before taxes	10.1	%	10.4	%	17.5	%	(2.1	%)	(46.0	%)
Tax expense	3.2	%	1.9	%	4.6	%	73.5	%	(63.3 | %)
Profit for the year	6.9	%	8.5	%	12.9	%	(18.5	%)	(39.8	%)

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