

DR REDDYS LABORATORIES LTD

Form 20-F

August 10, 2005

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

- o REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934  
OR**
- þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended March 31, 2005  
OR**
- o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 1-15182  
DR. REDDY S LABORATORIES LIMITED  
(Exact name of Registrant as specified in its charter)**

**Not Applicable**  
(Translation of Registrant's name into English)

**ANDHRA PRADESH, INDIA**  
(Jurisdiction of incorporation or organization)

**7-1-27, Ameerpet  
Hyderabad, Andhra Pradesh 500 016, India  
+91-40-23731946**

(Address of principal executive offices)

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
<b>American depositary shares, each representing one equity share</b>	<b>New York Stock Exchange</b>

**Equity Shares\***

**New York Stock Exchange**

**\* 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 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 each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

**76,518,949 Equity Shares**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No o

Indicate by check mark which financial statement item the registrant has elected to follow.



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**Currency of Presentation and Certain Defined Terms**

In this annual report on Form 20-F, references to \$ or U.S.\$ or dollars or U.S. dollars are to the legal currency of the United States and references to Rs. or rupees or Indian rupees are to the legal currency of India. Our financial statements are presented in Indian rupees and translated into U.S. dollars and are prepared in accordance with United States Generally Accepted Accounting Principles ( U.S. GAAP ). References to Indian GAAP are to Indian Generally Accepted Accounting Principles. References to a particular fiscal year are to our fiscal year ended March 31 of such year. References to our ADSs are to our American Depository Shares.

References to U.S. or United States are to the United States of America, its territories and its possessions. References to India are to the Republic of India. All references to we, us, our, DRL, Dr.Reddy s or the Com mean Dr. Reddy s Laboratories Limited. 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.

Except as otherwise stated in this report, all translations from Indian rupees to U.S. dollars are based on the noon buying rate in the City of New York on March 31, 2005, for cable transfers in Indian rupees as certified for customs purposes by the Federal Reserve Bank of New York, which was Rs.43.62 per \$1.00. No representation is made that the Indian rupee amounts have been, could have been or could be converted into U.S. dollars at such a rate or any other rate.

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

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

**Forward-looking and Cautionary Statement**

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

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Not applicable.

**ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

Not applicable.

**ITEM 3. KEY INFORMATION****3.A. Selected financial data summary of selected consolidated financial data**

The selected consolidated financial data should be read in conjunction with the consolidated financial statements, the related notes and operating and financial review and prospects, which are included elsewhere in this annual report. The selected consolidated statements of income data for the five years ended March 31, 2005 and selected consolidated balance sheet data as of March 31, 2001, 2002, 2003, 2004 and 2005 have been derived from our audited consolidated financial statements and related notes, which have been prepared and presented in accordance with U.S. GAAP.

	<b>Fiscal Year Ended March 31,</b>					
	<b>2001</b>	<b>2002**</b>	<b>2003**</b>	<b>2004</b>	<b>2005</b>	
	<b>(Rs. in millions, U.S.\$ in thousands, except share data)</b>					<b>Convenience translation into U.S.\$ (unaudited)</b>
<b>Income Statement Data:</b>						
Product sales	Rs.10,974.8	Rs.16,408.8	Rs.18,069.8	Rs.20,081.2	Rs.19,126.2	U.S.\$438,473
License fees		124.8			345.7	7,926
Services		89.1				
<b>Total revenues</b>	<b>10,974.8</b>	<b>16,622.7</b>	<b>18,069.8</b>	<b>20,081.2</b>	<b>19,471.9</b>	<b>446,399</b>
<b>Cost of revenues</b>	<b>5,735.8</b>	<b>6,869.0</b>	<b>7,847.6</b>	<b>9,346.1</b>	<b>9,385.8</b>	<b>215,172</b>
<b>Gross profit</b>	<b>5,239.0</b>	<b>9,753.7</b>	<b>10,222.2</b>	<b>10,735.1</b>	<b>10,086.1</b>	<b>231,227</b>
<b>Operating expenses, net:</b>						
Selling, general and administrative expenses	2,818.9	3,674.1	5,103.2	6,562.9	6,810.5	156,131
Research and development expenses, net	508.8	742.4	1,411.8	1,991.6	2,803.3	64,267
Amortization expenses	482.3	487.7	419.5	382.9	350.0	8,024
Foreign exchange (gain)/loss	(62.1)	(209.0)	70.1	(282.4)	488.8	11,206
<b>Total operating expenses</b>	<b>3,747.9</b>	<b>4,695.2</b>	<b>7,004.6</b>	<b>8,655.0</b>	<b>10,452.6</b>	<b>239,627</b>
<b>Operating income/(loss)</b>	<b>1,491.1</b>	<b>5,058.5</b>	<b>3,217.6</b>	<b>2,080.1</b>	<b>(366.5)</b>	<b>(8,400)</b>
	(31.5)	(130.5)	(92.1)	(44.4)	(58.1)	(1,332)

Equity in loss of affiliates						
Other (expense) / income, net	(387.0)	154.5	683.2	504.2	531.6	12,186
Income before income taxes and minority interest	1,072.6	5,082.5	3,808.7	2,540.0	107.0	2,454
Income taxes (expense)/benefit	(321.4)	(153.8)	(398.1)	(69.2)	94.3	2,161
Minority interest	(9.3)	(14.9)	(6.7)	3.4	9.9	228
Net income	Rs.741.9	Rs.4,913.8	Rs.3,403.9	Rs.2,474.2	Rs.211.2	U.S.\$4,843
Earnings per equity share:						
Basic	Rs.11.74	Rs.64.63	Rs.44.49	Rs.32.34	Rs.2.76	U.S.\$0.06
Diluted	Rs.11.74	Rs.64.53	Rs.44.49	Rs.32.32	Rs.2.76	U.S.\$0.06
Weighted average number of equity shares used in computing earnings per equity share:*						
Basic	63,177,560	76,027,565	76,515,948	76,513,764	76,518,949	76,518,949
Diluted	63,177,560	76,149,568	76,515,948	76,549,598	76,559,801	76,559,801
Cash dividend per share (excluding dividend tax)	Rs.1.75	Rs.7.00	Rs.2.50	Rs.5.00	Rs.5.00	U.S.\$0.11

\* Each ADR represents one equity share. Historical figures have been adjusted to reflect the two for one stock split effected in October 2001.

\*\* Effective as of fiscal 2003, we selected the retroactive modified method of adoption described in Statement of Financial

Accounting  
Standards  
No. 148  
*Accounting for  
Stock Based  
Compensation  
Transition and  
Disclosure.*

Accordingly,  
the operating  
results for the  
year ended  
March 31, 2002  
and 2003, which  
are the only  
prior periods  
impacted, have  
been modified  
in accordance  
with the  
retroactive  
modified  
method of  
adoption.



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	<b>Fiscal Year Ended March 31,</b>					<b>2005</b> Convenience translation into U.S.\$ (unaudited)
	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	
	<b>(Rs. in millions, U.S.\$ in thousands, except share data)</b>					
<b>Other Data:</b>						
Net cash provided by / (used in):						
Operating activities	Rs.617.1	Rs.4,652.8	Rs.4,366.7	Rs.3,999.2	Rs.2,291.6	U.S.\$52,536
Investing activities	(689.4)	(1,532.9)	(1,954.7)	(6,506.1)	632.9	14,509
Financing activities	(87.7)	1,421.8	(153)	(376.1)	1,931.3	44,276
Effect of exchange rate changes on cash	81.5	88.8	(95)	(14.2)	55.8	1,279
Expenditures on property, plant and equipment	(489.0)	(1,090.3)	(1,515.7)	(2,415.6)	(1,749.2)	(40,100)
<b>Balance Sheet Data:</b>						
Cash and cash equivalents	Rs.478.9	Rs.5,109.4	Rs.7,273.4	Rs.4,376.2	Rs.9,287.9	U.S.\$212,927
Working capital	795.4	9,518.6	12,023.5	11,103.3	10,770.9	246,926
Total assets	11,882.9	18,967.0	23,091.7	26,619.3	29,288.4	671,443
Total long-term debt, excluding current portion	1,003.4	47.0	40.91	31.0	25.1	576
Net Assets	5,240.5	15,457.4	18,831.8	21,039.4	20,953.2	480,357
Total stockholders equity	5,240.5	15,457.4	18,831.8	21,039.4	20,953.2	480,357

**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 average of the noon buying rate in the City of New York on the last business day of each month 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.

**Fiscal Year Ended**

<b>March 31</b>	<b>Period End</b>	<b>Average</b>	<b>High</b>	<b>Low</b>
2001	46.85	45.88	46.90	43.70
2002	48.83	47.80	48.83	46.88
2003	47.53	48.43	49.07	47.53
2004	43.40	45.96	47.46	43.40

2005	43.62	44.86	46.45	43.27
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The following table sets forth the high and low exchange rates for the previous six months and are based on the average of the noon buying rate in the City of New York on the last business day of each month during the period for cable transfers in Indian rupees as certified for customs purposes by the Federal Reserve Bank of New York:

<b>Month</b>		<b>High</b>	<b>Low</b>
February 2005		43.73	43.28
March 2005		43.70	43.44
April 2005		43.72	43.48
May 2005		43.62	43.21
June 2005		43.71	43.44
July 2005		43.59	43.05

On August 8, 2005, the noon buying rate in the city of New York was Rs.43.44 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**

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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 our research and development efforts do not succeed, this may restrict our introduction of new products, which is critical to our business.**

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

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

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

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

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

Selling prices of active pharmaceutical ingredients and generic drugs typically decline, sometimes dramatically, as additional companies receive approvals for a given product and competition intensifies. 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 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. Our ability to sustain our sales and profitability on any product over time is dependent on both the number of new competitors for such product and the timing of their approvals.



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

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

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

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

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

Also, governmental authorities, including the U.S. Food and Drug Administration ( U.S. FDA ), heavily regulate the manufacture of our products. If we or our third party suppliers fail to comply fully with such regulations, then there could be a government-enforced shutdown of production facilities, which in turn could lead to product shortages. A failure to comply fully with such regulations could also lead to a delay in the approval of new products.

**If there is a change in government regulations regarding the amount of revenue that we may be able to derive from a particular product, our revenues may decrease.**

Governments throughout the world heavily regulate the marketing of our products. Most countries also place restrictions on the manner and scope of permissible marketing to physicians and to other health care professionals. The effect of such regulations may be to limit the amount of revenue that we may be able to derive from a particular product. In addition, if we fail to comply fully with such regulations, then civil or criminal actions could be brought against us. In addition to normal price competition in the market place, the prices of our pharmaceutical products are restricted by price controls imposed by governments and health care providers in several countries. Price controls operate differently in different countries and can cause wide variations in prices between markets. Currency fluctuations can aggravate these differences. The existence of price controls can limit the revenues we earn from our products.

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

Regulatory agencies may at any time reassess the safety and efficacy of our products based on new scientific knowledge or other factors. Such reassessments could result in the amendment or withdrawal of existing approvals to market our products, which in turn could result in a loss of revenue, and could serve as an inducement to bring lawsuits against us.

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

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Our business inherently exposes us to potential product liability. From time to time, the pharmaceutical industry has experienced difficulty in obtaining desired amounts of product liability insurance coverage. Although we have obtained product liability coverage with respect to products that we manufacture, if any product liability claim not covered by insurance or exceeding the policy limits were sustained against us, it could harm our business and financial condition. This risk is likely to increase as we develop our own new-patented products in addition to making generic versions of drugs that have been in the market for some time.

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

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

Our success with our innovative 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 will be breached and we will not have adequate remedies for any such breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors or we may not be able to maintain the confidentiality of information relating to such products.

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

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

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 amended the Hatch-Waxman Act and provides that the 180-day market exclusivity period provided under the Hatch-Waxman Act is triggered by the commercial marketing of the product. However, the Medicare Prescription Drug Act also contains forfeiture provisions, which, if met, will deprive the first Paragraph IV filer under section 505(j) of the Hatch-Waxman Act of exclusivity. As a result, under certain circumstances, we may not be able to exploit our 180-day exclusivity period since it may be forfeited prior to our being able to market the product.

In addition, legal and administrative battles over triggering dates and shared exclusivities may also prevent us from fully utilizing the exclusivity periods.

### **If we are unable to defend ourselves in patent challenges, we could be subject to injunctions preventing us from selling our products, resulting in a decrease in revenues, or we could be subject to substantial liabilities that would lower our profits.**





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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 a new drug application. The expense of any such litigation and the resulting disruption to our business, whether or not we are successful, could harm our business. The uncertainties inherent in patent litigation make it difficult for us to predict the outcome of any such litigation.

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

**If we elect to sell a generic product prior to the completion of all appellate level patent litigation, we could be subject to liabilities for damages if a lower court judgment upon which we are relying is reversed.**

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 often face significant patent litigation. Depending upon a complex analysis of a variety of legal and commercial factors, if we win a lower court decision in such patent litigation, we may, in certain circumstances, elect to market a generic product even though an appeal of the lower court decision is pending. Should we elect to proceed in this manner, we could face substantial patent liability damages were a higher court to overturn the trial court's decision.

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

We market our products in 86 countries. Our products are marketed in most of these countries through our subsidiaries as well as joint ventures. As we do not have the resources to market and distribute our products ourselves in all our export markets, we also market and distribute our products through third parties by way of marketing and agency arrangements. These arrangements may be terminated by either party providing the other with notice of termination or when the contract regarding the arrangement expires. We may not be able to successfully negotiate these third party arrangements or find suitable joint venture partners in the future. Any of these arrangements may not be available on commercially reasonable terms. Additionally, our marketing partners may make important marketing and other commercialization decisions with respect to products we develop without our input. As a result, many of the variables that may affect our revenues and net income are not exclusively within our control when we enter into arrangements like these.

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

We may incur substantial costs in compliance with requirements of environmental laws and regulations. In addition, we may discover currently unknown environmental problems or conditions. We are subject to significant Indian 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. If any of our plants or the operations of such plants are shut down, we may continue to incur costs in complying with regulations, appealing any decision to close our facilities, maintaining production at our existing facilities and continuing to pay labor and other costs which may continue even if the facility is closed. As a result, our overall operating expenses may increase and our profits may decrease.

**Our equity shares and our ADSs may be subject to market price volatility, and the market price of our 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,

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- speculative trading in our shares and ADSs,
- changes in the weight given to our shares in Stock Exchange, Mumbai (BSE) and National Stock Exchange (NSE) indices, and
- developments relating to our peer companies in the pharmaceutical industry.

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

Several areas of the world have experienced terrorist acts and retaliatory operations recently. If the overall economy of the world is affected by such acts, our business and results of operations may be adversely affected as a consequence.

**If we have difficulty in identifying acquisition candidates, obtaining satisfactory acquisition financing or integrating companies that we merge with or acquire, our business may be harmed.**

We may acquire or make strategic investments in complementary businesses or products, or enter into strategic partnerships or alliances with third parties in order to enhance our business. 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 or at all. Our acquisition strategy may require us to obtain additional debt or equity financing, resulting in additional leverage, or increased debt obligations as compared to equity, and dilution of ownership. We may not be able to finance acquisitions on terms satisfactory to us. The inability to identify suitable acquisition targets or investments or the inability to complete such transactions may affect our competitiveness and our growth prospects.

Acquisitions may involve a number of risks, including diversion of management's attention, failure to retain key acquired personnel and clients, unanticipated events or circumstances, legal liabilities and amortization of acquired intangible assets, some or all of which could harm our results of operations and financial condition. Our inability to successfully integrate companies that we have acquired or merged with, or companies that we acquire or merge with in the future, could harm our business.

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

Our full time directors together with members of their immediate families, in the aggregate, beneficially own 26.3% of our issued shares. 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 control by these directors and their family members could delay, defer or prevent a change in control of us, impede a merger, consolidation, takeover or other business combination involving us, or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, even if that was in our best interest. As a result, the value of your ADSs may be adversely affected or you might be deprived of a potential opportunity to sell your ADSs at a premium.

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

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

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

In some of our key business operations, such as the manufacture, formulation and packaging of products, we rely on third parties for the timely supply of specified raw materials, equipment, contract manufacturing, formulation or packaging services and maintenance services. Although we actively manage these third party relationships to ensure continuity of supplies on time and to our required specifications, some events beyond our control could result in the complete or partial



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failure of supplies or in supplies not being delivered on time. Any such failure could adversely affect our results of business and results of operations.

**If we do not effectively manage our operations in our foreign subsidiaries and review equity investees, these operations may incur losses or otherwise adversely affect our business and results of operations.**

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

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

Our principal subsidiaries are located in the United States, United Kingdom and Russia and each has significant local operations. A significant portion of our revenues are in other currencies, especially the U.S. dollar, Euro and Pound sterling, while a significant portion of our costs are in Indian rupees. As a result, if the value of the Indian rupee appreciates relative to these other currencies, our revenues will decrease.

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

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

**If there is a change in accounting standards, it may affect our reported results of operations.**

New or revised accounting standards and rules promulgated from time to time by United States or Indian accounting standard boards may significantly affect our reported results of operations. Any change in accounting standards may affect our reported results of operation. The preparation of financial statements in accordance with U.S.GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets (including intangible assets), liabilities and related reserves, revenues, expenses and income. Estimates, judgments and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets (including goodwill and other intangible assets), liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our financial position and results of operations.

**If we were to experience a supply interruption, we might be unable to meet the active pharmaceutical ingredients needs of our generics and formulations segments, and our needs might conflict with those of our active pharmaceutical ingredients customers.**

Many of the active pharmaceutical ingredients and formulations that we manufacture, distribute and sell are dependent on highly specialized raw materials. In the event that we experience a shortage in our supply of raw materials, we might be unable to fulfill all of the active pharmaceutical ingredients needs of our generics and formulations segments, which could result in a loss of production capacity for these segments. In addition, this could result in a conflict between the active pharmaceutical ingredients needs of our generics and formulations segments and the needs of customers of our active pharmaceutical ingredients segment, some of whom are also our competitors in the formulations segment. In either case, we could potentially lose business from adversely affected customers and, we could be subjected to lawsuits.

**Compliance with new and changing corporate governance and public disclosure requirements diverts management time and attention from revenue-generating activities to compliance activities, which may adversely affect our business.**

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Changing laws, regulations and standards relating to accounting, corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations, NYSE rules, Securities and Exchange Board of India rules and Indian stock market listing regulations, are creating uncertainty for companies like ours. 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. 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 their performance of duties. As a result, we may face difficulties attracting and retaining qualified board members and executive officers, which could harm our business.

**Employees are vital for the continuous growth of our business**

The single greatest advantage of any company is its people. Their skills and intellect are critical to the successful achievement of our business goals and objectives. If we are unable to retain our key personnel, it may adversely affect our business operations.

**RISKS RELATING TO INVESTMENTS IN INDIAN COMPANIES**

We are an Indian company and a substantial part of our operations are conducted, and most of our assets are located, in India. In addition, approximately 34.4% of our total revenues for fiscal 2005 were derived from sales in India. As a result, the following additional risk factors apply.

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

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

**A significant change in the Indian government or in its economic liberalization and deregulation policies may adversely affect the Indian economy, the health of which our business depends upon.**

The Indian government has traditionally exercised and continues to exercise a dominant influence over many aspects of the economy. Any significant change in its economic policies could have a significant effect on private-sector entities, including us, and on market conditions and prices of Indian securities, including our shares and our ADSs. India's trade relationships with other countries can also influence Indian economic conditions, which in turn can affect our business.

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

India has experienced communal disturbances, terrorist attacks and riots during recent years. If such disturbances continue or are exacerbated, our operational, sales and marketing activities may be adversely affected. Additionally, India has from time to time experienced hostilities with neighboring countries. The hostilities have continued sporadically. The hostilities between India and Pakistan are particularly threatening, because both India and Pakistan are nuclear powers. Hostilities and tensions may occur in the future and on a wider scale. These hostilities and tensions could lead to political or economic instability in India and harm our business operations, our future financial performance and the price of our shares and our ADSs.

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**If inflation continues to rise in India, we may not be able to increase the prices of our products in order to pass the costs along to our customers and our profits may decline.**

According to the monthly report for April 2005 released by the Indian Ministry of Finance, the annual inflation rate in India, as measured by the benchmark wholesale price index (Base 1993-94=100), was 6.7% in fiscal 2005 as compared with 5.5% in fiscal 2004. The rate of inflation may continue to rise. We may not be able to pass these costs on to our customers by increasing the price we charge for our products. If this occurs, our profits may decline.

**If environmental conditions in India including drought, floods and earthquakes, affect our main facilities, our revenues could decline.**

Our main facilities are situated around Hyderabad, in India. This region has experienced earthquakes, floods and droughts in the past and has experienced droughts in recent years. In the event of a drought so serious that the drinking water in the region is limited, the government could cut the supply of water to all industries including our facilities and this would adversely affect our production operations and reduce our revenues. Even if we take precautions to provide back-up support in the event that a natural disaster occurs in parts of India affecting our main facilities, environmental conditions may affect our facilities, harming production and ultimately our business.

**Wage pressures in India may increase our costs and reduce our profit margins.**

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.

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

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

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

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

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

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

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**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 exchanges 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 on stock markets could affect the market price and liquidity of our shares

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

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

**If you are not able to exercise preemptive rights available to other shareholders, your investment in our securities 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 75.0% of the company's shareholders present and voting at a shareholders' general meeting. U.S. investors in our ADSs may be unable to exercise preemptive rights for the shares underlying our ADSs unless a registration statement under the Securities Act of 1933 is effective with respect to the rights or an exemption from the registration requirements of the Securities Act is available. Our decision to file a registration statement will depend on the costs and potential liabilities associated with a registration statement as well as the perceived benefits of enabling U.S. investors in our ADSs to exercise their preemptive rights and any other factors we consider appropriate at the time. We might choose not to file a registration statement under these circumstances. If we issue any of these securities in the future, such securities may be issued to the depositary, which may sell them in the securities markets in India for the benefit of the investors in our ADSs. We cannot assure you as to the value, if any, the depositary would receive upon the sale of these securities. To the extent that you are unable to exercise preemptive rights, your proportional interests in us would be reduced.

**ITEM 4. INFORMATION ON OUR COMPANY**

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

Dr. Reddy's Laboratories Limited was incorporated in India under the Companies Act, 1956, by its promoter, Dr. K. Anji Reddy as a Private Limited Company on February 24, 1984. We were converted to a Public Limited Company on December 6, 1985 and listed on the Indian Stock Exchanges in August 1986 and on the New York Stock Exchange on April 11, 2001. We are registered with the Registrar of Companies, Andhra Pradesh, Hyderabad, India as Company No. 01-4507. Our registered office is situated at 7-1-27, Ameerpet, Hyderabad - 500 016, Andhra Pradesh, India and the telephone number of our registered office is +91-40-23731946. The name and address of our registered agent in the United States is Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Boulevard (Bldg II), Bridgewater, New Jersey 08807.

**Key business developments:**

In April 2004, we acquired Trigenesis Therapeutics, Inc., a U.S. based privately owned dermatology company. This acquisition provided us with access to certain products and proprietary drug delivery technology platforms for developing a pipeline of differentiated specialty products in the d