



#### Dr. Reddy's Laboratories Limited

Annual Report 2004-05

The cover of this annual report is a faithful representation of the 'perlecan' target.

The expression of this target has shown therapeutic properties to block inflammation, proliferation and thrombosis in arteries.



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\* including Management Discussion & Analysis

## Chairman's Letter



Dear Share Lordes

At a critical inflexion point in the history of your Company, I write to you in two overlapping capacities first as your Chairman and chief fiduciary committed to protecting the present, and second as a scientist committed to securing the future.

There can be little doubt that 2004-05 has been a very challenging year for your Company. While our journey to becoming a discovery-led global pharmaceutical player continues unabated, it is a fact that we performed well below par during the year. Because of intense competition and severe pricing pressures in the U.S. generic markets for two of our key products, fluoxetine and tizanidine, and in Europe for an active pharmaceutical ingredient (API) called ramipril, your Company suffered a fall in revenue for the first time in its history. Revenue fell by 3 per cent from Rs. 20,081 million in 2003-04 to Rs. 19,472 million in 2004-05. Unfortunately, we had no significant new product launches either in generics or in APIs which could have counteracted the pricing pressures and lifted overall revenue.

I am proud to say that your Company did not react to the fall in revenue by adopting a myopic and eventually self-defeating cost cutting strategy — that of drastically reducing its R&D programmes and investments. We have consistently felt that the only viable way of securing higher growth and profits and thereby reaching global scale of operations is through successful R&D. Therefore, despite short-term market reversals, we actually raised R&D investments by almost 41 per cent, from Rs. 1,992 million in 2003-04 to Rs. 2,803 million in 2004-05. Today, R&D investments account for 14 per cent of the total revenue of your Company, which is not only the highest among all Indian pharmaceutical players but also is proportionately in line with global best-in-class.

From a purely short-term perspective, the fall in revenue combined with higher R&D investments contributed to a sharp, unprecedented drop in your Company's profits. However, I need to emphasise that it is a short-term phenomenon. For one, we have put corrective processes in place to further reduce operational costs and gain markets, which ought to reverse what occurred in 2004-05. For another, and more importantly, long term sustainable growth of your Company's businesses — and hence shareholder value — critically hinges upon executing a successful R&D programme.

Let me elaborate on this a bit. At the level of APIs and generics, the global market is getting increasingly competitive and commoditised. In the developed markets of the U.S. as well as Europe, pharmaceutical majors are getting cleverer at preventing entrants from getting exclusivity through aggressive legal defences, authorised generics deals, development of combination products and strategic over-the-counter switching. Added to this is the rapidly growing competition from low cost generic and API suppliers from India and Eastern Europe. Playing a pure generics and API game without adequate investments in R&D and a protective shield of intellectual property rights (IPRs) is the sure path to corporate involution and marginalisation.

In other words, excelling in the basic business operations will be necessary, but not sufficient. To maintain a long term presence in the global pharmaceutical markets and to grow profitably will require companies to be even more focused on R&D and creation of successful IPRs. This does not mean research for the thrill of pure scientific discovery. Instead, it refers to what we in the Company call 'smart R&D'. What does this mean?

'Smart R&D' consists of two components. First, it involves doing research in a manner that can maximise the expected value of a company's R&D pipeline. This requires critically re-examining the existing R&D portfolio - and necessitates giving up work on a large number of molecules across sundry segments in favour of a more intensive, focused approach towards developing the most scientifically promising, best-in-class molecules in key therapeutic areas. We have done this in your Company. Four years ago, we were looking at targets to deal with diabetes, anti-infectives, pain management, cancer, cardiovascular and metabolic disorders, among others. Today, we are more focused on metabolic disorders, obesity, cardiovascular and cancer, which are the leading diseases of the developed world, and are rapidly migrating to middle and lower middle income developing countries. Your Company has methodically separated the potentially winning molecules from the 'also rans', eliminated the latter from its R&D portfolio, and earmarked disproportionately higher investments on the former.

The second component of 'smart R&D' involves creating a smart organisation that uses the levers of co-development, out-licensing and attracting risk capital not only to create key global alliances, but also to de-risk and mitigate the costs of clinical trials and product development.

The old model of global pharmaceutical majors in which all elements of R&D from molecular selection to clinical trials were under a single organisational roof is proving to be too expensive and risky. In its place, we are seeing networks of innovative alliances — between boutique R&D companies and pharmaceutical players, between different pharma companies, between pharma players and clinical research organisations — many of which are mediated by third party risk capital of venture capital enterprises.

Your Company has embraced this notion of alliances. The first steps were taken in March 2005 when ICICI Venture Funds Management Company chose to partner with us for commercialisation of the Company's U.S. ANDAs in the generics business. In a U.S.\$ 56 million deal, ICICI Venture will fund the development, registration and legal costs related to the commercialisation of most of the U.S. ANDAs filed (or to be filed) in 2004-05 and 2005-06. As and when each of these generics is commercialised, we will pay ICICI Venture a royalty on net sales for five years. This partnership is the first of its kind in India, where the pharmaceutical company de-risks its R&D financials, while the investor supplies risk capital for research and development.

As I write, we are working on structuring similar mutually beneficial models for our innovation-led businesses. It is premature to share any details at this stage; but I assure you that the information will be properly disseminated as and when these deals are finalised.

Thus, we will continue to focus on R&D — and do so by doing smart science through smart organisational structures and alliances. And, as a scientist, businessman and your chairman, I feel confident that your Company now has a quality pipeline that ought to deliver significant value in the future.

Having said this, let me not gloss over the short term prospects. While we may get some R&D payments that can de-risk the business and mitigate costs in the near future, the real payoffs from new molecules are expected to occur only after three to four years. In the meanwhile, we will have to pare operational costs, drive the API, generics and branded formulations markets, and re-establish and then grow the revenue base that we lost in 2004-05. There is no doubt that 2005-06 will be a challenging year — one that will demand the best efforts of all the employees of your Company.

2004-05 was a wake-up call for all of us in the Company. But it has also served a purpose: that of making each of us more determined than ever before. There is nothing like a year of adversity to strengthen, re-focus and re-channel entrepreneurial drives. I have seen this happen in the Company. Now, armed with the power of smart R&D and the additional commitment of each employee, we have re-dedicated ourselves to pursue the goal of becoming a discovery-led, scientifically respected global pharmaceutical player.

This isn't optimism. I see it as the writing on the wall. And with your support, it can happen earlier than you think.

Yours sincerely,

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Dr. K. Anji Reddy Chairman

## Investing for a Sustainable tomorrow



At Dr. Reddy's, we see ourselves as an attractive proxy for the prevailing and prospective growth of the Indian and global pharmaceutical industry.

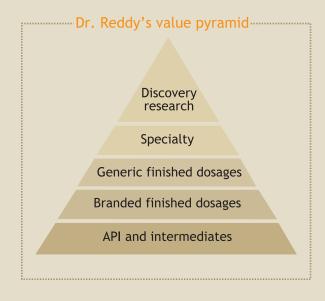
Over the years, the Company consistently strengthened its capability through the following business-enhancing initiatives:

- Being proactive: In terms of people, commercial, R&D and regulatory investments leading to enhanced capabilities.
- Being progressive: Graduation to the innovation-led businesses, leading to a migration to the highest end of the value chain.
- Global outlook: Successful leverage of the product portfolio across key international markets in different forms leading to profitable and sustainable growth.
- Customise: Adaptation of strategies for global and local requirements leading to robust customer relationships.

More importantly, Dr. Reddy's scaled up from one pharmaceutical business to another in seeking to realise its true potential. The result is a presence today across a comprehensive business range: from the manufacture of APIs and finished dosages at one end leading to specialty segments that serve as a bridge to the Company's innovation-led business of discovery at the highest end of the pharmaceutical value chain.

The Company's decision to be extensively present in these segments was a result of its strategic resolve to scale its business with speed in response to a rapid growth in opportunities emerging within the industry environment. So on the one hand, this decision was influenced by the scope to enhance shareholder value in a sustainable way on the basis of the segment's prevailing size, relevance, profitability and extent of contribution that the Company's presence could make in addressing the unmet medical needs of community. On the other hand, the decision was influenced by the need to extend from one business to another and take advantage of the investments in R&D and marketing infrastructure.

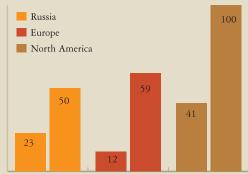
To realise its true potential as a global value-driven pharmaceutical organization, the Company recognized that it would not be enough to merely scale its product portfolio but to supplement it with a wide, deep and consistent presence across the key global markets. Over the last few years, the Company has done just this, as a result of which it has rapidly evolved from an India focus to a global presence with



progressive investments in visibility, specialized professionals and state-of-the-art infrastructure.

At Dr. Reddy's, this long-term commitment is reflected in the Company's consistent investments in key markets to build a strong marketing and regulatory infrastructure, enabling it to attract rich people skills on the one hand and participate in a larger share of the value chain on the other. This is best showcased by the Company's growing presence in the U.S., the largest pharmaceutical market in the world: it entered this market through product partnerships but rapidly graduated to marketing products under its own label. Besides, over a period of five years, the Company invested in rapidly expanding its six-member U.S. team into a 61-member organization, quite on the lines of its successful strategy for a growing market like Russia, where it created a strong marketing team of more than 100 members to detail its brands.

#### Revenue from key markets (U.S.\$ million)



2000-01 2004-05 2000-01 2004-05 2000-01 2004-05

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This then is the advantage that Dr. Reddy's enjoys over a number of its competitors: even as they are still trying to only create a presence in these markets, the Company already enjoys a front-end commercial infrastructure in the U.S., Europe, Russia and China, representing individually and cumulatively a large market for the Company's generic and innovation-based products (as and when they mature).

At Dr. Reddy's, this proactive transformation from a single business to a multi-business presence across the value chain as well as from a single market to diverse markets is a result of the Company's objective to scale the business through a willing embrace of challenges, reinvention of systems and processes and planning for a profitable and sustainable future.

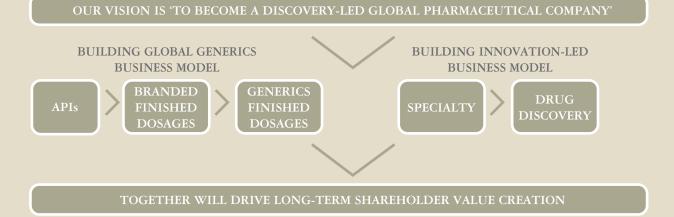
To do so, the Company invested in the right people resources and leadership. It created a manufacturing and commercial infrastructure benchmarked to international standards that would enable it to emerge as a discovery-led global pharmaceutical Company. More importantly, the Company invested in a rich pipeline of products – one of the largest in the industry – expected to unleash its true value over the near-term concurrent with its focus on the evolution of various systems and processes in line with a rapidly changing industry and global environment.

At Dr. Reddy's, a number of these diverse initiatives have been knitted together by a culture of excellence that runs across its businesses, processes and functions. At the Company, this culture of excellence has been institutionalised through the creation of a business process excellence framework and reflected in the building of global quality systems, integrated product development teams as well as sound governance practices benchmarked with the best international standards. Going ahead, the Company will continue to invest in strengthening the right leadership and establishing the next level of processes and systems critical to competing effectively in the global marketplace.

So, even if the dynamics of the various markets change within a rapidly evolving regulatory environment and most countries move towards the protection of intellectual property, Dr. Reddy's will be attractively positioned to leverage the value of its globally competitive research and discovery capabilities, strong intellectual property management and legal teams, regulatory competencies and world-class infrastructure.

As a result, what Dr. Reddy's has done over the last few years is lay the foundation for profitable and sustainable progress towards its objective of emerging as a successful global pharmaceutical organization.

From a strategic perspective, the Company addressed the potential inherent in its businesses at two levels, each requiring the investment of a different mindset, resources and skill sets for the reason that these businesses not only address varied customers and their needs but also belong to varied cycles of growth and maturity before they can truly emerge as independently sustainable businesses.





The generics model (including API and finished dosages businesses) is one where the Company expects to leverage the potential in its existing markets, products and synergies, and across its three businesses for maximum benefit. This is well illustrated through the single product omeprazole, which has established itself in different businesses and markets, growing rapidly to a global revenue of U.S.\$ 45 million (in excess of U.S.\$ 10 million each in India, Russia and U.K.). Going ahead, the Company expects to replicate this differentiated approach across more products, accelerating growth in the process.

At Dr. Reddy's, it would be relevant to note that the Company's API and branded finished dosage businesses, strategically invested with resources, are now on the verge of unleashing considerable value through accelerated launches; being self-sufficient, they will support the nascent growth of generics, specialty and discovery, the Company's three other businesses. The Company's generics business possesses a short-to-medium term maturity curve, has attracted consistent investments and will require additional support for it to mature into a sustainable growth engine. The Company is unleashing the value of investments through an expansion of its global presence in these businesses through a wider reach on one hand and the expansion of its product pipeline on the other.

At Dr. Reddy's, the innovation businesses of specialty and discovery research represent the other growth areas. The specialty business is in the initial period of investments, with a medium-term maturity curve that will serve as a bridge to building its discovery business. The discovery business, on the other hand, has a longer gestation and will require investments across the long-term for the full value of its pipeline to be realized. Both businesses will lead to the Company launching its own NCEs globally in niche therapeutic spaces with the objective to generate stable and attractive returns.

At Dr. Reddy's, we are optimistic that both these businesses possess the potential to considerably enhance stakeholder value as they are adequately protected by a global intellectual property framework. Once mature, these businesses will generate sustained and stable cash flows derived through innovation-driven and patent-protected franchises.

At Dr. Reddy's, in addition to these businesses, its Custom Pharmaceutical Services business has strengthened its position in emerging as a partner of choice for large global innovators as

well as emerging pharma companies. From providing chemistry and manufacturing services to innovator pharmaceutical companies across the globe, this business has transformed itself into becoming a preferred supplier for the entire value chain of pharmaceutical services - from discovery all the way to the market. This approach will help the Company partner closely with customers early and through the complete drug development life cycle, a big advantage in a segment marked by few players who truly understand the pharmaceutical business and the intricacies involved in bringing a molecule to the market. The Company has a trained scientific talent pool with a rich understanding of the cGMP manufacturing and regulatory requirements for synthesis and manufacture of an NCE from pre-clinical stage to commercialization. With India strongly positioned to emerge as one of the preferred outsourcing hubs in the new product patent era, the Company is attractively positioned to leverage its infrastructure to address significant growth opportunities.

The Company is also growing its biologics business through a focus on the development of a global bio-generics portfolio for the emerging as well as developed markets. Biologics presents significant growth opportunities to both, innovator as well as generics companies. As per IMS data, biotech products accounted for 27 percent of the active research and development pipeline and 10 percent of global sales in 2004. The Company has proactively invested in this growing space in preparation of an emerging environment when the regulatory pathway for the development of biogenerics is crystallized. It is investing in building infrastructure and R&D capabilities for the development of a biologics portfolio with the regulatory framework in mind: launch in near regulated markets as a precursor to an entry into the regulated markets.

At Dr. Reddy's, the significant investments in the commercialisation of its pipeline, the lead time involved in product maturity and a competitive environment for some of its key products has resulted in a temporary decline in profitability. Even as the Company remains committed to its long term investments, it is exploring risk-reward partnerships to reconcile its short-term profitability with enhanced long-term shareholder value. In the opinion of the Company, this strategy – invest today for sustainable returns – will strengthen the business and return it to its erstwhile growth trajectory in the foreseeable future...

# Strong pipeline

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