

# DRIVING GROWTH

Dr. Reddy's Laboratories Ltd. | Annual Report | 2001–2002

BOARD OF DIRECTORS	04
	06 CHAIRMAN'S LETTER
DISCOVERY RESEARCH	10
	12 ACTIVE PHARMACEUTICAL INGREDIENTS
GENERIC	14
	16 BRANDED FORMULATIONS
EMERGING BUSINESSES	18
	20 CUSTOM CHEMICAL SERVICES
SAFETY, HEALTH & ENVIRONMENT	22
	24 HUMAN RESOURCES
DR. REDDY'S FOUNDATION	26
	30 INTANGIBLES ACCOUNTING
DIRECTORS' REPORT	34
	46 MANAGEMENT DISCUSSION & ANALYSIS
CORPORATE GOVERNANCE	70
	88 ADDITIONAL SHAREHOLDERS INFORMATION
FINANCIALS	103
	165 SUBSIDIARIES FINANCIALS
NOTICE OF AGM	343
	348 GLOSSARY

# highlights

## Sales

**Driven by fluoxetine** and international branded formulations, sales increased by 58% from Rs. 9,841 million in 2000-01 to Rs. 15,578 million (US\$ 319 million) in 2001-02. Fluoxetine sales of Rs. 3,286 million (US\$ 67 million) contributed to 21% of the total turnover. Without fluoxetine, sales grew by 25%.

**International sales** of branded formulations grew by 55% to Rs. 2,015 million (US\$ 41 million), driven by the growth in sales to Russia. Overall

## Profits, ROCE, RONW & EPS

**Earnings before interest, taxes, depreciation and amortisation (EBITDA)** doubled from Rs. 2,606 million in 2000-01 to Rs. 5,314 million (US\$ 109 million) in 2001-02. EBITDA margin increased from 26% in 2000-01 to 34% in 2001-02.

**Profit after tax (PAT)** more than trebled — from Rs. 1,445 million in 2000-01 to Rs. 4,597 million (US\$ 94 million) in 2001-02. PAT

## Research & Development

**An anti-diabetic molecule** — DRF 4158 — was licensed to Novartis. This will fetch the company US\$ 55 million through up-front and milestone payments.

**Eleven abbreviated new drug applications** (ANDAs) were filed during the year in the US, taking total filings to 23.

## International Listing & Acquisition

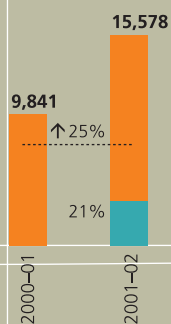
**On April 11, 2001,** became the first Indian pharmaceutical company to list on the New York Stock Exchange.

**In the fourth quarter** of 2001-02, acquired BMS Laboratories and its subsidiary, Meridian Healthcare UK Limited, for £9 million. Meridian is a

niche generic player with marketing rights to over 100 products.

**Total Sales**  
COMBINED, RS MN

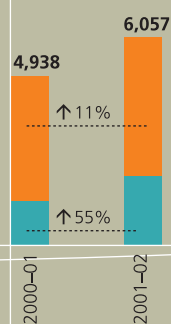
↑ **58%**



FLUOXETINE

**Branded Formulations**  
SALES, RS MN

↑ **23%**



INTERNATIONAL  
DOMESTIC

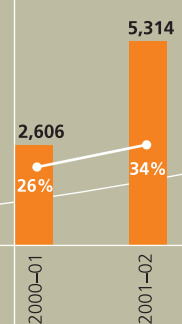
**Active Pharmaceutical Ingredients**  
SALES, RS MN

↑ **16%**



**EBITDA**  
RS MN

↑ **104%**



EBITDA MARGIN

<p>sales of branded formulations grew by 23% — from Rs. 4,938 million in 2000-01 to Rs. 6,057 million (US\$ 124 million) in 2001-02.</p>	<p><b>With fluoxetine 40 mg,</b> became the first Indian pharmaceutical company to launch a generic with 180-days marketing exclusivity in the US.</p>	<p><b>Sales of active pharmaceutical ingredients</b> increased by 16% — from Rs. 4,312 million in 2000-01 to Rs. 4,997 million (US\$ 102 million) in 2001-02.</p>	
<p>margin stood at 30% of total turnover.</p>	<p><b>Return on capital employed (ROCE)</b> increased from 19% in 2000-01 to 31% in 2001-02.</p>	<p><b>Return on net worth (RONW)</b> increased from 26% in 2000-01 to 32% in 2001-02.</p>	<p><b>Earnings per share (EPS)</b> grew from Rs. 22.83 in 2000-01 to Rs. 60.41 in 2001-02.</p>
<p>Eight of the 13 ANDAs pending with USFDA are para IV filings.</p>	<p><b>8 new drug master files (DMFs)</b> filed during the year in the US, taking total filings to 26.</p>	<p><b>Promoted a new</b> wholly owned drug-discovery service subsidiary — Aurigene Discovery Technologies, which will focus on automated medicinal chemistry, structural biology and structure-based drug design.</p>	



# chairman's letter

6

## DEAR SHAREHOLDERS

2

2001-02 HAS BEEN an

excellent year for your Company.

Here are a few financial facts. Sales increased by 58 per cent to Rs. 15,578 million, or US\$ 319 million. Earnings before interest, taxes, depreciation and amortisation (EBITDA) doubled to Rs. 5,314 million, or US\$ 109 million. Profit after tax (PAT) more than trebled to Rs. 4,597 million, or US\$ 94 million. And, earnings per share (EPS) grew from Rs. 22.83 in 2000-01 to Rs. 60.41 in 2001-02.

I am as happy as you will be with these results. But it is not my intention to dwell on the financial aspects of your Company.

These are discussed in detail in the chapter on Management Discussion and Analysis.

As a scientist, I subscribe to the dictum of George W. Merck, founder of the eponymous global pharmaceutical major, that the fundamental business of a drug company is not to make

profits, but to produce medicines that cure diseases. And when a company successfully innovates and produces such drugs, profits

take care of themselves. I will, therefore, use this opportunity to share with you my vision of Dr. Reddy's Laboratories, and how your Company is poised to realise this dream.

The vision of our 18-year old enterprise is as simple as it is difficult: "To be a discovery-led global pharmaceutical company."

We began in 1984 and, like some other players of that era in India, concentrated on strengthening reverse engineering capabilities to produce high quality bulk drugs and formulations at low costs, and sell them in the domestic market. The importance of these skills cannot be exaggerated, for they created the technological foundations for your Company's successful foray into the international generics market.

However, even in the early days, we realised that the ultimate accolade for a pharmaceutical company comes from the strength of its drug discovery programme and the size of its new chemical entity (NCE) pipeline. Consequently, we were one of the very few pharmaceutical companies in India that started investing in new drug discovery capabilities and research. And we did so even when we had far less money in the coffer.



Dr. K Anji Reddy CHAIRMAN

**T**HE ULTIMATE ACCOLADE FOR A PHARMACEUTICAL COMPANY COMES FROM THE STRENGTH OF ITS DRUG DISCOVERY PROGRAMME AND THE SIZE OF ITS NEW CHEMICAL ENTITY (NCE) PIPELINE.

MANY FELT THIS was a daunting task. Even today, I am often inundated by various “facts and figures”: for every new drug that is launched, some 10,000 molecules fail; that the average cost of bringing an NCE to market is over US\$ 800 million; and the time taken is anything between 10 and 12 years.

Our response to such data has been that in the area of discovery research we cannot be a prisoner of averages. The test of successful R&D driven pharmaceutical company should be its ability to consistently beat these so-called averages. Your Company exemplifies this tenet.

Your Company filed its first patent applications in USA in 1995, covering novel anti-diabetic & anti-cancer molecules. Despite having sales and market capitalisation that are significantly less by global standards, we have succeeded in creating a substantive NCE pipeline. Today, we have no less than 10 NCEs in various stages of development, of which two are at Phases II and III of clinical trial. Thus, our achievements in drug discovery reinforce our belief that there is little correlation between innovation and size.

LET ME GIVE A FEW examples of your Company’s R&D and discovery

programme. DRF-2725, one of our anti-Type 2 diabetic NCEs licensed to Novo Nordisk, has commenced Phase III clinical trials. DRF-2593, also addressing Type 2 diabetes and licensed to Novo Nordisk, is in late-Phase II trial. Yet another anti-Type 2 diabetic NCE, DRF-4158, has been licensed to Novartis. An anti-cancer NCE, DRF-1042, has completed Phase I clinical trial.

I have been told that a defining characteristic of a discovery-driven mid-sized US pharmaceutical company is that it has something like eight late-stage NCEs in its pipeline. Although Dr. Reddy’s is far smaller in size, we should be able to meet this norm in the next five years. And, as we go forward, we will follow a calibrated strategy of licensing-out our molecules which facilitates our going up the value chain.

R&D requires state-of-the-art laboratories. By the middle of 2002-03, your Company will have five such facilities in India and the US. Three are already in business: Dr. Reddy’s Research Foundation (DRF) and the new Technology Development Centre (TDC) at Hyderabad; and Dr. Reddy’s US Therapeutics Inc. (RUSTI), located in Atlanta, USA. By September 2002, our subsidiary, Aurigene Discovery Technologies, will have set-up a highly

# chairman's letter

8

specialised research laboratory in Boston, USA — the new global hub of discovery research. And Aurigene's Bangalore laboratories will go fully on-stream by December 2002.

**LED BY DR. UDAY** Saxena, recently appointed as the Chief Scientific Officer of the group, RUSTI is a bio-pharmaceutical company dedicated to discovery and design of novel therapeutics. The focus therapies are diabetes, inflammation, lipid metabolism, oncology and cardio-vascular diseases. RUSTI has developed a technology platform and a discovery approach based upon the CMS® pathway. A lead molecule in restenosis is currently in the late pre-clinical stage.

At the time of writing, data seems to suggest that RUSTI may have discovered a new gene that could be used as a novel target for the treatment of diabetes.

Aurigene is a post-genomic discovery services company that will focus on building skills in automated medicinal chemistry, structural biology and structure based drug design. The initial focus of Aurigene will be to establish alliances with pharmaceutical companies for chemistry and protein services and other related drug discovery activities.

We plan to leverage the strengths of each research facility to generate more discovery research and NCEs. RUSTI will use its molecular biology technology platforms for target identification, validation and high-throughput screening. Aurigene will use its skills in structure-based drug design to bridge the gap between structural biology and medicinal chemistry. DRF will use its strengths in organic chemistry and pharmacology for lead optimisation, lead profiling and pre-clinical trials. And, by focuses on chemistry process development, TDC will help in reducing the chemical cost of producing NCEs.

**DISCOVERY RESEARCH**, however, needs sustained funding. This brings me to the strategic role of generics in achieving the corporate vision of Dr. Reddy's. With a large number of block-buster drugs going off-patent by 2005, the global generics market is set to explode. Any company that successfully challenges patents in the US market will reap phenomenal benefits during the mandated marketing exclusivity period. Your Company's 58 per cent growth in sales in 2001-02 was very much due to the 180-days exclusivity granted to its fluoxetine 40 mg capsules.

The generics challenge, therefore, is to

**T TAKES COURAGE** AND VISION TO LOOK BEYOND TODAY'S VICISSITUDES AND FIND HOPE. BUT IF WE DON'T SEIZE THE MOMENT AND CHALLENGE OUR CAPACITIES WE WILL REMAIN PYGMIES IN THIS WORLD OF GIANTS. THE FUTURE BELONGS NOT TO THOSE WHO MERELY SEEK OPPORTUNITY, BUT TO THOSE WHO CREATE IT...

DR. K ANJI REDDY

9

ensure that your Company gets the benefits of such marketing exclusivity for different formulations on a more or less regular basis. We have already filed 23 abbreviated new drug applications (ANDAs) with the US Food and Drug Administration. Of these, we have USFDA approvals for 10; and the 13 that are pending, including eight Para IV patent challenges, represent a potential annual market of US\$ 11 billion. We are fairly confident of capturing a reasonable share of this potential market.

Generics is an important part of our business per se. But it assumes even greater significance to your Company as a source of finance for funding discovery research. We view generics as the instrument to generate

cash for ploughing back into discovery.

I am an optimist. And the results of your Company over the last few years have renewed that optimism. I believe that within the next five to six years, Dr. Reddy's Laboratories should be able to fulfil its vision of being a discovery-led global pharmaceutical company. When that happens, it will be a great moment for the Company. And a greater moment for science in India.

Thank you for your good wishes and support.

DR. K ANJI REDDY  
Chairman



# discovery research

**D**r. Reddy's drug discovery program is at the heart of its vision—to be a global, discovery-led major. With 260 scientists focussed exclusively on discovery research, 23 patents, and a 9 molecule pipeline, it has built an array of discovery skills. The Research Foundation in India has world-class chemistry and strong pharmacology skills. Its Atlanta, USA lab focuses on early stage research skills, like target identification and high throughput screening.

Aurigene, a discovery services unit, adds automated medicinal chemistry and structure-based drug design to the mix.

**1994**

**Commenced:** Drug discovery in metabolic disorders, cancer, inflammation & bacterial infections; one of the first Indian companies to do so

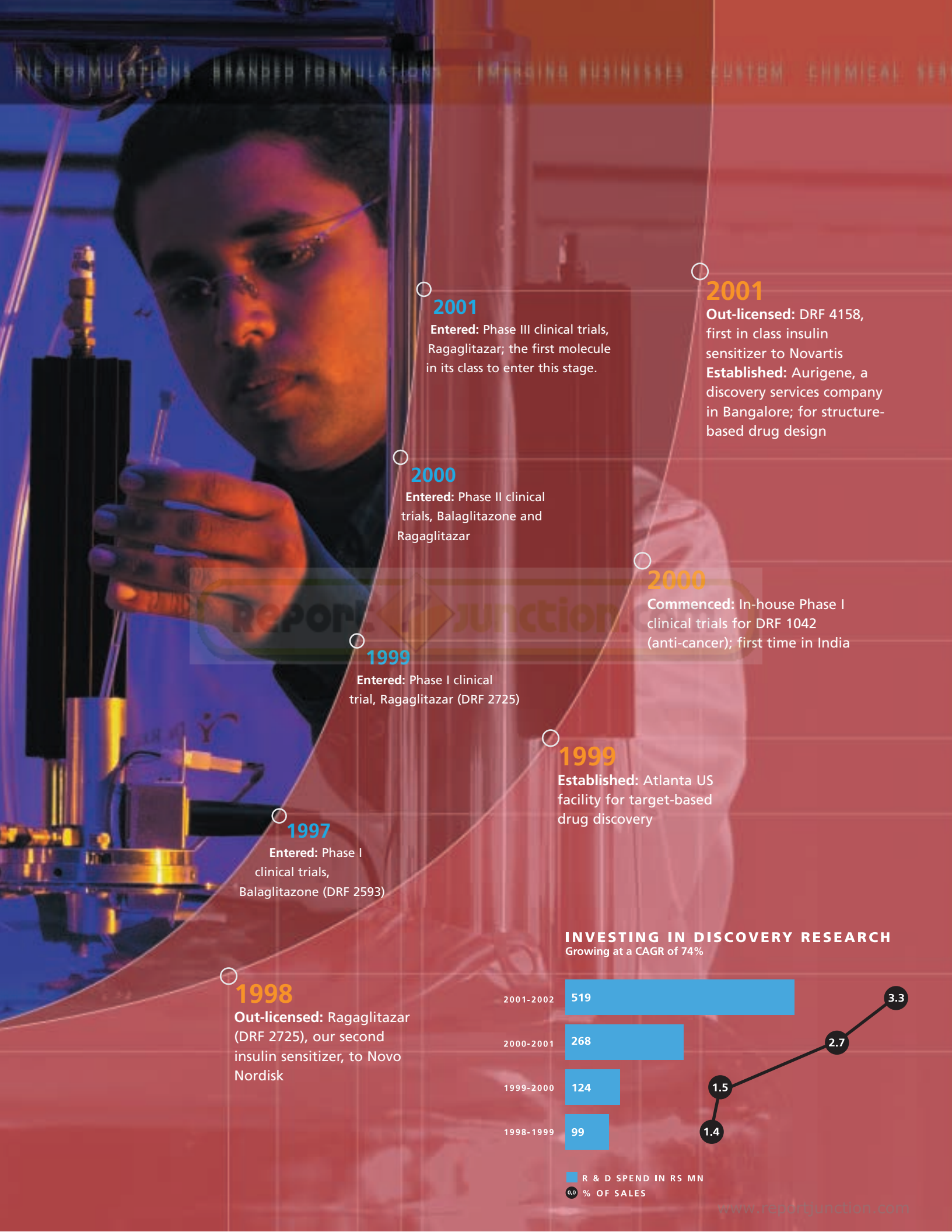
**1995**

**Filed:** Our first patent application in the US for anti-diabetic & anti-cancer molecules; currently 67 patents filed; 23 granted

**1997**

**Out-licensed:** Balaglitazone (DRF 2593), our first insulin sensitizer, to Novo Nordisk; the first from India





## 2001

**Entered:** Phase III clinical trials, Ragaglitazar; the first molecule in its class to enter this stage.

## 2001

**Out-licensed:** DRF 4158, first in class insulin sensitizer to Novartis

**Established:** Aurigene, a discovery services company in Bangalore; for structure-based drug design

## 2000

**Entered:** Phase II clinical trials, Balaglitazone and Ragaglitazar

## 2000

**Commenced:** In-house Phase I clinical trials for DRF 1042 (anti-cancer); first time in India

## 1999

**Entered:** Phase I clinical trial, Ragaglitazar (DRF 2725)

## 1999

**Established:** Atlanta US facility for target-based drug discovery

## 1997

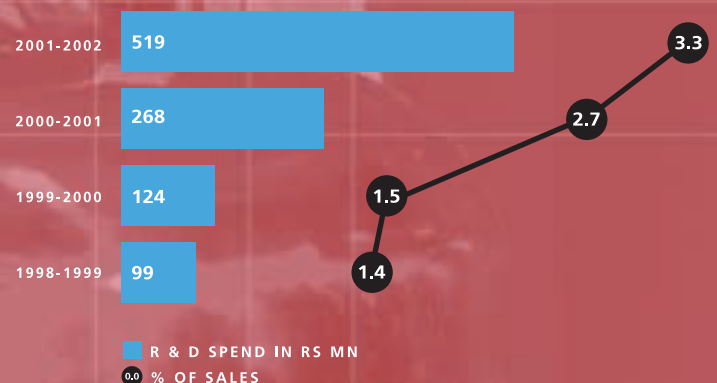
**Entered:** Phase I clinical trials, Balaglitazone (DRF 2593)

## 1998

**Out-licensed:** Ragaglitazar (DRF 2725), our second insulin sensitizer, to Novo Nordisk

### INVESTING IN DISCOVERY RESEARCH

Growing at a CAGR of 74%





# APIs

**D**r. Reddy's API division is a proven manufacturer of bulk actives. Today, its emphasis is on building profitable revenue from exports to regulated markets like USA and Western Europe. It offers an unparalleled portfolio for the US market, and has tie-ups with large US generic companies. All six of its manufacturing facilities are

USFDA inspected. Its state-of-the-art infrastructure gives it speed, flexible scale, competitive cost and its excellent process chemistry skills ensure that its portfolio keeps up with market needs. Apart from its own profitable operations, the vertical integration it offers makes it critical to the success of other divisions of Dr. Reddy's.

**1984**

**Commenced:** Operations at its first facility, Jeedimetla, manufacturing Ibuprofen; currently has six multi-ton facilities

**1986**

**Entered:** International market, exported methyldopa to Germany

**1988**

**Exported:** Ibuprofen, to US, Japan, Spain, Italy, emerging as the largest exporter from India with over 400 MT in sales