Dr. Reddy’s Laboratories is one of the largest research-driven pharmaceutical companies in India.

Background

Dr. Reddy’s Laboratories is a vertically integrated, global pharmaceutical company with proven research capabilities. The second largest pharmaceutical company in India, Dr. Reddy’s manufactures and markets a wide range of pharmaceutical products in India and overseas. Founded by Dr Anji Reddy, an entrepreneur-scientist, in 1984 at Hyderabad, the company produces finished dosage forms, API, diagnostic kits, critical care and biotechnology products. The company has over 190 finished dosages and 60 API currently in production.

In 1986, Dr. Reddy's entered the international markets with exports of Methyldopa. In 1987, it obtained its first US FDA approval for Ibuprofen API and started its formulations operations. In 1988, the company acquired Benzex Laboratories Pvt. Limited to expand its bulk actives business. Dr. Reddy’s raised a GDR issue of US$ 48 million in 1994 and laid the foundation stone for a finished dosages facility to cater to the highly regulated markets such as USA. In the year 2000, the company merged with Cheminor Drugs Limited.

In the same year, Reddy US Therapeutics, a wholly-owned subsidiary, was established at Atlanta, US to conduct target based drug discovery.

In 2002, it made its first overseas acquisitions and acquired two UK companies, namely BMS Laboratories Limited and Meridian Health Care (UK) Limited. The two firms produce oral solids and liquids. In 2003, Dr Reddy’s set up a joint venture with Venturepharma in South Africa called Dr Reddy’s Laboratories (Proprietary) Ltd, South Africa to establish its presence in the Southern Africa Development Community (SADEC) countries and sub-Saharan African territories. The company has six US-FDA inspected plants. In November 2005, the company entered into a definitive agreement to acquire Roche’s API business at the state-of-the-art manufacturing site.

<table>
<thead>
<tr>
<th>Company</th>
<th>Products</th>
<th>Established</th>
<th>Founder</th>
<th>Distribution</th>
<th>Production plants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Reddy's Laboratories</td>
<td>Pharmaceuticals</td>
<td>1984</td>
<td>Dr. Anji Reddy</td>
<td>India, Americas, Europe, Middle East, Asia Pacific, Africa</td>
<td>India, UK, Mexico</td>
</tr>
</tbody>
</table>
Sales of Ramipril amounted to over 6.5 per cent of the total company revenues in 2004. Other major sellers for the company’s API business included ciprofloxacin, ranitidine hydrochloride, naproxen sodium and ibuprofen. In 2005, branded formulations accounted for 40 per cent of total sales, API accounted for 36 per cent of total sales while generics accounted for 18 per cent of total sales. The company’s API division reported filing 16 DMF with the US FDA in 2004. This took the total number of DMF on file in the US to 56, and the company filed a further 9 during 2005. Dr Reddy’s had three ANDA approved in 2004, for ciprofloxacin, fluconazole and citalopram.

Dr Reddy’s generic formulations business has been operational since 1998. In 2005, Dr Reddy’s filed 13 ANDA with the FDA. The company’s generics pipeline included 45 ANDA pending approval with the FDA. Of these, the company reported that 9 contained Paragraph IV certification. Dr. Reddy’s plans to maintain its momentum by filing between 15 and 20 ANDA during 2005.

Financial Analysis

While Dr. Reddy’s witnessed a healthy growth rate in its revenues between 2001 and 2004, the year 2005 was a difficult one for the company. Revenues declined in rupee terms (though in dollar terms there was a slight increase) which resulted in a decline in Cuernavaca, Mexico including all employees and business supply contracts.

Foreign Investors are the largest shareholders in the company (46.77 per cent equity stake) followed by the promoters (26.29 per cent of the equity stake). Mutual funds, financial institutions and other institutions hold 13.15 per cent equity stake and non-promoter corporate hold 1.42 per cent of the equity stake. The public holds the remaining stake.

Products and Brands

Dr. Reddy’s manufactures API and finished dosage forms and markets them globally, with a focus on United States, Europe, India and Russia. In addition, the drug discovery arm of the company conducts basic research in the areas of diabetes, cardiovascular, inflammation and bacterial infection. The core businesses of API and branded formulations are well established with an impressive track record of growth and profitability. The generics business started operations in 2001 and focuses primarily on the North America and EU markets.

The company’s current best selling API product is Ramipril, first introduced in non-US markets in 2003.
Dr. Reddy's has been a pioneer in establishing the presence of Indian pharma in the global arena. In 1990, Dr. Reddy's became the first Indian manufacturer to export norfloxacin and ciprofloxacin to Europe and Far East. In 1991, first formulation exports to Russia were commenced. Dr. Reddy's started its drug discovery programme in 1993 and within three years it achieved its first breakthrough by outlicensing an anti-diabetes molecule to Novo Nordisk in March 1997. By licensing the anti-diabetic molecule, DRF 2593 (Balaglitazone), to Novo Nordisk, Dr. Reddy's became the first Indian pharmaceutical company to out-license an original molecule. The same year, it also filed its first ANDA with the US FDA for Ranitidine. In 2001, the company was the first Indian pharmaceutical company to obtain 180-day exclusive marketing rights for a generic drug in the US market with the launch of fluoxetine 40 mg capsules.

Dr. Reddy’s contribution in making ‘Made in India’ global

The company enjoys a strong presence in USA, Western Europe, Russia and India. While India accounted for 35 per cent of total turnover in 2005, USA accounted for 22 per cent of total turnover. Russia and CIS accounted for 15 per cent of sales while Europe accounted for 14 per cent of sales.

Profitability has been negatively impacted in the past few years as a result of the company’s increase in research and development (R&D) expenditure and long-term investment activities to enhance its pipeline and other infrastructure. The expenditure on R&D has been continuously increasing as the company stresses on innovation for growth. R&D expenditure as a percentage of total turnover increased from 5 per cent in 2002 to over 18 per cent in 2005.

Dr. Reddy's entered the global generic market with exports of Ranitidine-75 mg and Fluoxetine to North America. In 2001, the company entered into an exclusive co-marketing and development agreement with Par Pharmaceuticals Inc. covering fourteen generic pharmaceuticals products to strengthen the company's position in the US generic market and to get a substantial cost advantage on account of its vertical integration.
providing for the strategic investment by Dr. Reddy's to acquire 100 per cent of betapharm Group, Germany for 480 million in cash.

Factors fuelling Dr. Reddy’s global initiatives

Aiding the company's growth is Dr. Anji Reddy’s passion for research and drug discovery and his vision to establish India’s first discovery led global pharmaceutical company. Today, the company has over 950 scientists working across the globe, around the clock. Dr. Reddy’s actively pursues a basic research programme and focuses on cancer, diabetes, bacterial infections and pain management. The company has several pharmaceutical products in development.

In fact, Dr. Reddy’s was able to establish itself as a supplier of high quality pharmaceuticals very early on in the global market. In 1988, the company’s process for Ibuprofen, a popular anti-inflammatory drug, was so advanced that Ethyl Corporation, US, had to accept its superiority in front of the US Trade Representative and ask for tariffs to be put against Dr. Reddy’s to achieve a level playing field.

In 2003, Pliva signed an agreement with Dr Reddy’s for development and marketing of 11 oncology products. Dr Reddy’s would be responsible for developing the API and preparing the DMF for the products, whilst Pliva would be responsible for formulating the products and filing the necessary marketing authorisation applications. Pliva would have the exclusive marketing rights for 11 Central and East European countries, while Dr Reddy’s gained an opportunity to enter this market.

In September 2005, Dr Reddy’s entered into a co-development and commercialisation agreement with Denmark’s Rheoscience AG involving a diabetes drug. The agreement, over balaglitazone, will involve Rheoscience funding all costs for the Phase III clinical trials, while Dr Reddy’s will compensate Rheoscience a share of the development costs. In turn, Rheoscience will obtain the marketing rights to the EU and China, while Dr Reddy’s will garner the marketing rights for United States and rest of the world. The agreement will cover a period of 10 years from commercialisation.

In 2005, the company entered into a definitive agreement to acquire Roche’s API business in Cuernavaca, Mexico, including all employees and business supply contracts. The total investment outlay is about US$ 59 million including working capital. This business involves the manufacture and sale of API including intermediates to Roche and other innovator companies. This acquisition adds unique steroids manufacturing capabilities to Dr. Reddy’s.

In February 2006, Dr. Reddy’s and 3i, Europe’s leading private equity house, jointly announced that they had entered into a definitive agreement providing for the strategic investment by Dr. Reddy’s to acquire 100 per cent of betapharm Group, Germany for 480 million in cash.
known as just 'copycats' to 'innovators'. Through its success, Dr. Reddy's pioneered drug discovery in India.

**Future plans**

Dr Reddy's is taking steps to grow its business across regions, and expects Brazil, Europe and India to emerge as the key growth drivers in the next few years and is thus focusing aggressively on these markets. It is very positive on growth prospects in Russia as well, with price realisations being better in Russia (sells branded formulations) than in the regulated markets.

Dr Reddy’s recent US$ 59 million acquisition of Roche’s API business in Mexico will help it jump-start its plans for the custom pharmaceutical services (CPS) business. The CPS business involves providing solutions to innovator pharmaceutical companies right from the time a potential drug molecule is in the research stage till the product reaches the market. The acquisition provides an opportunity for the company’s CPS business to grow ten-fold to US$ 100 million over the next 18 months and further de-risk the company’s strategy, which is currently focused on research and generics.

At the level of API 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. 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. Dr. Reddy's has also been taking adequate measures on this behalf.

Dr Reddy’s acquisition of betapharm gives it a strong presence in Europe and it will target 60 per cent of the pharmaceuticals expected to lose patent protection between 2002 and 2008. Dr. Reddy's has also roped in venture capitalists and set up a separate integrated drug development company called Perlecan Pharma with an aim to mitigate the risks involved in drug research, reduce R&D expenses and push up overall future profitability of the company.

**Globalisation at a glance**

- Revenues from international markets constitute nearly 66 per cent of total sales, with most of them coming from US and Europe
- 15 ANDA approvals for drugs in its portfolio in the US
- Acquisitions of international pharmaceutical companies in Germany and Mexico
- Business interest in over 60 countries and exports to over 100 countries

www.drreddys.com