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Betting on biotech

Dr Reddy's is concentrating now on biotechnology-based products and going for acquisitions to provide a base for launching them

The buzz around biotechnology-based medicines is growing louder, with every passing week, and a significant share of the responsibility for this rests with Dr Reddy's Laboratories. The youthful management of the Rs6,500 crore company, which is almost at the top of the heap in the Indian pharmaceutical industry, has realised that it's no longer enough to be the largest manufacturer of existing medicines. To maintain its position of leadership, the company has to find a way to ride the coming boom in biotechnology-based products.

For nearly two decades, medicines like monoclonal antibodies, interferon and many others remained a preserve of the industrialised countries, because only a minuscule fraction of the people in Asia, Africa and Latin America could afford them. However, as the patent protection on more and more of these drugs comes to an end, a whole new world promises to open up for companies such as Dr Reddy's. At present, about $40 billion worth of biotech drugs are dispensed in the US, which accounts for about 15 per cent of all drugs purchases in America, according to IMS Health Inc, a research company based in Fairfield, Connecticut. These products include Enbrel, the arthritis drug, and Aranesp for anemia, both produced by Amgen Inc, as well as Herecpetin (for breast cancer) and mabthera (for blood cancer), both of which are produced by Roche.

Recognising this, Anji Reddy, the chemical scientist, who founded the company over 20 years ago, now travels extensively abroad in search of new opportunities. Though he remains the chairman of the company that bears his name, he has practically left the day-to-day operations in the capable hands of his son Satish Reddy and son-in-law G.V. Prasad. In

Prasad and Reddy: soaring to new highs

the six years since they took over the reins of the company in 2001, the duo have transformed the top management team, bringing a number of people from other industries and easing out several old timers who were unable or unwilling to adapt to the fast changing pharmaceutical industry.

Working in tandem, Reddy as managing director and Prasad as chief executive officer have taken the company to new heights, as sales turnover soared from slightly over Rs1,000 crore in 2001 to Rs2,426 crore in 2006, and then to Rs6,509 crore in fiscal 2007. On the way, they acquired the German company Betapharm and developed a strong base for launching a series of sophisticated biotechnology-based products. This will enable the company to release at least one biotech product into the market each year in the next few years.

Though the 168 per cent jump in sales revenues that the company saw in fiscal 2007 may be too steep to repeat in the current year, Merrill Lynch, an equity research firm, expects Dr Reddy's to post sales figures of about Rs5,560 crore in fiscal 2008. Edelweiss, another brokerage firm also estimates the current year's revenues at Rs5,500 crore. Dr Reddy's has also reported approximately 50 per cent year-on-year growth in its profits in the past five years and, this year too, has recorded a huge leap from Rs146.7 crore in 2006 to Rs965.9 crore in fiscal 2007.

Fiscal 2007 was an unusual year, because the company got additional revenues of about $196 million for a contract to supply of ondansetron as an authorised generics producer. This is a technique often used by companies whose products are about to come off patent protection to ward off their competitors. The first company to get approval to produce the off-patent drug is granted exclusive rights to market the drug for 180 days, during which time other potential competitors are kept out of the picture. The patent holder often 'authorises' a selected company to manufacture the drug and assists it to obtain the necessary approvals from regulatory authorities. The latter company thus becomes the 'authorised generic' manufacturer and usually reaps a windfall. But such an opportunity is one-time and may not be available in subsequent years.

Drop in sales

Not surprisingly, therefore, in its latest quarterly results (second quarter of fiscal 2008), Dr Reddy's has reported a sharp decrease in its sales revenue (Rs1,270 crore in this quarter, as against Rs2,000 crore in the corresponding quarter of the previous year). Similarly, the profit after tax (PAT) for the latest quarter is Rs267.2 crore, compared to Rs279.8 crore in the same quarter of fiscal 2007.

In addition, the revenues generated by Betapharm, the German company that Dr Reddy's acquired two years ago, have also declined substantially (Rs190 crore in the latest quarter as against Rs260 crore in the same quarter of fiscal 2007), partly on account of supply constraints and appreciation of the rupee against the Euro.

When the Betapharm acquisition

FINANCIALS

(Rs crore)	2007	2006	2005	2004	2003	2002
Total revenues	6509.5	2,427	1,952	2,010	1,807	1,662
Gross profit	3087.6	1,185	1,013	1076.7	1022.2	975.4
As % of revenues	47.0	49	52	54	57	59
R&D expenses	246.3	215.3	280.3	199.2	141.2	74.2
Operating income	1122.5	144.2	-28.9	204.9	321.8	505.9
As % of revenues	---	6	-1	10	18	30
PAT	932.7	162.9	211	247.4	340.4	491.4
EPS (Rs)	58.6	21.28	2.8	32.3	44.5	64.6
Dividend* (Rs)	5.0	5	5	7.5	---	---

*Face value Rs. 5. Year ending March 31. Figures based on consolidated U.S.GAAP financials

took place in March 2006 for an enterprise value of €480 million (about Rs2,000 crore), independent analysts felt that Dr Reddy's had paid too much. "The transaction will bring some debt onto the company's books. One will have to see whether the company will be able to generate enough revenues to offset this. Also, the German market is a bit different from other markets. Here, the first three players command a lion's share of the market, while Betapharm, which is number 4, has a market share of just five per cent," one analyst observed (*Business India*, 12 March 2006).

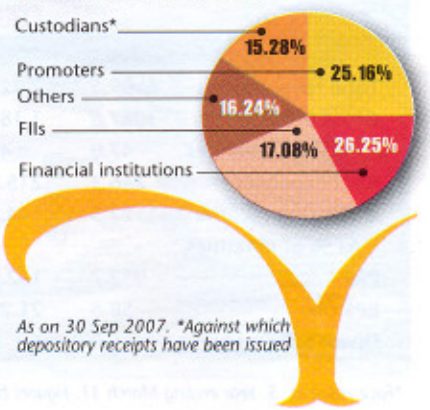
Cartikeya Reddy: leader of the future

More than 18 months after these remarks were made, they have proved to be partly true. "The payback calculations have gone partly awry," agrees Satish Reddy, while stressing that Betapharm was the 'last big opportunity' available for acquisition in Europe. Betapharm also fits in well with the portfolio of generic products that Dr Reddy's has. The German company's business model, in which almost all the manufacturing was being outsourced, also suits Dr Reddy's well, because it enables the Indian company to manufacture most of Betapharm's products in its own factories.

In fact, over 70 per cent of this transition is complete, thus making it likely that in Betapharm will yield much better revenues in the next year or two. Pharmaceutical industry analysts also predict that, once the integration is complete, Betapharm could contribute to an increase of 10-15 per cent in the gross margin of the Indian company. "Give us one more year," Reddy says.

Interestingly, while Reddy says that there are no further acquisitions on the radar, and that they are still "evaluating opportunities", Prasad claims that the company has about $250 million set aside for acquisitions and would be able to raise more cash, if required. When asked specifically about the likelihood of a $300 million buyout in the near future, Prasad would neither confirm nor deny the strong market rumours that are doing the rounds.

SHAREHOLDING PATTERN



*As on 30 Sep 2007. *Against which depository receipts have been issued*

Even as it pushes harder and further into the regulated markets of the US and Europe with its generic drugs and aggressively pursues opportunities in the semi-regulated markets of Latin America, Dr Reddy's is also examining possibilities in the "custom pharmaceuticals" segment. This means that even within the generic drugs space, there are special formulations of a medicine, which companies in the west would like to outsource. With its highly sophisticated capabilities in chemical manufacturing, Dr Reddy's is well placed to exploit these opportunities. In the current year, this component of the business yielded revenues of nearly $150 million, thus contributing as much as 10 per cent of the total revenues of the company.

Investing steadily

While it strives to develop and expand its reach in the global generics market, with continuous efforts to develop new formulations of existing medicines, reduce manufacturing costs and tackle the ever increasing competition from companies in China, Russia and Argentina, Dr Reddy's has also been investing steadily in its bio-pharmaceutical business.

According to Satish Reddy, their work in the biological drugs began as far back as 1998, as a result of which their first product, named Grafeel, was launched in 2001. Their second biological product, Reditux, was launched in April this year. The latter is a monoclonal antibody, intended for use in treatment of non-Hodgkins Lymphoma, a type of blood cancer seen in nearly 20,000 Indians each year. Globally, the branded value of retuximab (the scientific name of reditux) is more than $3 billion because, in the West, it is also approved for use in the treatment of rheumatoid arthritis, says Cartikeya Reddy, who

Leaders in biopharmaceuticals

The biotechnology industry in India has registered a huge 31 per cent growth in the past 12 months, and crossed the $2 billion in terms of sales revenues, according to a recent survey by the Association of Biotech-Led Enterprises (ABLE) of India. Of this, more than 70 per cent comes from biopharmaceuticals, that is, medicines based on biotechnology. This includes vaccines, and sera, where the leaders are Serum Institute of India and Panacea Biotec, monoclonal antibodies from Biocon and Merck, a medicine to treat scars from Wockhardt and several others.

Wockhardt's claim to fame is insulin, produced from animal sources – usually cattle or pigs, since it is one of the largest producers of injectible insulin in the world. Novo Nordisk, the other global leader in this segment, is more focused on human insulin, which is believed to be purer and safer than animal insulin.

Another widely used product is erythropoetin, where Biocon and Wockhardt are among the major producers. Erythropoetin is used for the treatment for certain forms of anemia in which red blood cells are not generated in sufficient numbers. Biocon also produces filgrastin, which brings it in head-to-head competition with Dr Reddy's, and streptokinase, which is used for the treatment of severe heart diseases.

Other important players in the Indian biopharmaceuticals sector include Bharat Biotech, which is also into vaccines, Intas Biopharmaceuticals, which has entered into collaboration with a US company to produce a vaccine against some forms of cancer in women, and Strides Arcolab, which has acquired a fermentation facility in Italy. Intas is also working with Progenetics LLC of the US on developing a treatment for hemophilia, a very common form of bleeding disorder.

Anji Reddy: founder to patriarch

quit from US giant Genentech in 2003, to join Dr Reddy's as head of biologics research.

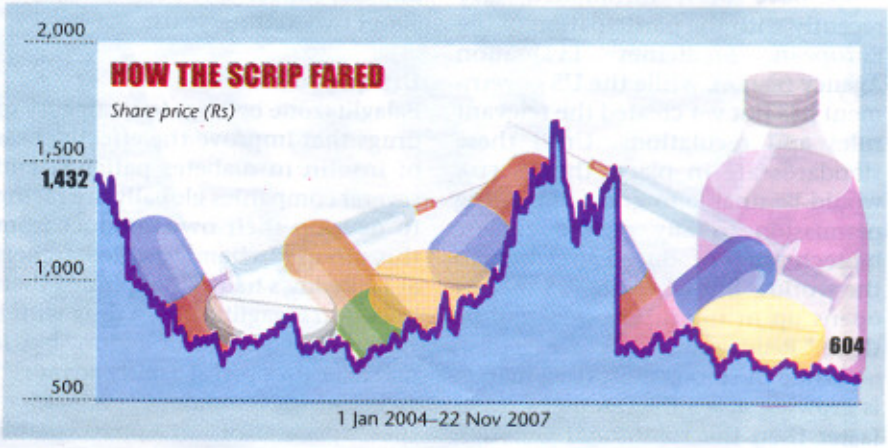
In keeping with their commitment towards the bio-pharmaceutical sector, the management has decided to set up a separate biologics research facility with an estimated investment of $30 million (Rs120 crore). The construction has already begun and, when completed, it would give a considerable boost to the company's efforts in this direction.

According to its stated objectives, at least eight biological products are expected to emerge from the stable of Dr Reddy's in the next few years, with one product hitting the market every year. All of these would be products that are scheduled to go off-patent during the coming decade and would mostly be targeted at cancer and the so-called auto-immune diseases. The latter are a group of disorders in which the body's own defence mechanism spins out of control and start causing damage to various organs. Among the commonest diseases of this category worldwide is rheumatoid arthritis. Others include a variety of serious digestive disorders, a form of hepatitis, some types of anemia, and even ankylosing spondylitis – a total of 40 diseases affecting different parts of the body have been identified as belonging to the auto-immune category.

Scaling up capacity

To do this, Reddy's may double the number of people in its biotech division from 170 to 340 in the next two years and plans to spend about $20 million (Rs80 crore) in strengthening its production capacity in this segment. Thus, their capacity for manufacturing reditux, currently limited to a 200-litre fermentation tank at a facility outside Hyderabad, will be quadrupled with the setting up of three tanks by the end of this year. At a later stage, its fermentation capacity would be augmented with three 5,000-litre tanks to enable the company to manufacture other monoclonal antibodies as well.

When asked why his department was focussed so sharply on just two therapeutic areas, instead of looking at a wider spectrum of disease, Cartikeya Reddy pointed out that practically all the patented biological products were in these areas. Hence, the generic biotech industry, by its



very nature, would have to limit itself to these segments.

With all this, the bio-pharmaceutical side of the business accounts for just 5 per cent of the current revenues of the company. The reason: the highly lucrative markets of the US and Europe, where dozens of Indian companies have made their fortunes by marketing traditional generic drugs, have not really opened up to generic biological products. Since these products are highly sophisticated and complex, special guidelines and standards need to be laid down to ensure that they are effective and safe.

In Europe, the regulatory guidelines have been formulated very recently with the participation of the European Medicines Evaluation Agency (EMEA), while the US government has not yet created the relevant rules and regulations. Until these standards are in place, the US FDA would be unable to grant marketing permission to any of the generic biotech drugs produced anywhere in the world. "But when the US market opens up in the future, we shall be there," Reddy said.

While the bio-generic drug market is growing at a stupendous 14 times faster than the traditional generics, the holy grail that everyone is searching for is the first globally patented drug to come out of an Indian company. In Dr Reddy's case, the most promising new chemical entity (NCE) is balaglitazone, which represents a completely new approach to the treatment of diabetes. This is clearly a growth area with the diabetes-affected population in India alone estimated to be over 35 million and climbing steadily each year. About four months ago, Balaglitazone went into phase III clinical trials, the final stage of testing before the company can apply to the Drug Controller General of India (DCGI) for permission to launch the drug in the market. This phase is expected to be completed in about two to three years.

Unique initiative

Balaglitazone belongs to a category of drugs that improve the effectiveness of insulin in diabetes patients, and several companies globally are racing to develop their own product from this group of chemicals. Researchers at Dr Reddy's had earlier pinned their hopes on ragaglitazone, a drug with a similar mechanism of action, but it had to be dropped at a fairly advanced stage of development because of the appearance of unacceptable side effects.

In another unique initiative, the company began clinical trials of what is called a 'polypill' that is a combination of existing drugs, which is intended for people at risk of serious heart disease, diabetes and other lifestyle ailments. The polypill comprises of aspirin, which is supposed to reduce blood clotting, statins, which are a recent addition to the cardiac physician's armoury, beta-blood and ACE-inhibitors to control blood pressure. The trials launched in the beginning of this year were supposed to be conducted by a joint panel of doctors from India and New Zealand, and was supposed to be completed by the end of 2007.

The Health Research Council of New Zealand has invested about NZ $350,000 to support the co-ordination of the trial in their country, while Dr Reddy's would incur an expenditure of NZ $7.5 million (about Rs23 crore) in developing the pill and supplying it for clinical trials all over the world. Satish Reddy however admitted that the entire programme is behind schedule by almost one year and would be completed only by early 2010. Such are the hazards of new drug development.

• SUMIT GHOSHAL