CARRY ON, DR REDDY

The good times have started to roll for the pharma major, thanks to some big generic orders, acquisitions and research breakthroughs, but sustainability is what counts

NANDITA DATTA

The positive flow of news from Dr Reddy's Laboratories refuses to ebb. Just when you thought the company would bat easy after a large acquisition in Europe (Betapharm) and a small one in Mexico plus two 'authorised generic' deals under its belt, it hits more home-runs. On October 27, the pharmaceutical major announced outstanding first-half numbers—revenue at Rs 3,408.8 crore showed a 199% jump over the corresponding period last year, while net profit at Rs 419.5 crore was up 239%. Even better, profit margins at the operational level doubled to 19%. Before that, on October 10, Dr Reddy's announced its third 'authorised generic' deal—this time with GlaxoSmithKline for Sumatriptan

MONEY IN A CAPSULE: If Dr Reddy's growth strategy works, there could be more manufacturing plants across the globe, like this one in Hyderabad

Photographs: SHOME BASU

Succinate (the generic version of Imitrex, that's prescribed for acute migraine attacks, and has sales of $890 million in the US). This was just after the company inked an agreement with ClinTec International, UK, on September 27, to jointly develop the former's anti-cancer compound, that's currently undergoing Phase II clinical trials. And the latest—on November 13, Dr Reddy's filed a shelf registration with the US Securities and Exchange Commission for a proposed American Depository Shares issue of up to 13.5 million shares. For a company that has been through some very challenging times, and in not too distant a past, this looks like payback time.

But G V Prasad, Vice-Chairman and CEO, prefers to play things down. "I don't see our current performance as a turnaround because turnarounds usually happen when you cut costs and do things differently. Fundamentally, we didn't do things any different and are on the same trajectory that we were on earlier. Yes, we did sign some deals that turned out very well for us. But other than that, we're just doing our job," he says.

Company sources say this is typical Prasad—serious, solemn and no-frills. But try speaking to the Big Man himself and you get the real mood in the company. In a telecon, Chairman Anji Reddy was in high spirits because he had heard some great news from his team of scientists at the research laboratories. "If you check my blood pressure it'll be quite high," he joked. Nobody would say if it's typical Reddy though.

Innovation-Driven Future

However, more than a happy chairman and a matter-of-fact CEO, it's the high growth and great prospects for the future that made us look into Dr Reddy's. Where is this growth coming from? "If you look at the key drivers of our performance over the last few quarters, they reflect the strength of our integrated business model," says Prasad. The core businesses of active pharmaceutical ingredients (API) and finished dosages have been growing consistently; investments in strengthening the pipeline and infrastructure for key markets have started yielding results (evident from the significant growth in Russia, turnaround in India and unlocking the generics pipeline in the US); and expansion initiatives into new markets and businesses are paying off. And what is the roadmap for the future? "In the medium term, growth will come from our global generics business, in the medium-to-long term, our innovation-driven businesses will drive growth. To begin with, it'll be specialty products—reformulating old drugs by improving efficacy—and then research-led products," says Prasad.

He is confident that the global generics business will continue to grow well for the next few years. In the first half of 2006-07, the company has notched up generic revenues of Rs 1,885 crore, up from Rs 405.6 crore in the whole of last year. Of course, a large part of this is on account of the two authorised generic launches (Simvastatin and Finasteride) and the Betapharm acquisition in Germany.

True, the two authorised generics will lose their exclusivity in December 2006, while the launch of the third (signed last month) will happen only in 2009. However, apart from the regular pipeline, there's a big opportunity in the form of Ondansetron (GlaxoSmithKline's nausea drug whose patent expires December-end), which Dr Reddy's hopes to launch by January. Dr Reddy's was the first to file generic application for

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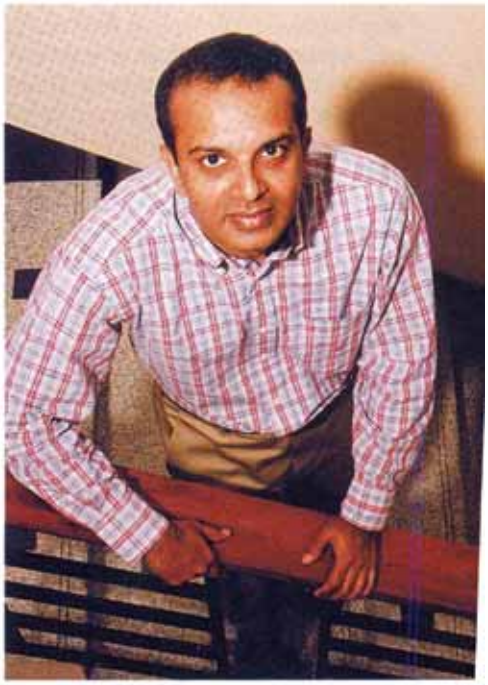
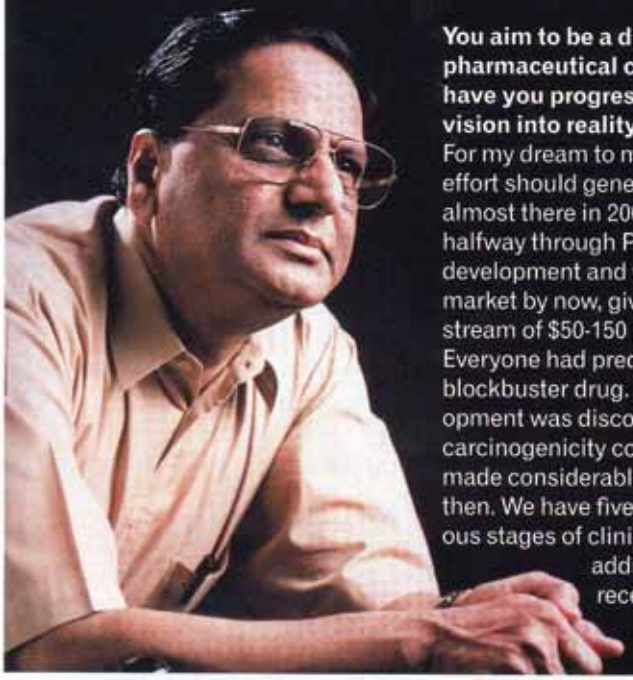
> SATISH REDDY, MANAGING DIRECTOR AND COO, DR REDDY'S



"We've many potential blockbusters"

Dr Anji Reddy, Chairman, Dr Reddy's Laboratories, is very keen to turn Dr Reddy's into a discovery-led pharmaceutical company. Unfazed by the research setbacks of a few years ago, he tells Nandita Datta, "I wouldn't have it any other way."



You aim to be a discovery-led global pharmaceutical company. How far have you progressed in turning this vision into reality?

For my dream to materialise, the R&D effort should generate money. We were almost there in 2002. Ragaglitazar was halfway through Phase III clinical development and would have hit the market by now, giving us a royalty stream of $50-150 million every year. Everyone had predicted it would be a blockbuster drug. However, the development was discontinued because of carcinogenicity concerns. But we have made considerable progress since then. We have five compounds in various stages of clinical development. In addition, six others have recently been cleared and we have been adding three new chemical entities (NCEs) to our pipeline every year at a discovery spend of $20 million per year. Come 2010, about 20 NCEs will be in various stages of clinical development. There are also many in the pipeline that can be potential blockbusters. Also, by then we will have our first NCE in the market—that will be the time when this dream will begin to take shape. The difficulties for discovery—led companies are manifold, but the rewards are also handsome. For example, in addition to Ragaglitazar-a class of drugs that was first discovered in our laboratories—three more compounds from three different companies (Merck, BMS and AstraZenecca) failed to make it to the market. Tougher safety norms are adding to the cost of development and, in this environment, adding one

this product and, hence, it expects the six-month exclusivity to fall into its lap. Another opportunity could be a possible authorised generic deal with Bristol-Myers Squibb for Plavix, a blockbuster cardiac drug with revenues in excess of $1 billion. Company officials are, however, tight-lipped about this.

Prasad believes that the key to success in the US generics business is gaining critical mass (and that for him is $200-300 million revenue excluding upsides) by building up a good product portfolio. "Today we may be there because of the upsides, but that's not how we want it," he retorts. To achieve this, he says the company will try to maximise the value of its current pipeline of 56 pending ANDAs by launching all the products on day one. "We will also look at more authorised generic opportunities and hopefully build a branded generics business in the US," notes Prasad. The latter poses a real challenge as it entails huge costs—Ranbaxy, the only other Indian company to have experimented with this idea, had abandoned it.

Dr Reddy's also wants to broadbase its presence in Europe and is eyeing Spain and Italy. And it's likely to take the acquisition route in certain markets in Europe, says Prasad who thinks attempting to grow organically in Germany would have been foolish. "In Spain, we think we can manage organically, but for Italy we're debating whether to take the acquisition route to jumpstart the business," he says. But he denies that the company is actively looking for an acquisition either in the US or Europe. "If we do want to acquire anything in the US, it'll be to jumpstart our specialty products business. And in Europe, the idea would be to expand geographically," he says.

Third World First

Global generics is only one aspect of Dr Reddy's business—a bigger share of the company's revenues actually comes from branded formulations or finished dosages (40.9% of total revenue). And, contrary to popular perception, the generics business does not command the highest margins; the credit goes to branded formulations that boast of an impressive 69% gross profit margin.

The good news is that the Indian market is beginning to look up. Satish Reddy, Managing Director and Chief Operating Officer, says, "India is

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drug once in a while will not take you anywhere. You must have a robust pipeline with sizeable numbers. I think we have already achieved this.

There was a time when things were going very wrong with Dr Reddy's, especially in R&D? But, today, it seems you're on the right track. How have you achieved this transformation?
You have to understand one thing about us—we don't want to just play safe and have a 20% targeted growth. There are companies who're doing well walking this path, but that's not us. We believe that the hallmark of an internationally respected pharmaceutical company is the strength of its product development capabilities and drug discovery pipeline. We did not react to the fall in revenue in 2004-05 and adopt a myopic and self-defeating cost cutting strategy—that of drastically reducing R&D programmes and investment. Even at that time, we maintained that the only viable way of securing higher growth and profits and reaching global scale of operations is through successful R&D. So, despite short-term market reversals, we actually raised our R&D investments. As far as the R&D setbacks are concerned, it's part of the game and you have to live with it. If Ragaglitazar had happened, it would have changed the face of Dr Reddy's. It didn't, but that one failure didn't stop us. We moved on and built a new pipeline, which is the envy of anybody today.

Last year, you addressed one big concern—that of high costs and risks associated with new drug development—by partnering with the venture capital arms of ICICI and Citibank. Is that one of the reasons why you are so bullish about this discovery-led journey?
As I mentioned before, we have kept the discovery-led research at $20 million. At that spend we are able to add three compounds into our pipeline every year, which is something very unique because if you see some of the big companies with $5-billion R&D budgets, they turn out about seven or eight (compounds). It's not the billions that'll bring about a big discovery, it's the leadership and passion. Every one of our 300 scientists is very passionate about research. That's what helps in drug discovery.

So when will we see the first drug from your lab hitting the market?
I would say, pragmatically, by 2010 we should have our first drug in the market. We are pretty optimistic that we will get there. Once we have a drug in the market, the whole equation will change. This image that we have—of being a generics company—will give way to us being termed as a discovery-led company. Eventually, say, 15 years down the line, if we truly become a discovery-led company, we may also look at hiving of our generics business into another company.

beginning to see good traction, growing at 15% per annum, and the reason is more brand development. Over the last few years, Indian companies launched a host of products without bothering to build the brand and this impacted pricing and growth. Now that the patent law is in place and the number of launches has come down, companies are looking at sprucing up their portfolio through better marketing." He says his company has consolidated the flagship brands by adding new lines to address the requirements of all sub-groups of patients. The sales force has also been re-organised by adding new divisions to create greater customer focus. "As a result of these initiatives, products that were launched in the last three years now contribute about 13% to our total revenue," says he. Apart from strengthening the existing portfolio, he says the company will also explore in-licensing deals to grow above industry average.

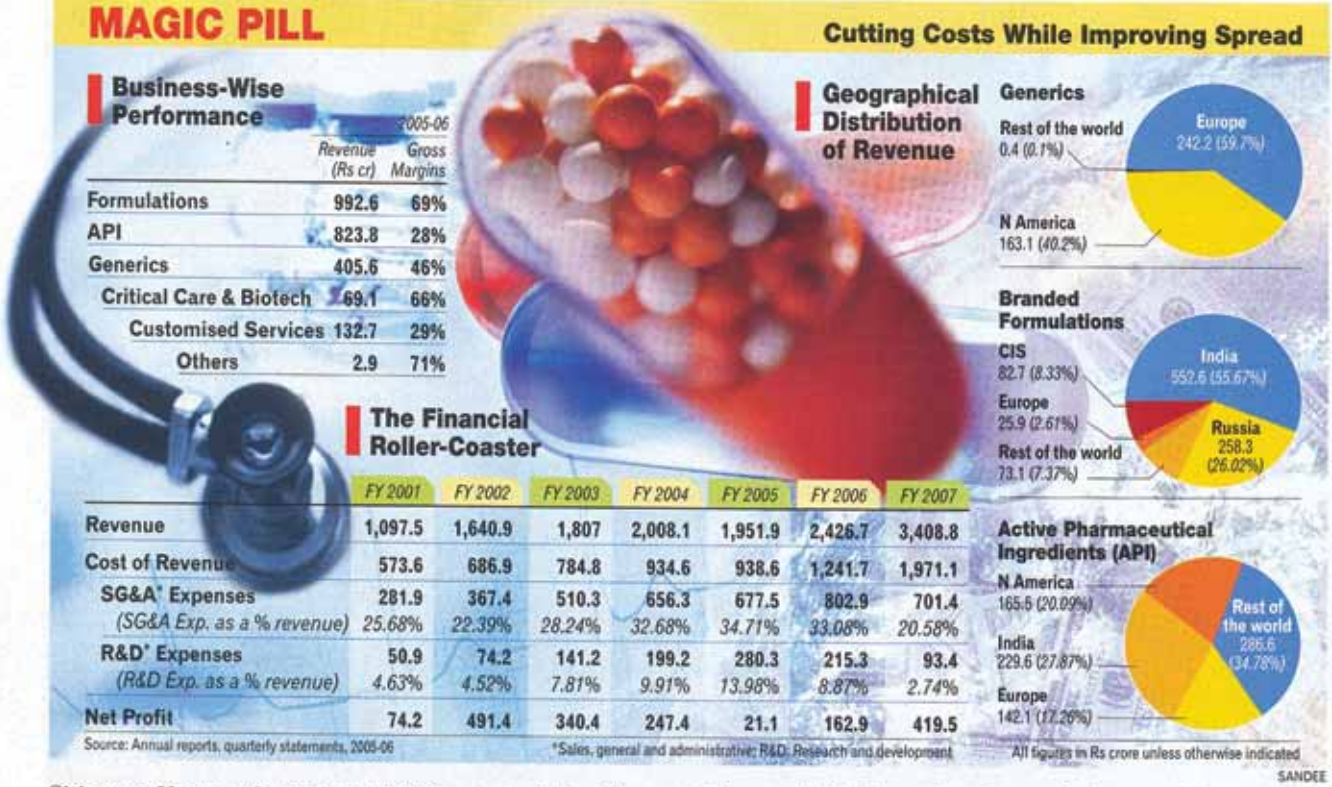
Meanwhile, the Russian dream continues full throttle for Dr Reddy's. "We were among the first to enter the prescription market in Russia and have over the years managed a solid brand positioning, good distribution capabilities and a strong product pipeline. Today, when the market is booming, we will obviously profit from it," says Reddy, adding that a 25-30% growth is possible even on a high base. Dr Reddy's is also eyeing growth opportunities in new markets. Latin America—with two big markets, Brazil and Mexico—appears attractive. "They are not commoditised," explains Reddy. While entry strategies are being planned for Mexico, Dr Reddy's is also planning to increase therapeutic coverage in Brazil and scale up CIS operations to leverage its pipeline developed for Russia. Its presence in South Africa will be enhanced by leveraging the generic pipeline developed for the US and Europe. Dr Reddy's has a pipeline of over 81 cumulative drug master filings (or DMF) in the US, 42 in Europe and 28 in Canada. With a number of patent expiries coming up in these markets over the next few years, the API business' growth path is well laid out.

R&D On A High

But the one aspect that has transformed Dr Reddy's over the last one year is its research and development initiatives. To de-risk its business model, Dr Reddy's teamed up with

MAGIC PILL

Cutting Costs While Improving Spread



Business-Wise Performance

	2005-06 Revenue (Rs cr)	2005-06 Gross Margins
Formulations	992.6	69%
API	823.8	28%
Generics	405.6	46%
Critical Care & Biotech	69.1	66%
Customised Services	132.7	29%
Others	2.9	71%

Geographical Distribution of Revenue

The Financial Roller-Coaster

	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Revenue	1,097.5	1,640.9	1,807	2,008.1	1,951.9	2,426.7	3,408.8
Cost of Revenue	573.6	686.9	784.8	934.6	938.6	1,241.7	1,971.1
SG&A* Expenses	281.9	367.4	510.3	656.3	677.5	802.9	701.4
(SG&A Exp. as a % revenue)	*25.68%*	*22.39%*	*28.24%*	*32.68%*	*34.71%*	*33.08%*	*20.58%*
R&D* Expenses	50.9	74.2	141.2	199.2	280.3	215.3	93.4
(R&D Exp. as a % revenue)	*4.63%*	*4.52%*	*7.81%*	*9.91%*	*13.96%*	*8.87%*	*2.74%*
Net Profit	74.2	491.4	340.4	247.4	21.1	162.9	419.5

Source: Annual reports, quarterly statements, 2005-06

*Sales, general and administrative; R&D: Research and development

Active Pharmaceutical Ingredients (API)

All figures in Rs crore unless otherwise indicated

SANDEE

Citigroup Venture Capital and ICICI Venture Funds to form a drug development company, Perlecan Pharma, with an equity capital of $52.5 million ($22.5 million contributed by each of the two VC firms and $7.5 million by Dr Reddy's Laboratories). Perlecan would undertake the task of developing and commercialising four new chemical entities (or NCEs) and, in return, all the rights and titles were transferred to it. The idea was simple. Fast-track the development of these drugs to Phase IIa and then seek out-licensing, co-development or joint commercialisation opportunities. Another financial deal was inked with ICICI Venture under which the latter agreed to fund the development, registration and legal costs of commercialising abbreviated new drug applications (or ANDAs), necessary to market generic drugs in the US, during 2004-05 and 2005-06. In return, Dr Reddy's would pay a royalty once these were commercialised.

As a result of these two deals, the company's R&D expenses as a percentage of revenue dropped to 3% in the first half of 2006-07 from 9% in 2005-06 and 14% in the year before.

And the labs are doing well. With nine NCEs in various stages of clinical studies, Dr Reddy's research pipeline will be the envy of any Indian company. Company officials are optimistic about the most advanced one—DRF 2593, also called Balaglitazone. This has completed Phase II clinical trials and data from the carcinogenicity studies have been positive. And so expectations are rife that it will enter Phase III trials soon. This NCE is being jointly developed by Rheoscience, Denmark, which will take care of all the costs associated with the Phase III trials. Dr Reddy's would pay its share of the cost to the Danish company in return for full rights over North America, Japan and the rest of the world excluding Europe. While it's still premature to talk about the likelihood of this product coming into the market, there is no denying that this one compound has the potential to change the face of Dr Reddy's. Just three years ago, its anti-diabetes compound Ragaglitazar, had entered Clinical Phase III, but was dropped and trials suspended after tumours were found in long-term animal studies.

With nine NCEs in various stages of clinical studies, Dr Reddy's research pipeline looks robust

Now the big question. Where does Dr Reddy's Laboratories go from here? Will $1 billion be the next revenue milestone? "We will cross that this year itself," says Prasad. But he's quick to add, "We are not looking at any $2 billion or $3 billion revenue milestone. We have some qualitative goals—to build critical mass for our generics business in the US and Europe, expand our branded formulations business into new geographies, take our first product from discovery research into global launch as early as possible and launch a branded business in the US. And we are working towards these goals, numbers are secondary." And that says it all! ❑