





# Rediscovering DRL

The miraculous properties of turmeric notwithstanding, who would have imagined the son of a turmeric farmer from Andhra Pradesh would one day become the doyen of the Indian pharma industry?

Anji Reddy, the founder of Dr Reddy's Laboratories (DRL), was not only one of the most respected drug makers in the country, he was instrumental in establishing India firmly on the global generics map and making medicines affordable to a vast majority.

But what set him apart from the rest of Indian big pharma was his belief that Indian drug manufacturers could better their reputations, from being mere copycats to ones that focused on innovation and drug discovery. And Anji Reddy walked the talk, kicking off drug discovery as early as 1993 and becoming the first company to out-license a molecule to an innovator company. Unfortunately, the failure of Balaglitazone (named after Lord Balaji), which was also the first lead molecule to come out of DRL's drug discovery, compelled the visionary leader to change course forever. He realised the hard way that building a researchfocused company was beyond the scope of a company its size. Now, drug discovery is no longer DRL's main mission, but research continues to be an area of priority: though insignificant compared with overall sales, at ₹790

crore, the company's R&D spend is still the largest in Indian pharma.

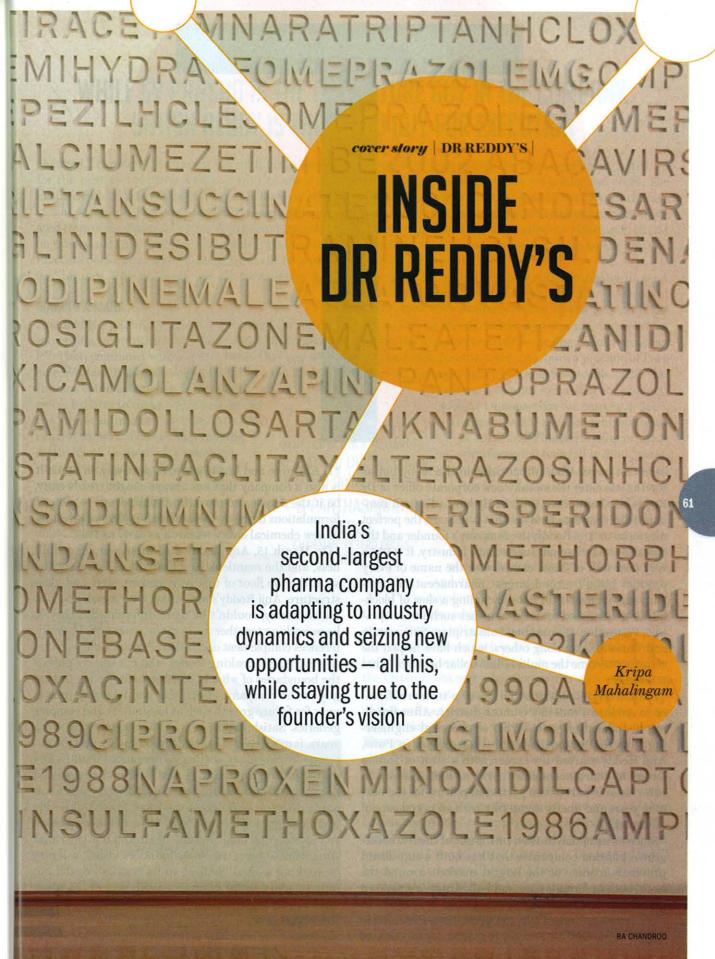
As Anji Reddy's legacy passes to his son-inlaw, GV Prasad, and son, Satish Reddy, the company is re-inventing each of its businesses to adapt to the changing pharma landscape. DRL is bringing stability to its revenue, while continuing to invest in future areas of growth such as biosimilars and complex generics. Associate Editor Kripa Mahalingam takes a look at whether the new game plan will work. Turn to page 60 for more.

But the bigger question is whether DRL will go down the road taken by promoters of other Indian pharma companies, and sell out. For some time now, the promoters have been holding 25% stake in the company with no visible inclination to hike it any further. While Anji Reddy always wanted his company to have a history like that of the 640-year-old Merck, whether that will indeed be the case, only time will tell.

N MAHALAKSHMI

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here's no larger-than-life portrait in the lobby but as soon as you enter the swanky new corporate office of Dr Reddy's Laboratories (DRL) in Hyderabad's posh Banjara Hills, your eyes land on what is perhaps the perfect memorial to Anji Reddy, the company's founder and the doyen of the Indian pharmaceutical industry. It is DRL's very own wall of fame, etched with the name of every product India's second-largest pharmaceutical company has launched till date, including a slew of blockbuster generic and branded launches such as Omeprazole, Fluoxetine, Olanzapine, Sumatriptan, Simvastatin and Finasteride, among others, which have helped the company become the multi-billion dollar behemoth that it is today.

Kallam Anji Reddy was the son of a turmeric farmer in Andhra Pradesh's Guntur district. After finishing his education with a PhD in chemical engineering from the National Chemical Laboratory in Pune, Anji Reddy started his career with a stint at Indian Drugs & Pharmaceuticals (IDPL) in 1969. He quit in 1975, became part of two partnership firms for the next nine years and finally set up DRL with an initial capital of ₹25 lakh.

Since its inception in 1984, DRL is one of the few homegrown pharma companies that has built a significant presence in some of the largest markets around the world both in formulations and bulk drugs (also known as active pharmaceutical ingredients, or API). Over the past decade, revenues and net profit have grown from ₹1,933 crore and ₹251 crore, respectively, in FY04, to

₹11,626 crore and ₹1,545 crore, respectively, in FY 13. It is also a company that has always caught trends early, be it the decision to move from bulk drugs to generic formulations in the overseas market in 1990 or investing in new chemical entity research as early as 1993.

On March 15, Anji Reddy died after a prolonged illness, and the mantle passed formally to two men who sit at the top floor of this very modern, steel-and-glass structure. Anji Reddy's son-in-law, GV Prasad, and son, Satish Reddy, couldn't be more different. But they've been working together for so many years now, their differences complement each other. Prasad is the more reserved, plain-speaking leader who constantly pushes the boundaries of what is possible; he is the big picture guy in the company, identifying and investing in avenues for future growth such as biosimilars and complex generics. Satish Reddy, who at 46 is younger by seven years, is more open, a quick decision-maker and the goto guy for execution, scaling up operations in DRL's key markets. Over the years, Prasad, who is chairman and CEO of DRL, and Satish, the vice-chairman and managing director, have learnt the ropes from Anji Reddy and shaping DRL's future based on its founder's passion to innovate and take on challenges. And it is clear that DRL, while staying true to its founder's vision, will now be making several changes to its business model not only to adapt to the changing landscape of the pharmaceutical industry but also seize upcoming opportunities across geographies and products. "The fundamental DNA of the company is to innovate, and that hasn't

# WHILE GV PRASAD IS THE BIG PICTURE GUY IN THE COMPANY, SATISH REDDY IS THE GO-TO GUY FOR EXECUTION

changed," declares GV Prasad. "Growth is the agenda for the next two to three years. I want to see a shift in the depth of innovation in all our businesses, which means our product pipeline should be clearly differentiated from competition." Putting Europe and India back on track is also high on the DRL agenda. "Making these markets perform as well as the others will be a priority," he adds. Will DRL's new growth formulation work?

**MAKING A MARK** 

Anji Reddy's guiding principle for business was to start something where others felt "there was a battle to tackle". That, combined with his firm belief that any medicine Western pharma companies could produce, Indians could produce at better quality and price, led him to make DRL's first API for the overseas market in 1986. At the time, IDPL was about to stop making methyldopa because of a manufacturing glitch — and what IDPL was wary of producing, no one in India would touch. Anji Reddy promptly decided to start making methyl-

dopa, telling the then-managing di-

rector MP Chari that if the IDPL equipment lasted for six months, they would make it work for two years. The gamble paid off and DRL went on to the become the biggest supplier of methyldopa to German pharma major Merck. The following year, after its plants got USFDA approval, it began supplying ibuprofen to the US, and DRL was in business.

In 2001, DRL was the first Indian company to get a 180-day marketing exclusivity for anti-depressant Fluoxetine. The company raked in \$56 million (₹258 crore) during the six-month period; more importantly, it was the first step towards becoming a global generics player. In the coming years, DRL built a pipeline of Para

IVs (patent challenges) and first-to-file (FTF) status, giving it 180-day exclusivity for products such as Ondansetron for nausea in 2006,

Olanzapine (20 mg) for schizophrenia in 2011, and Finasteride for prostate problems and hair fall in 2013, bringing in more than ₹1,000 crore as revenue. It was also the first generic company across the world to become an 'authorised generic supplier', where it could market the drug partnering with the innovator company without risk of litigation. Between 2006 and 2008, DRL was the authorised gener-

ic supplier for Merck's Zocar and Proscar and Glaxo's Imitrix, which earned the company over ₹2,000 crore. "Dr Reddy's was one of the few companies to be successful overseas both in API and formulation. Everybody was talking conceptually about how you can sell in the US but it was only when companies such as Ranbaxy and DRL executed their US strategy that smaller companies such as ours felt confident about our foray," says Rajeev Nannapaneni, vice-chairman and CEO, Natco Pharma. The Hyderabad-based company currently supplies DRL oncology drugs in the Indian market.

Certainly, DRL's success served as inspiration for others to start on their own. B Parthasaradhi Reddy, the chairman of the Hetero Drugs group, is very proud that he was one of the first employees at Dr Reddy's Laboratories (DRL). "I began my career under Anji Reddy and everything I learnt in this business is because of him," he says. Parthasaradhi first worked with Anji Reddy at Uniloids in 1979 as a research trainee and moved to head research at DRL in 1984 after a brief stint at another Anji Reddy company, Standard Organics. "Back in 1984, he would talk about how DRL would become a

Anji Reddy was a visionary. Back in 1984, he spoke of DRL becoming a billion-dollar company

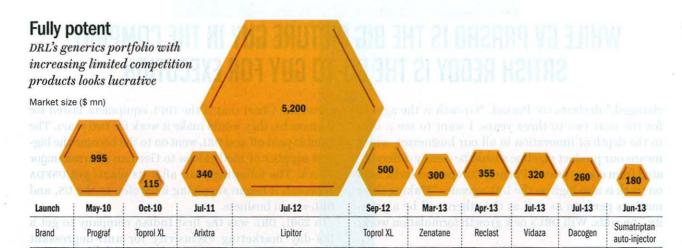
-B PARTHASARADHI REDDY

CHAIRMAN, HETERO DRUGS GROUP



RA CHANDROO

Generic



Atorvastatin

Source: Analyst reports

Decitabine

multi-billion dollar company — at a time when ₹100 crore of revenue was considered huge. That was the kind of visionary he was." Parthasaradhi left DRL in 1993 to set up his own pharma company but his connect with the company remained strong. "I continued to watch and learn even from the outside."

Tacrolimus : Lansoprazole Rx : Fondaparinux

He is one of several pharma company promoters who have been inspired to entrepreneurship thanks to DRL — Aurobindo Pharma's Ram Prasad Reddy, Divi Lab's Murali K Divi and Raghvendra Rao of Orchid Pharma all either worked with Anji Reddy or struck out on their own after seeing his track record.

### **EXCLUSIVE GENERICS**

If Anji Reddy was the quintessential risk-taker, Prasad is credited with driving the core operations of the company, transforming DRL from a mid-sized pharma company to a global player. And Satish excels at execution, spearheading the company's move over the past several years from being API-focused to becoming a branded formulations player.

As a result, while global generics continue to be DRL's mainstay, contributing 71% of overall revenues, what has changed is the company's focus. Over the past four years, the business has grown nearly three-fold to \$738 million, driven by key product launches such as Fondaparinux, Sumatriptan, Atorvastatin, Tacrolimus and Olanzapine. "A large part of our portfolio was dependent on Para IVs and FTFs. We have not given that

All their [DRL's]
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use of capital rather than
chasing scale

Metoprolol XL

Isotretinoin

—PRASHANT NAIR DEPUTY HEAD OF RESEARCH, CITI INDIA up, but our priorities have changed: we are focusing now on limited competition products where we have some advantage on technology," points out Satish Reddy.

Limited competition products are

generics that could be off-patent

Zoledronic acid : Azacitidine

but are complicated, with a higher technological component; they are either in niche therapeutic areas or delivered differently in, say, topical or injectable forms. Currently, DRL has a pipeline of 200 ANDAS (abbreviated new drug application, an application for introducing a generic version of a branded drug that is coming off patent in the US). According to Prashant Nair, deputy head of research, Citi India, about a third of the company's future ANDA filings are for products with a high technology threshold, where competition could be limited. "This should help the company differentiate itself in the US pharma mar-

There will also be a cost advantage: unlike in Anji Reddy's time, the core generics business is witnessing cut-throat competition and price erosion after the exclusivity period is as high as 90-95% in some products.

In complex generics, limited competition means price erosion is only about 30-35%. At DRL, revenue from limited competition products is expected to increase from \$238 million (₹1,428 crore) in FY13 to \$438 million (₹2,628 crore) over the next two years, driven by the generic launches of Reclast,

driven by the generic launches of Reclast, Zometa, Dacogen as well as Vidaza (see: Fully potent).

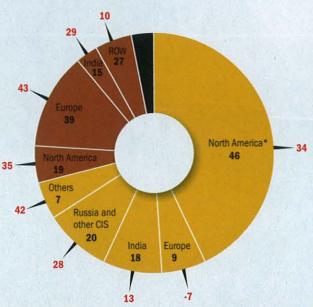
ket," he adds.

## No cold war here

The US and Russia are DRL's blockbuster markets

#### Segment-wise revenue breakup in %

71/24 Global generics\* 26/29 Pharmaceuticals and Active Ingredients 3/12 Proprietary products & others



\*Excluding one-off opportunities

Source: Company, Kotak Securities

What is DRL's strategy for moving beyond plain vanilla generics? It is first focusing on building capabilities. "We are aggressively looking for opportunities to acquire capabilities in limited competition products," says Satish Reddy, pointing to the Octoplus acquisition as a case in point. "You will see more such moves that will shorten the time in developing our capabilities," he adds. In October 2012, DRL paid €27.4 million to acquire the Netherlands-based Octoplus to augment its focus in the injectables segment. The injectables market is valued at \$2.8 billion, and some of DRL's filings in this segment include the \$2.9-billion multiple sclerosis drug Copaxone and \$500-million anticoagulant Angiomax. Generic versions of both drugs are expected in mid-2015 and the prospects are attractive since no other company has filed to offer a generic version.

#### FOR RUSSIA, WITH LOVE

Another important part of the company's growth engine are the emerging markets. DRL's focus on emerging markets isn't a new move for the company - while the company is present in countries such as South Africa, Venezuela, Australia, New Zealand, Vietnam, Myanmar and Sri Lanka, Anji Reddy had a soft spot for Russia. He said the former USSR had helped the Indian pharma industry considerably in its early stages: when he was with IDPL, there was much technology transfer from Russia to develop medicines here and make healthcare affordable. DRL's founder felt the burden of debt and in 1998, demonstrated his commitment to Russia by staying put even through the rouble crisis.

Like Anji Reddy, Prasad and Satish pay extra attention to Russia and it returns the interest. In FY13, Russia contributed ₹1,400 crore to DRL's topline and since 2009, the market has grown steadily at an average 20%, driven by its major brands in the prescription segment and the impressive growth of some of its new brands in the OTC portfolio, whose contribution has increased from 13% to 34% of overall sales (see: No cold war here). "Dr Reddy's was able to anticipate that the brands in the prescription segment are likely to see pricing pressure from the [Russian] government, which is now telling doctors to prescribe generic products. So, they decided to scale the OTC business," points out Hemant Bakhru, analyst at CLSA.

Now, the dynamics of the Russian market are changing. While the mandate to prescribe generic drugs



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instead of brands products wherever substitutes are available is a positive for DRL, there is also an import substitution bill in the offing, which if passed, will require foreign generic and innovator companies to have a manufacturing presence in Russia. "We are watching how the situation evolves," says Prasad, adding that the company is willing to invest in local manufacturing facilities if required. In addition, DRL is also looking to not only acquire brands to augment its product portfolio but also make in-licensing deals such as the one with Cipla where it has marketing exclusivity for some Cipla OTC brands in Russia and Ukraine.

Meanwhile, another deal, with GlaxoS-mithKline Pharma in 2009, is expected to drive emerging market revenue in the next three to four years. Already, revenue from other emerging markets has grown nearly three times from over ₹195 crore in FY09 to ₹553 crore in FY13. The GSK Pharma deal covers 100 products and intends to tap emerging markets stretching

from Asia Pacific to Latin America. Products will be made by DRL and licensed to GSK, which will file registrations and distribute them either singly or with DRL in the chosen markets. India isn't part of the deal. But then, India is a whole 'nother story in any case.

### A PASSAGE TO INDIA

Despite its success in the US and other markets, or perhaps because of it (at least, to some extent), DRL is still not a big player in India. Ironically, the country's second-largest pharma company isn't in the top 10

in the domestic pharma market. "We have lagged behind in our performance in the domestic market," agrees Prasad. "We have done a number of things to fix

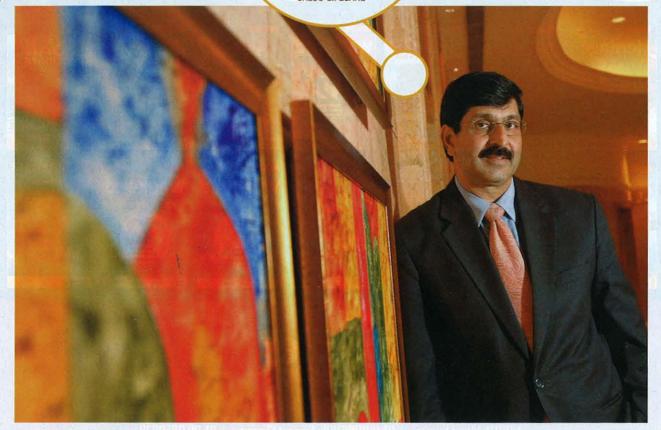
that and have come back to industryplus growth rates, but that is still not adequate."

It's understandable why Dr Reddy's wanted to focus on the US market — it made sense to focus on scaling up operations in the world's largest

No one is aunching novel pro

launching novel products in the domestic industry and Dr Reddy's can fill that gap in the market

> -KEWAL HANDA FOUNDER, SALUS LIFECARE



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## DRL OVER THE YEARS

**1984:** Anji Reddy quits state-owned Indian Drugs & Pharmaceuticals (IDPL) to start DRL with ₹25 lakh corpus

finally had to write

1986: DRL goes public and enters international markets with methyldopa exports after IDPL stops producing drug owing to technical reasons

1987: Becomes first Indian company to make its plant USFDA compliant, thus marking DRL's foray into the world of generics

**1991:** Among early Indian companies to enter Russia, but opts for private pharmacies rather than traditional government route

1997: Licenses anti-diabetic molecule (Balaglitazone) to Novo Nordisk, validating Anji's belief that research is the future of pharma

**1999:** Acquisition of American Remedies catapults DRL as the 5th largest Indian pharma company

2001: First Asia-Pacific (ex-Japan) entity to list on NYSE, helping DRL not just raise money but also improve transparency. Wins first patent challenge with 180-day marketing exclusivity for generic drug (Fluoxetine 40 mg) in the US, giving DRL confidence to build first-to-file pipeline and ushers in an era of patent challenges

2005: Acquisition of Roche's API business in Mexico helps DRL turn suppliers to innovators, a difficult market to crack until then

**2006:** Crosses \$1 billion in revenues with the acquisition of Betapharm in Germany, but change in regulations make acquisition unviable

**2007:** DRL sees biosimilars as a growth area, launches Reditux (Rituximab), the world's first monoclonal antibody biosimilar. Reditux goes on to be a market leader in its segment

**2008:** Post setback in research, DRL decides to acquire technology platforms to strengthen R&D capabilities. Acquires Dow Pharma's small molecules business in the UK

**2009:** Strategic alliance with GSK for 100 products in emerging markets validates strength of product portfolio and manufacturing capabilities

**2011:** Achieves critical size as revenues cross \$2 billion, helping DRL take larger bets in product development

**2012:** Strengthens capabilities in injectables and biosimilars through acquisitions and builds an impressive product portfolio in each of its businesses following a deal with Merck Serono and acquisition of Octoplus

generics market. But there's no denying that the decision took attention away from the home market. Also, DRL gets a large chunk of its revenue from acute therapies, which aren't growing as fast in India as chronic drugs. And, unlike companies such as Sun Pharma and Cipla, which flooded the market with several new products, DRL has focused on a few selected brands. For sure, that turned some of its products such as Omez, Nise and Ciprolet into market leaders, but the limited portfolio meant it lagged in market share.

Now, Satish and Prasad are working to correct that. In the past four years, the sales force has been beefed up by over 50% to 4,600 and marketing has been expanded to rural areas. DRL has also focused on new product launches and line extensions of its key brands on gastro-intestinal, cardiovascular, pain management and oncology therapies, which account for 60% of its revenues. That has helped the company grow in line with the market average of 14% between FY09 and FY13 (after hitting a low of 5% in 2009), but the path ahead remains challenging. "It will be an uphill task for Dr Reddy's to get ahead of its peers in the Indian market. It takes time to scale up individual brands because you need to gain ac-

# UNLIKE COMPANIES SUCH AS CIPLA AND SUN PHARMA, DRL HAS FOCUSED ON A FEW BRANDS

ceptance from the medical community, which happens only gradually. India is not like the US where you can launch a blockbuster generic and gain significant market share overnight," points out CLSA's Bakhru.

As with other markets and its strategy for specialised generics, here, too, DRL is considering acquisitions — individual brands as well as entire portfolios — as a way to rapidly gain scale and market share. "The market has no room for so many players. The entry of MNCs has raised the expectations of valuations, but at some point of time, consolidation will happen. Increasingly, smaller players will find it difficult to keep up as costs are going up and they don't have a large portfolio. We are waiting for valuations to reach reasonable levels," says Satish Reddy. Recently, DRL walked away from the Mumbai-based Elder Pharmaceuticals since it felt the bids for the debt-ridden company were too high.

#### BANKING ON BIOSIMILARS

Acquisitions aside, what may help drive growth in India over the long term is DRL's biosimilars business. Biosimilars are generic equivalents of biotech drugs, such as insulin, growth hormones etc. In 2007, DRL launched Reditux in India, the first biosimilar monoclonal antibody

(which makes it easier for the immune system to find

Globally, the biosimilars market is ex-

pected to cross \$4-6 billion by 2016 from

 the cost is pegged at \$100-200 million, with 70% going towards clinical development. "While product launches in biosimilars in the developed market is still some time away, DRL will have the first mover's advantage among Indian companies, given the investment the company has already made and the high entry barriers in the business as it takes time to develop capabilities," says Krishna Prasad, analyst at Kotak Institutional Equities. In the past five years, the company has invested over ₹3,600 crore to increase ca-

though, it packed up operations in more than 30 markets. "We were in so many markets that it created complexity in operations. Instead, we streamlined our operations so there would be more predictability in revenues rather than be present in many countries," says Satish Reddy.

Then there's the Betapharm acquisition. In 2006, DRL paid \$560 million for the German generic drug maker, the largest buyout by an Indian pharma company. It seemed like a good idea at the time: Germany was the second-largest generics market after the US. But things unravelled soon after, when the German government allowed procuring of generics through ten-

ders; health insurers began procuring medicines from vendors with the lowest bids,

> leading to massive price erosion. DRL finally had to write off nearly half its investment; it brought down the workforce from 400 to 80 people and transferred the manufacturing to India. Despite it not being the highest bidder, DRL walked away with the deal that took 85 days to clinch because the promoters of Betapharm felt the business fit between both com-

panies would be better. While it did seem the deal put DRL ahead of its peers in Germany, there were concerns even at the time that it was too expensive. "There was a fair bit of aggressive bidding by all the companies in the fray, including Ranbaxy, Teva, Sandoz, Wockhardt and Nicholas Piramal. I think Dr Reddy's did get carried away because the deal also brought it closer to its \$1 billion revenue target for 2008," says an analyst on condition of anonymity.

Now, looking back, Satish Reddy admits, "Germany didn't work out the way we wanted. Now, our focus is shifting from the tender business to specialty products but you have to give it some time before we get our act together. Our European strategy is still evolving because the market itself is changing."

> While Betapharm was a failed buy, it did bring some valuable lessons. First, the acquisition made Prasad and Satish Reddy realise that chasing scale is not always a successful strategy. "Today, we are acquiring smaller companies that add to our capabilities. We are not acquiring for scale," confirms Prasad. The Octoplus buy is a perfect example of the changed focus, as is the 2008 acquisition of Dow Pharma's small molecules business in the UK and 2011's buy of GSK's penicillin facility in the US. While

We will see India emerge as a strong contender on the innovation side once it establishes its foothold in the

> **GLENN SALDAHNA** MD. GLENMARK

generics world



## AFTER THE BETAPHARM EXPERIENCE, DRL IS NOT SEEKING SCALE, BUT IS INSTEAD LOOKING AT STRATEGIC CAPABILITY FITS

Dow Pharma augmented DRL's manufacturing and research capabilities in its custom pharmaceutical services business, the GSK business resulted in additional revenues through brands such as Augmentin and Amoxil. "All their strategic decisions have been centred on optimal use of capital rather than chasing scale," says Nair of Citi.

#### SPOTLIGHT ON RESEARCH

Another change at DRL is its changed focus on research. Back in 1993-94, Anji Reddy started a research arm at DRL, the first Indian company to do so. It was also the first company to out-license a molecule, Balaglitazone, to Novo Nordisk in 1997. The molecule is named after Balaji, the presiding deity at Tirupati. But, interestingly, it wasn't Anji Reddy's first choice, who wanted to name it Venglitazone after Lord Venkateswara, the

more formal name of Balaji. But the World Health Organisation rejected it since it would clash with another molecule, Englitazone.

In 1998, DRL out-licensed another diabetes molecule, Ragaglitazar, to Novo Nordisk and a third molecule to Novartis Pharma in 2001 for \$55 million. But all of them were eventually discontinued as the results from clinical trials were unsatisfactory. "Getting a new molecule to market is a huge challenge. More than 90% of molecules that enter trials fail because the human body is never fully understood. Research is a difficult game because you need deep pockets and deep understanding of the science," says Prasad.

Glenn Saldahna, managing director of another Indian pharma company Glenmark, agrees with Prasad. "It took even Japan a couple of decades to become a destination for innovation. The momentum is building and





CUTTING EDGE: DRL's buyout of Dow Pharma's small molecules business has beefed up its research capabilities

we will see India emerge as a strong contender even on the innovation side after establishing its foothold in the generics world," he says optimistically. Glenmark, too, has out-licensed three molecules and already raked in over \$200 million as a result.

What is the big change at DRL when it comes to research? It is focusing on areas where the risk is lower and the translation from lab to commercial products is higher. When DRL started research in 1993, it chose diabetes and cardiovascular therapy as its areas of focus, given that India has the largest diabetic population in the world. But, given the huge costs and low success of its clinical trials, it has moved away from those two areas, into anti-infectives, pain management and dermatology. In addition, the company is now also looking at incremental innovation, which means taking an existing molecule and changing the way it is delivered. It currently has 21 proprietary products in the pipeline, of which six are in clinical development in the areas of pain management, psoriasis and migraine.

At the same time, DRL is also spending more on research than ever before. In FY13, the company invested ₹790 crore on R&D, 34% more than the ₹591 crore it

spent the previous year. That's also a lot more than other Indian pharma companies. In FY13, Ranbaxy spent ₹450 crore, Sun ₹676 crore and Lupin, ₹710 crore. "Since we have achieved considerable scale in revenues, we are able to take larger bets on research," says Prasad.

Certainly, the numbers at DRL are looking good. Revenues grew from ₹6,944 crore in FY09 to ₹11,626 crore in FY13 and operating margins (excluding FTF sales) saw an impressive improvement from 16% to 20.3% over the same period, thanks to increasing contribution of complex generic products. Analysts expect revenues to increase to ₹17,479 crore in FY16, with operating margins climbing further to 22.5%. As a consequence, net profit should rise from ₹1,545 crore last year to ₹2,670 crore in FY16. While the business continues on the growth path, Anji Reddy's successors haven't forgotten his dream. "He was really driven by challenges and things done for the first time. Drug discovery was his passion — he wanted DRL to be the first Indian company to take a molecule from lab to global launch," says Prasad. "In his last months, he used to call this his 'unfinished agenda'." If Prasad and Satish Reddy manage to fulfil that dream, it will be a fitting tribute.