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Rethinking R&D

07 May 2008 | News

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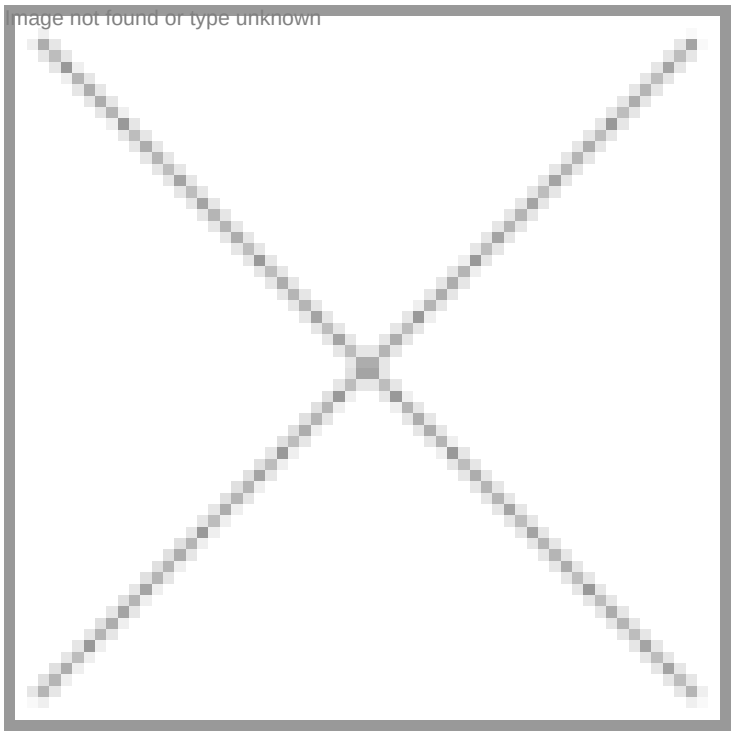

Rethinking R&D

R&D in Indian biotech is poised for a big leap. With more and more companies shifting focus from generics to new drug discovery research, innovation seems to be the buzz word driving the industry, with key players hiving off their R&D units to further research.

Sun Pharma, Nicholas Piramal and Ranbaxy belong to a new league of companies, who have spun off their R&D units into separate entities, thus setting the trend for others to follow suit. However, Hyderabad-based Dr Reddy's Laboratories recognized the need for new drug discovery and development over the next decade as early as 2005. It established Perlecan Pharma, India's first integrated drug development company along with Citigroup Venture and ICICI Venture.

Why hive off?

Glenmark demerges generics business into a separate entity

With companies living off their R&D arms, Glenmark Pharmaceuticals Ltd (Glenmark), recently implemented the reorganisation of its business into specialty and generics, thus transferring its generics and Active Pharmaceutical Ingredients business to a subsidiary, Glenmark Generics Limited (GGL). The process began in Q3 FY 2007-08. GGL will undertake the development, manufacture and distribution of generic formulation and API businesses. The parent company, Glenmark Pharmaceuticals Ltd will continue to directly manage the novel R&D, biologics and branded formulation businesses of the Glenmark group including India, Brazil, Rest of Latin America (excluding Argentina), Russia/CIS, Africa and Asia.

Dr Reddy's - Advancement of NCE assets

For Dr Reddy's, one of the earliest companies to recognize the importance of research, the formation of Perlecan Pharma was an innovative financial agreement, primarily a derisking strategy given the unpredictability of novel research and the large financial commitments involved therein. "Being the first Indian pharma company to bet big on NCE research, Dr Reddy's has always believed in the success of NCE research to establish a sustainable, growth oriented business. Perlecan Pharma provided Dr Reddy's drug discovery program, a model to rapidly advance its existing as well as future NCE assets through phase II trials and seek out-licensing, co-development or joint commercialization opportunities thereby enhancing the value of the pipeline," a spokesperson from Dr Reddy's was quoted as saying.

Sun Pharma - Promote growth of both generics and drug discovery by separation

Mumbai-based Sun Pharmaceutical Industries soon followed suit by demerging its R&D operations, including new drug delivery systems, into a new company called Sun Pharma Advanced Research Company (SPARC). The demerger was approved by the Board in February 2006 while the transfer of business happened from March 1, 2007. The difference between generic development, engineering and innovative R&D in terms of risk profile, longer timeframes and considerably large resource requirements in the future was the principal reason for the demerger. "The rationale for the demerger was to promote growth in the innovative and generic businesses, because they have inherently different characteristics. Drug discovery, both new molecules and drug delivery systems, is a high risk-high return proposition, and the challenges-resources, certain time to market and likelihood of a product ever coming to market are very different from those for a generic business, Dilip Shanghvi, CMD, Sun Pharma, said. "The generic business has a defined timeframe, uses known and established skill sets and has certainty of reaching market. The idea was to offer both the businesses the kind of environment that would be most conducive to growth," he added.

Nicholas Piramal - Strengthen research on NCEs

In August 2007, the board of directors of Nicholas Piramal India Limited (NPIL) approved the proposal to demerge its New Chemical Entity (NCE) research unit into a separate company. This was done in order to strengthen research on the NCE front on which it started work since 2002. The company which expected to have eight compounds in clinical trials by end of its 07-08 financial year, also wanted to minimize the increased spend as clinical development costs constitute about 2/3rd of the total R&D cost of a drug. Hence, it wanted to complete development up to proof-of-concept (end of phase II) for all its pipeline compounds and bring to market certain niche compounds on its own. The company expects to list the demerged entity by May-June 2008.

Wockhardt - Focus on R&D business

In January this year, pharma major Wockhardt spun off its innovative R&D business into a separate company. The new company is expected to be involved in new drug discovery program and the innovative new technologies being developed by the R&D team. The company will be a listed company and is scheduled to come into effect from January 1, 2009. Commenting on the development, Wockhardt chairman, Habil Khorakiwala, said, "The R&D business has great potential and needs to be a focused entity for carrying out unrelenting research activities for the future. At Wockhardt, we recognise this fundamental need and are re-structuring our R&D business to unlock true value for all our stakeholders. This will ease the company to invite strategic investors interested in the R&D business."

Ranbaxy - To create an independent pathway for NDDR

Ranbaxy cleared a scheme of demerger of the company's New Drug Discovery Research (NDDR) unit into a subsidiary, Ranbaxy Life Science Research Ltd (RLSRL) in February 2008. The move was cited to help create an independent pathway for NDDR with dedicated resources and an enhanced focus for long-term growth. The new R&D unit is expected to help leverage the company's state-of-the-art research infrastructure and a highly skilled scientific talent pool by aligning assets with priorities to accelerate the company's drug discovery programs. "The demerger of our NDDR unit into a separate entity establishes a robust structure to carry out path breaking research at the cutting edge of modern medicine. It will also enable RLSRL to create intellectual property at a faster pace while positioning it for the future," Malvinder Mohan Singh, CEO and MD, Ranbaxy Laboratories said. The proposed R&D arm is expected to be listed in the middle of this year.

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Analysts speak

An increased focus on NCEs seems to be one of the principal reasons for companies to hive off their R&D units, but the underlying reason runs deep. According to Hitesh Gajaria, executive director, KPMG India, "Generics have always been the mainstay of Indian pharma companies and their entry in the NCE/NDDS discovery and development segment is relatively new. In the last few years, a number of leading Indian companies have entered this space and successfully scaled up their R&D operations. However, they have traditionally relied on their generics business to fund their discovery operations."

He explains that as a company moves up the discovery value chain, funding becomes a serious issue. And in the light of the global generics market under severe pricing pressure, relying on this funding channel solely can restrict the ability of Indian pharma companies to further their R&D efforts. "This is where hiving off their R&D units into separate entities helps companies explore innovative long-term funding channels including attracting strategic investors to advance their discovery initiatives. Such a strategy improves focus on the NCE business and also enhances the scope for collaborations (out-licensing, in-licensing and joint development and commercialization) with other experienced players and facilitates easier expansion of discovery initiatives with increased flexibility. Further, this helps maintain focus on the traditional generics business segment," he added.

Utkarsh Palnitkar, partner, transaction advisory services and national sector leader, health sciences, Ernst & Young India, added in the same breath, "Creation of a separate company is an innovative way to mitigate the risks involved in the drug discovery business where, despite years of expensive research, the success ratio is still small."

"In most cases, the concerned companies have restricted the hive off to new chemical entities (NCEs) only. However, the drug delivery system, clinical and the generic part will remain intact with the parent. The rationale is that the generic business and innovation are two totally different businesses, with different time frames, certainty profiles and investments. The demerger thus provides greater flexibility and impetus to the drug discovery research program while unlocking significant value for the company and its shareholders," he adds.

NCEs in the pipeline

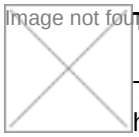
According to Gajaria, Indian players will spend $500 million in 2010 on NCE research and $1.2 billion by 2015. In the coming years, Indian companies will have gained significant expertise in this space and will certainly have some of its molecules launched globally. Dr Reddy's currently has four molecules in its NCE pipeline out of which only one is being co-developed along with Perlecan Pharma. The drug candidate DRL16536, currently in phase I trials and aimed at treating diabetes was one of the four new chemical entities that the company started with in 2005 with the formation of Perlecan Pharma. DRF-2593 co-developed along with Rheoscience, UK, is currently in phase III trials, DRF-1042, an anticancer target being co-developed along with Clintec International, UK, is in phase I clinical trials and DRF-2546 that addresses COPD is in pre-clinical stages.

Sun Pharma, which had demerged both its drug discovery and drug delivery units, has four NCEs in the pipeline with one of them soon to undergo phase III trials. Nicholas Piramal is developing 13 new chemical entities (NCEs) and expects to launch its first patented drug by 2010. Its lead molecule P-276 has recently been approved by the USFDA and clinical trials will soon commence for multiple myeloma â€“ a devastating type of cancer, in collaboration with Harvard Medical School and Dana Faber Cancer Centre, USA The company has two drug candidates in inflammation, one undergoing pre-clinical development and the second an oral herbal product, whose safety and efficacy is being evaluated in two phase II clinical trials in India. In the field of infectious diseases, an anti-fungal herbal product is currently in phase II clinical trials in India. A highly potent antibiotic drug candidate- active against methicillin resistant Staphylococcus aureus (MRSA) and vancomycin resistant Enterococcus (VRE) is in late pre-clinical development.

Wockhardt has two new chemical entities (NCEs) under clinical development. WCK 771, in phase II of clinical trials and is targeted at diverse staphylococcal infections like MRSA (Methicillin-Resistant Staphylococcus Aureus) - infections caused by a type of bacteria that is resistant to certain antibiotics - and VISA (Vancomycin Intermediate Staphylococcus Aureus). WCK 1152, is targeted at respiratory tract infections, including hospital-acquired infections, and is undergoing phase I clinical trials, to assess its safety.

Ranbaxy has around 10 programs comprising one molecule undergoing phase IIb trials (anti-malarial RBx 11160), another has completed phase I (RBx 9841 for urology), four are in pre-clinical development and rest in early stages of development. The company feels that if all goes well, its anti-malaria molecule may become the first NCE to come out of an Indian lab. RBx-

14255, the anti-bacterial molecule belonging to the Ketolide class, has completed exploratory toxicity studies. The IND enabling studies will be initiated in Q2 2008. As per the agreement with GSK in the COPD segment, the identified compound for this therapeutic category has been scaled up and IND directed toxicology and safety pharamacology studies have been initiated. In the anti-bacterial therapeutic segment several compounds that show much improved developability have been identified and are currently being profiled in order to identify a pre-clinical candidate.



The future of R&D

Though R&D requires huge investments, it does not guarantee new drugs. According to Hitesh Gajaria, sector head, pharma, KPMG India, "At present a few Indian pharma companies spend as much as 7-9 percent of their revenues on NCE and NDDS research, while the global average is over 14 percent. If an Indian player can successfully manage the R&D spin-off, this trend can significantly boost their investments in discovery research.

So is spinning off R&D a bubble waiting to burst? Would R&D units continue to attract investors? According to Hitesh Gajaria, executive director, pharma, KPMG India, "The ability of the Indian pharma companies to attract private equity investors would depend on parameters such as the breadth and depth of their NCE pipelines and the development status (phase, I /II/III etc.), target therapeutic indications and their market potential, the company's track record in developing molecules for similar therapeutic category, risk profile and potential in-license/out-license opportunities." Rajesh Jain, JMD, Panacea Biotec, is equally buoyant about this trend. "In view of the steady performance of Indian companies in domestic and international markets in the last decade, R&D would become a favorite domain for investments by private equity players as well as VCs, he said. Gajaria though adds a cautionary note. "However, given the high-risk nature of this business, in our view, private equity investors that have a longer-term investment horizon of 8-12 years may be better funding channels as compared to the capital markets."

Shalini Gupta with inputs from
Nayantara Som and Jahanara Parveen

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-Dilip Shanghvi, CMD, Sun Pharmaceuticals

What percentage of the company's revenues is spent on R&D?

At Sun Pharma Advanced Research Company (SPARC), the revenues will begin only once it licenses out a product or a technology, or has a product in the market. It has a burn rate of about $20-25 million annually, and no revenues. It will need $65-70 million to take projects ahead in the next few years. At Sun Pharma, which is a generic pharma company, we typically invest 8-10 percent of our turnover on R&D.

How much money do you plan to invest in the R&D unit(s) in the next few years and how much has been invested till date?

SPARC is likely invest $65-70 million in the next few years.

Has the unit(s) generated any revenues so far? How many people does it employ?

This year it had a small income related to technology transfer. SPARC employs 180 scientists across two research centers in Baroda and Mumbai.

What is the business model of the company after the hive off?

The revenue model is that of any R&D company, it creates intellectual property and seeks to maximize the returns on this asst. It will bring products and technologies to market across different markets, either on its own or with partners.

What is the vision for the R&D unit in the next few years? Are you looking at any acquisitions?

Broadly speaking, while maximizing the opportunity for each product, SPARC will also attempt to experience and internalize the basics of the new drug development lifecycle by carrying a drug candidate on its own, as long as possible. For SPARC, acquisitions are not a priority.

How much equity does the parent company hold in the R&D unit and how much will be held by the shareholders (percentage wise)?

In the way we have demerged our R&D, there is no parent company. No equity is held by Sun Pharma in SPARC. I own about 65 percent in Sun Pharma and as well as in SPARC, and the rest is with the public. All shareholders of Sun Pharma received the same number of shares in the R&D company (SPARC) as they had in Sun Pharma.

Sun Pharma Advanced Research Company (SPARC) is listed on the stock exchange. What are the benefits to the investor of getting listed?

The benefit to the investor is that depending on their own risk profile and the investing horizon, an investor can invest either in a generic company with predictable returns (Sun Pharma), or a research company with uncertain timeframe but a different magnitude of upside should a product clear all the phases of research and reach market (SPARC).

Nayantara Som