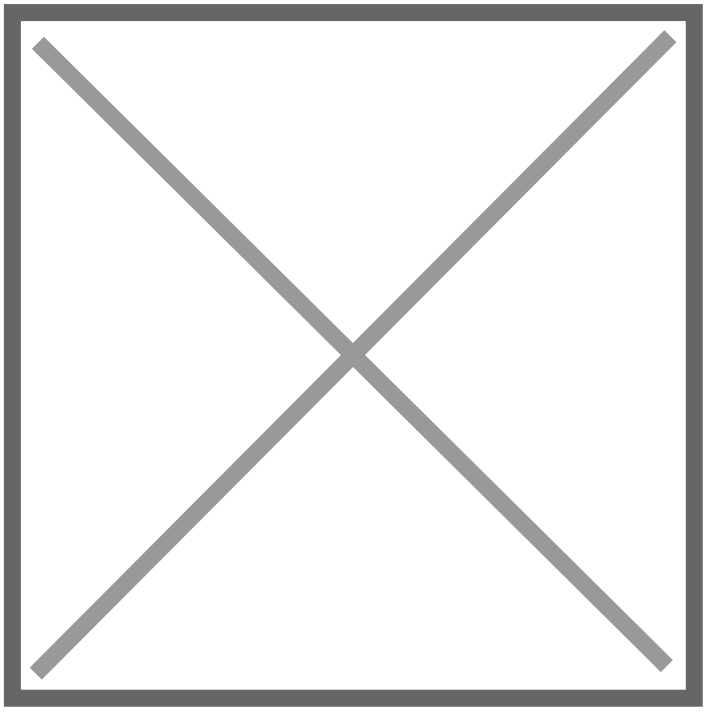
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Biotech bug bites Ranbaxy

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The company had identified biotech as a new area of investment in 2001. For, the worldover, pharma companies are betting on biotech to give them new drugs. So in 2002 it set up of an exclusive biotech research lab at the company's R&D center at Gurgaon (Haryana) near New Delhi. The company's R&D center is set amidst 17 acres of land, with a covered area of over 20,000 sq. mt. and is one of the largest R&D facilities in India.

Dr Kulvinder Saini is heading a 15-member team of scientists in this lab. At present, the core competence of the lab lies in the development and commercialization of generic active pharmaceutical ingredients (API) and bio-equivalent dosage forms in line with international regulatory and quality requirements. The company has committed R&D investments to the tune of $50-60 million (Rs 300 crore) this year. The company is on the lookout for research alliances in biotechnology and has identified medicinal and process chemistry, biological screening, pre-clinical development, and early clinical development as its main areas of focus. In biotech research, the company envisages forming committed alliances, co-marketing as well as exploring in-licensing agreements with other global pharma and biotech companies.

According to company officials, Ranbaxy provides a perfect platform for biotech research as it already has the expertise in multiple disciplines that will provide the crucial inputs that are key to success. These include medicinal chemistry, pharmacology, pharmacokinetics, bioanalysis and toxicology, process R&D, patents, medical and commercial inputs, high throughput screening, target protein production and so on.

Company officials say that Ranbaxy's foray into biotechnology will go a long way in the enhancement of early drug discovery. The company is also looking at partners in this area."Partnering with Ranbaxy for biotech research can provide cost-effective drug discovery, speedy candidate selection, diversity in formulation development and platform technology in the area of oral controlled release delivery systems, efficient pre-clinical development and early clinical development," said the official.

It's continued focus on R&D has resulted in several approvals in developed markets and significant progress in NDDR. The Company has already filed four IND (Investigational New Drug) applications with the Drugs Controller General of India (DCI) and has an active NCE pipeline. Its first NCE RBx 2258, for BPH has been licensed to Schwarz Pharma AG of Germany, to develop, market and distribute the product in USA, Japan and Europe, while the company has retained the rights for all other markets.

Ranbaxy's anti-asthma molecule, RBx 7796 (Clafrinast) is in phase I clinical trials in India. The company is awaiting approvals to conduct phase 1 clinical trials for RBx 7644 (Ranbezolid), an extended spectrum Oxazolidinone from the DCI for both its oral and intravenous usage in India. RBx 7644 (Ranbezolid) is presently undergoing phase I clinical trials in the UK.

Ranbaxy also has three molecules in the late discovery stage and one in pre-clinical. The company's major research focus is in the areas of anti-infectives, urology, respiratory, anti-inflammatory, metabolic disorders and anti-cancer segments.

Ranbaxy's first NDDS (New Drug Discovery Research) innovation once a day Ciprofloxacin has been licensed to Bayer AG, the originators for select markets. Ranbaxy has filed two new drug applications (NDAs) in the US for Metformin syrup and Ofloxacin tablets. Ranbaxy's NDDS focus will be in developing prescription products and value added dosage forms and expand its platform technologies.

Ranbaxy's president (R&D) Dr Rashmi Barbhaiya was confident about the new market. "Ranbaxy and India have tremendous opportunities to create a big success in pharmaceuticals, particularly in new drug discovery. This is going to require an enhanced driving force for innovation and will require vital investment and alliance building, both within the industry and with the government."

The target to achieve $ 1 billion sales by 2004 in line with its vision and to maintain a robust growth post 2005. To translate these objectives and to optimize value creation, the Ranbaxy has adopted a multi-pronged strategy.

Ranbaxy is making a transition from a generic company to a specialty pharmaceutical company with an ultimate intent of transforming into a research-based organization. It manufactures and markets branded generic pharmaceuticals and active pharmaceutical ingredients. The company's products are sold in over 70 countries with its manufacturing operations in seven countries and a ground presence in 25 countries. It has employed diverse strategies, including exports, alliances, partnerships and acquisitions to gain the flexibility needed for viable and profitable business operations worldwide.

Dr Barbhaiya said the company has few priorities such as to improve the probability of success, building robust R&D organization by channeling the energy of the teams into right
direction.

Emphasizing on the strength of Indian Pharma industry he said, "The Indian industry is full of young talent. The only concern is to motivate them to work in the country and check the brain-drain." Apart from this he added that the cost effectiveness in the Indian market is also play key role to attract the corporates to invest here.

"Geonomics,proteonomics pharmacogeonomics are among the emerging areas of biotech research in India. There are preliminary guidelines established by the government for working on recombinant plants and microorganisms. However, regarding medical biotech research, there is an urgent need for policy formulation especially for pharma sector. This will actually solve a lot of problems for us and it should happen soon otherwise we will loose time."

Suggesting his views to improve the regulatory front for research and business, he said, "There should be single entry, regulatory system should be based on telecom model for biotech and genomic research. There is also a need for strong industry academia interaction as well as involving public bodies and NGOs for policy making."

Ranbaxy had global sales worth $ 764 million(Rs 3,710 crore) with a growth rate of 39 percent .Overseas markets accounted for 72 percent of the sales. The major contributors were USA, Brazil, UK and other emerging
markets.

Faiz Askari