

## Biocon eyes R&D and brand building

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*Biocon's new hedging strategy would allow it to face the challenges in future with a sense of confidence and resilience.*

Established in 1978, Biocon and its two subsidiary companies, Syngene International Pvt Ltd and Clinigene International Pvt Ltd form a fully integrated biotechnology enterprise, specializing in biopharmaceuticals, custom research and clinical research. With successful initiatives in clinical development, bio-processing and global marketing, Biocon delivers products and solutions to partners and customers across the globe. Many of these products have US Food and Drug Administration and European Medicines Agency acceptance. Biocon launched the world's first recombinant human insulin, INSUGEN, in November 2004, using Pichia expression and India's first indigenously produced monoclonal antibody, BIOMAb-EGFR, in 2007.

Biocon posted a consolidated revenue of Rs 912.34 crore for the year ending March 31, 2009 as against Rs 876.93 crore in 2007-08. The Biocon Group's consolidated revenue (including AxiCorp) have increased 53 percent from Rs 1,090 crore in FY 2007-08 to Rs 1,673 crore in FY 2008-09. Consolidated revenue (excluding AxiCorp) increases 10 percent from Rs 1,090 crore to Rs 1,194 crore. The EBITDA (including AxiCorp) grew 16 percent from Rs 335 crore to Rs 388 crore.

Unpredictable rupee depreciation induced by the global economic crisis has adversely impacted its consolidated FY 2009 earnings, wherein losses of Rs 147 crore on account of MTM were incurred. "The financial year 2009 has been one of our most challenging years where foreign currency volatility made it difficult to manage a sharply depreciating rupee resulting in large MTM losses. This has been a learning for us and our new hedging strategy enables us to address the years ahead with a sense of confidence and resilience," stated Kiran Mazumdar Shaw, CMD, Biocon.

"Our branded formulations business under our healthcare umbrella has made rapid strides in garnering market share for our key brands in cardiology, diabetology, nephrology and oncology. We see this as a high growth segment in our business strategy in future," she added.

The German pharma company, AxiCorp GmbH, has contributed 29 percent to Biocon's revenue. AxiCorp has recently won

the German AOK tender for Metformin, which is an important milestone both in terms of making inroads into the generics market as well as laying the foundation for Biocon's diabetes franchise in Germany.

The company's future prospects are being driven by a robust R&D engine which is making good progress in both biogenerics and novel biologics programs. The company is all set for significant incremental investments in these segments.

In a recent development the company's conjugated insulin molecule, IN-105, has successfully completed early phase clinical trials for safety and efficacy. Currently a phase-III pivotal study for oral insulin (IN-105) has been initiated across various hospitals in India, consequently patient enrollment is in progress. Biocon's T1h (Anti CD6) monoclonal antibody program has also completed patient recruitment for phase-II clinical trials for both rheumatoid arthritis as well as psoriasis. On the biogenerics front, Biocon's development plan for regulatory acceptance of recombinant human insulin by EMEA and US FDA is also in progress. Its Insulin analogue, Glargine, is now set to enter into a similar development path for global registrations.

Commenting on the outcome of the US Biosimilar Bill, Kiran Mazumdar Shaw said, "Obama's call for biogenerics and affordable healthcare heralds a new era for biotherapeutics. Our pipeline of biogeneric monoclonal antibodies and insulins supported by a strong manufacturing base provides us with a unique opportunity to build partnerships with key players in this segment."

Biocon also recently launched Basalog, a long acting (24 hours) peak less human insulin analogue, Glargine, in India. The key advantage of this product is that it replaces other long acting insulins that do not act for 24 hours, therefore diminishing the discomfort of multiple insulin shots and the possibility of developing hypoglycemia (low blood sugar). Hence, Basalog offers better glucose control with the compliance of a single shot. The company is offering the drug at a cost which is 40 percent lower than what is being offered by the innovators. The affordable pricing which Biocon brings to the Indian market will provide greater access to such a vital drug.

Biocon has tied up with Bayer for their latest technology glucometer, Breeze 2, which allows a more convenient system of glucose monitoring. This new glucometer has been designed to incorporate a cartridge of 10 strips which needs to be loaded just once. Patients can therefore test themselves frequently with ease, avoiding periodic insertion of individual strips and thereby ensure better compliance in terms of blood glucose checks.

Biocon's BIOMAb-EGFR, a therapeutic monoclonal antibody-based drug, for treating solid tumors of epithelial origin, received the BioSpectrum Asia Pacific Product of the Year Award 2008. Biocon has also won the 2009 BioSingapore Asia Pacific Biotechnology Award for the Best Listed Company. Biocon was selected for the award on the basis of its significant market capital, sound business model and excellent management team.