

## Collective Expertise

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*Biocon's integrated business approach coupled with its collective expertise has enabled it to establish a significant presence in the global biopharmaceutical market.*

**Business:** Biopharmaceuticals and industrial enzymes

**CEO:** Kiran Mazumdar-Shaw

**Biotech Revenue:** Rs 823 crore

**Start-up Year:** 1978

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Biocon has reported a total sales of Rs 823 crore for the year ending March 2007 from the sale of biopharmaceuticals and enzymes. As a group, the company ended the year at Rs 990 crore. Revenues from the biopharmaceuticals and enzymes business grew 20 percent to Rs 823 crore from Rs 688 crore contributing 83 percent to operating revenues in FY 2007. Revenues from research services and licensing grew 63 percent to Rs 163 crore from Rs 100 crore, contributing 17 percent to operating revenues in FY 2007.

Biocon is today a biopharmaceutical company with strong capabilities in statins, immunosuppressants, recombinant insulin and a wide product range across key therapeutic segments including diabetology, cardiology and oncology. Biocon's R&D initiative began in 1984 with a focus on fermentation-derived microbial enzymes. Subsequently, it extended its research to new domains of knowledge, spanning bioprocess development, gene expression technologies, secondary metabolites, bioconversions and proteomics. Today, it leverages its multiple expertise to leading-edge recombinant biopharmaceuticals and human therapeutics. The invention of the PlaFactor and through it, the ability to pioneer novel production processes for therapeutic molecules, is testimony to Biocon's path-breaking R&D capabilities and exceptional engineering skills.

Biocon's subsidiary, Syngene, has entered into research partnership with Bristol Myers Squibb. The new Bristol-Myers Squibb and Syngene research facility is underway. Spread over approximately 150,000 sft, the facility is planned to ultimately house more than 400 scientists to help advance Bristol-Myers Squibb's discovery and early drug development in India. This is expected to significantly increase the scope of Bristol Myers Squibb's existing relationship with Syngene to further develop integrated capabilities in medicinal chemistry, biology, drug metabolism and pharmaceutical development. Through this symbiotic global partnership, Biocon's Syngene will provide research and development services for discovery and early drug development.

Biocon is developing Nasulin, an intra-nasal insulin spray with Bentley Pharmaceuticals.

The Drugs controller general of India has cleared Nasulin for phase 2 trials on type-2 diabetic patients, a company release said. Biocon's subsidiary, Clinigene International, will conduct and complete clinical trials by the end of the year. Bentley has completed pharmacokinetic clinical studies with Nasulin in India and expects to close a significant portion of the US phase 2 studies by the end of 2007. Nasulin is the second non-injectable insulin that Biocon is working on, besides the oral tablet-form insulin IN 105, which is almost on a parallel track at phase 1C. Both the drugs may be 3-4 years from commercial stage.

Biocon and Abu Dhabi's NMC Group signed an MoU to establish a JV to manufacture and market a range of biopharmaceuticals for the GCC region (Gulf Cooperation Council). This landmark agreement between the two companies heralds the region's first foray to develop and market life-saving biopharmaceutical products and will expand Neopharma's (NMC Group) existing portfolio with a range of Biocon's therapeutic products. These products will be in the cardiovascular, diabetes and oncology segments, which represent the fastest growing class of drugs in the \$ 5 billion GCC pharmaceutical market. This JV is a key milestone for Biocon's marketing foray in the Gulf.

Biocon launched BIOMAb-EGFR, a therapeutic monoclonal antibody-based drug for treating solid tumors of epithelial origin, such as head and neck cancers. The drug is the first of its kind to be clinically developed in India and is the first anti-EGFR humanized monoclonal antibody for cancer to be made available commercially anywhere in the world. The product has shown consistent positive outcome in clinical trials initiated both in India and globally and is being studied in global clinical trials for Colorectal, Lung Cancer, Glioma and Pancreatic cancers. BIOMAb-EGFR is produced at Biocon's state-of-the-art manufacturing facility-Biocon Park. Biocon has also granted an exclusive license to Ferozsons Laboratories for marketing BIOMAb-EGFR in Pakistan. Ferozsons Laboratories is a leading oncology company.

Biocon has a pipeline of 12 molecules that could be out-licensed over a period of 12 to 24 months. The company is in an advanced stage of discussion on three molecules. It is keen to out license an oral insulin molecule called IN105 for type II diabetes and potential drug for congestive heart failure. The others range from a monoclonal antibody from a monoclonal antibody for rheumatoid arthritis to a squamous cell antibody for non-Hodgkin's lymphoma.

Biocon launched a comprehensive portfolio of renal therapy products which are priced 35 percent lesser than those available in the market. Biocon's nephrology division is committed to finding solutions to kidney disorders using the highest standards of biotherapeutics and will simultaneously strive towards reducing the risks of the disease in the future, through progressive research and innovative therapies. The new immunosuppressant drugs for renal therapy include Ranodapt, Tacrograf, Cyclophil ME, Rapacan and Erypro. Immunosuppressants are medicines that inhibit or prevent the activity of the body's immune system. Its newly carved out nephrology division expects to release more drugs in the market which include certain aspects of kidney related eases. To achieve this end, Biocon will continue to increase investments in the R&D division. Biocon expects to double its R&D spend in 2007-08.

"Biocon truly believes that non-injectable insulins will drive the future of diabetes therapy the world over. The company wants to play a big role in the insulin market, currently valued at nearly Rs 300 crore in the country," said Rakesh Bamzai, president, marketing, Biocon.

Biocon's new product pipeline includes therapeutic biomolecules ranging from small molecules (e.g., statins, immunosuppressants) to recombinant proteins (human insulin and monoclonal antibodies) derived from microbial and mammalian cell culture based fermentation technologies.