



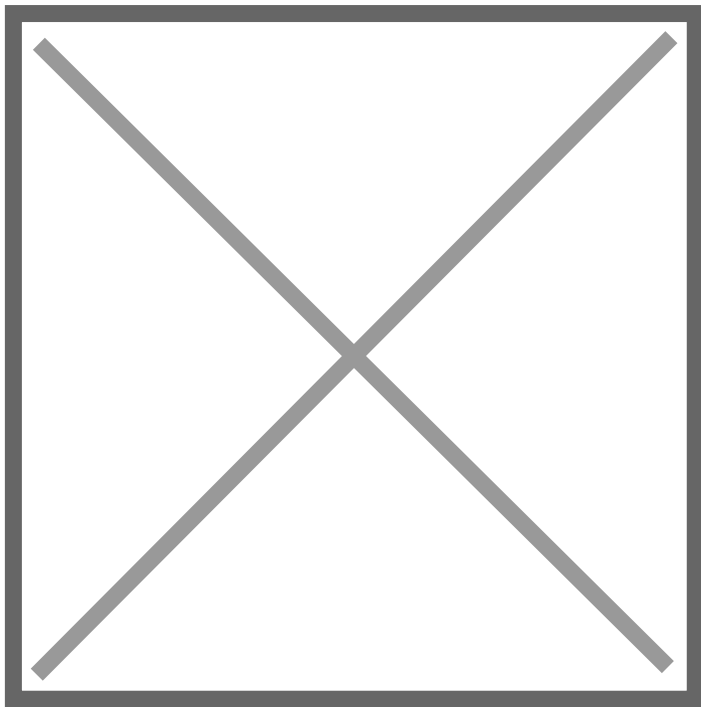
BioSpect

the business of Bio

24 years of leveraging the business of Bio
www.biospectrumindia.com

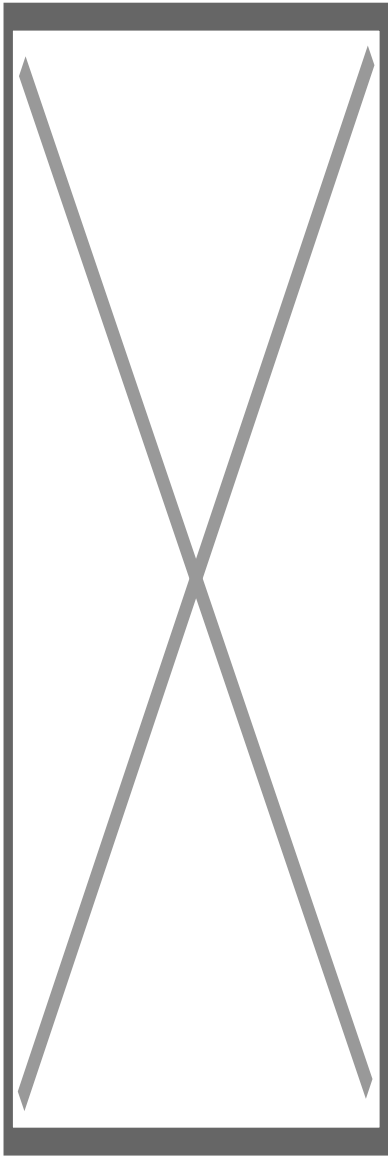
Biocon

11 July 2008 | News



Rank 2

Biocon



Strategic moves

Biocon has increased its capital expenditure to support business expansion. The company has a strong balance sheet, which it plans to use for strategic acquisitions and investments.

The total revenues of Biocon, one of India's premier biotechnology companies, for fiscal 2007-08 increased 19 percent to Rs 1,090 crore, up from Rs 990 crore in the previous year, and net profit increased by 3 percent to Rs 225 crore. The consolidated revenue (excluding enzymes) increased by 19 percent from Rs 881 to Rs 1,044 crore this fiscal. Impressive growth in research services helped Biocon post a fourth quarter profit of Rs 62.03 crore, a growth of 31.16 percent from Rs 47.29 crore in the same quarter last year. The company's net sales in the quarter that ended March 31, however, declined 5.92 percent to Rs 219.75 crore and total income fell by 1.09 percent to Rs 236.71 crore.

Biocon's profit growth has been maintained at the consolidated level despite the divestment of the enzymes business, currency appreciation and increased depreciation. The company has a strong balance sheet with high reserves and Rs 193 crore in net cash.

Commenting on the results, Kiran Mazumdar Shaw, chairman and managing director, Biocon, said, "We are pleased with our overall performance and have delivered the highest profits to date. We have increased our capital expenditure to support the business expansion that we anticipate across the group. We expect the year ahead to realize a good return on these investments, especially at Syngene and Clinigene. We have a strong balance sheet which we will use for strategic acquisitions and investments.

Established in 1978, Biocon and its two subsidiary companies, Syngene International and Clinigene International form a fully integrated biotechnology enterprise, specializing in biopharmaceuticals, custom research and clinical research. With successful initiatives in clinical development, bioprocessing and global marketing, Biocon delivers products and solutions to partners and customers across the globe. Many of these products have USFDA and EMEA 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.

Biocon last year acquired 70 percent controlling stake in German Pharma company, AxiCorp GmbH, for a consideration of ₹30 million. This acquisition is expected to enable Biocon the marketing and distribution of a range of pharmaceuticals including generics, biosimilars, biologics and innovative pharmaceutical products in Germany and Europe.

Biocon has commenced the phase IIa clinical trials for IN105. An open label, multi-centric, placebo controlled, single ascending dose study designed to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of IN105 under fed conditions in type II diabetic patients currently on Metformin therapy has been commenced at five investigation sites. The study is expected to be completed in August 2008 and will provide the data necessary to commence phase IIb clinical trials.

In another major development, Biocon has commenced phase IIb trials for T1h for rheumatoid arthritis (RA) and psoriasis. A randomized, open label, four arms parallel phase II clinical study to evaluate the safety and efficacy of anti-CD6 monoclonal antibody (T1h mAb) in combination with Methotrexate in patients with active rheumatoid arthritis has been initiated at 7 investigation sites. Another phase II clinical trial to evaluate the safety, efficacy and pharmacokinetics of anti-CD6 monoclonal antibody (T1h mAb) in patients with active psoriasis is also due to commence at five investigation sites. This has been designed as a single blind, randomized, multiple dose, multiple schedule, multi-centric, parallel study in patients with active moderate to severe psoriasis, with independent blinded disease activity assessment, and quality of life metrics assessment. These clinical trials will enable Biocon establish proof of concept for T1h and will add tremendous value to its licensing potential.

Biocon also commenced phase IIb trials for Glioma and NSCLC for BIOMAB EGFR. An open label, prospective, multi-centric study to evaluate the safety and efficacy of BIOMAB-EGFR (Nimotuzumab) as induction and maintenance therapy in combination with radiotherapy plus Temozolomide (concomitant and adjuvant) in Indian patients with Glioblastoma Multiforme is ongoing at eight investigational sites across the country. Another clinical trial designed as an open-label, randomized, comparative, multi-centric study to assess safety and efficacy of BIOMAB-EGFR and Nimotuzumab and in combination with chemotherapy versus chemotherapy alone in the treatment of patients with stage IIIB / IV Non Small Cell Lung Cancer (NSCLC) is also being initiated at 11 sites. These clinical trials will enable Biocon's oncotherapeutics division to expand its market share through label extensions.

Biocon has decided to split up its cardio-diabetes group by launching a stand-alone cardiology division. This new division is being launched to focus on brand building for its flagship statin-based product Statix as well as other products viz. Telmisat, Eptifibatide and its recombinant streptokinase product Myokinase. This division is envisaged to have an all-India presence through a 250+ strong field force.

Realizing the increasing demand in the market segment of pre-filled syringe systems over the past ten years, Biocon recently launched a safety device in the form of pre-filled syringes for two of its life saving products, GCSF (granulocyte-colony stimulating factor) and EPO (Erythropoietin). This innovative product has been launched in collaboration with Safety Syringes and is being introduced for the first time in India. ERYPRO Safe and NUFIL Safe will be the first two drugs that will be marketed using this novel device with other injectable products to follow in the future. Biocon's pre-filled syringe device incorporates features that provide for simple and safe handling, a discrete appearance of the injector and a retractable needle that reduces the chances of injuries during injection. Commenting on the launch of the pre-filled syringes, Kiran Mazumdar-Shaw explained, "The pharmaceutical industry has registered an increasing demand in the market segment of pre-filled syringe systems over the past ten years. These systems have the endorsement of healthcare professionals worldwide. There is a growing trend of injectable drugs moving into the pre-fill syringe as a presentation format. Worldwide, pre-filled syringe volumes have reached more than two billion units. The opportunity for Indian biotech companies in pre-filled syringes is immense as India is being viewed as a low-cost, high-quality manufacturing base. It has the largest number of USFDA approved plants outside the US."

"Biocon stands committed to building big brands of products"

-Dr Kiran Mazumdar-Shaw, CMD, Biocon

The biopharmaceuticals business still accounts for 75 percent share of your total business. Going forward, how do you see the growth from this line of business?

We are gearing up to increase our top line performance in biopharma. So the year ahead should see us delivering a better growth in terms of biopharma. We have grown by more than 100 percent in branded formulations sales compared to the previous year. We expect the growth to continue at this rate because the base is small. Biocon stands committed to build big brands of products like Insugen, BIOMAb-EGFR, and Statix.

What is the share of your statins business in your overall sales?

The share of statins right now is about 33-34 percent of the biopharmaceutical revenue. Our dependence on statins is reducing and growth is coming from other areas as well.

What is the broad classification of your biopharmaceutical products and their respective contribution to your biopharma sales?

I think statins is about a third of our business, immuno-suppressants and insulin account for another 25 percent, and then the rest are all miscellaneous products, including our branded formulations.

How much was the licensing income in the current year?

It was about Rs 45 crore and is added in the biopharmaceutical business.

What is Biocon's licensing strategy?

We have many programs to license. These are across the biosimilar and new drug molecule space. IN-105 is making good progress. We are in the process of conducting phase IIa trials and we will be entering into phase IIb trials, which is proof-of-concept trials. This is going to take another one year before we can really start aggressively licensing this molecule. As for T1h or anti-CD6, this is at the moment entering phase IIb trials, which are proof-of-concept trials that we need to evaluate in order to again make it ready for licensing. So, we believe that both these molecules will be available for licensing over the next 12-18 months and they are expected to deliver huge upsides. In addition, we have a pipeline of biosimilar molecules which we will continue to license as and when they complete some levels of clinical development. We already have quite a few products that are undergoing phase III clinical trials, like glargine and a few other products and once this happens, we will continuously look at licensing these out.

You have expanded to the Middle East...

We have set up a marketing company called Neo-Biocon in the Middle-East. This is a joint venture between us and Dr Shetty's Research Laboratories, called Neopharma and we are right now in the process of registering our products in that territory.

We established this company about 8-10 months back and by the end of this year, we will have all approvals in place. We will be starting our marketing activities in that territory by end of this year or beginning of next fiscal.