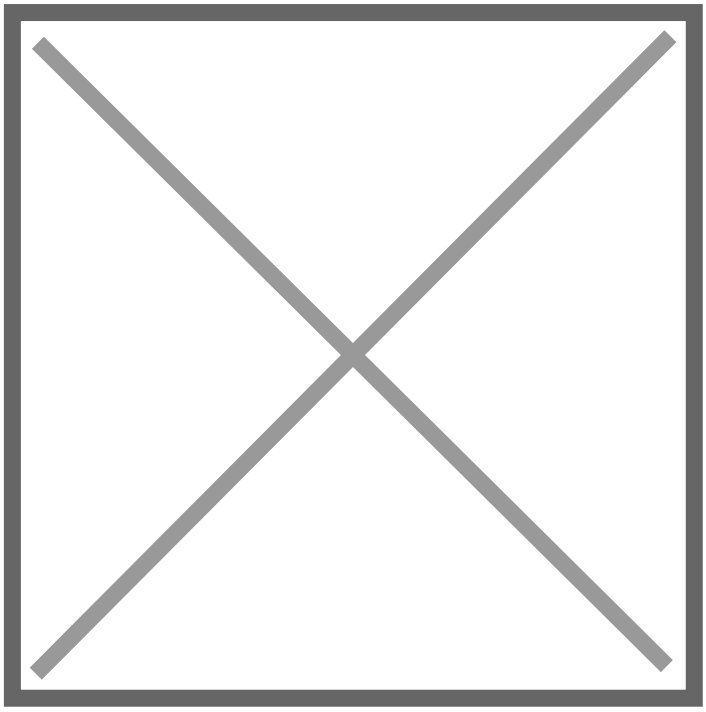
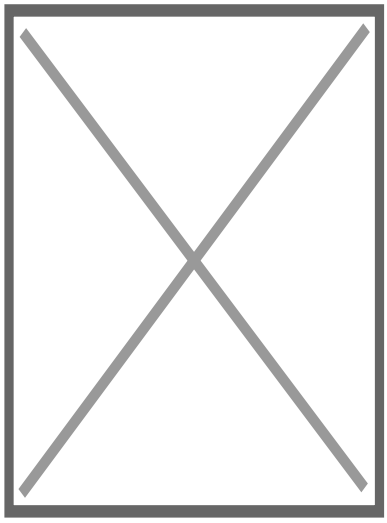
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Lupin's biological pursuit

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Dr Kamal Sharma, managing director, Lupin, Mumbai.

Having consolidated itself in the generics space, Lupin Pharma has now marked biologics as a top priority within the radar of its overall expansion plans Lupin Pharma has been very aggressive in the last few months announcing a spate of overseas acquisitions, capacity expansion plans and now its foray into biological venture. A statement made by company Chairman, Dr DB Gupta earlier last year categorically mentioned, "We have planned to make substantial investments in this area as we believe biotechnology is the frontier area of technology. Over 40 percent of all future discoveries in pharmaceuticals are expected from biologicals. I believe concrete outcome of our research work done should start getting market recognition soon. Our innovative research is focused largely on four areas--New Chemical Entity Research, New Biological Entity Research, Advanced Drug Delivery Systems Research, and Innovative Generics Research. In all these areas a sound base has been created including initiation in the Biotech area." Overall too, it has been all sunshine for Lupin Pharma which posted a consolidated net profit for the year ended March 31, 2008, of Rs 408.25 crore up by 32 per cent. Total income increased from Rs 2,212.76 crore for the year ended March 31, 2007 to Rs 2,912.82 crore for the year ended March 31, 2008. Chunk of the revenue share came from international operations.

The company's biotech sojourn began two years back when it set up an R&D unit dedicated just to specialized research and development of a basket of proteins. From then on the company has moved on at a breakneck speed. Dr Kamal Sharma, managing director, Lupin said, "We initiated our biological venture two years ago and obviously we began with plans of going into the R&D space. Within this period, we have developed some proteins and some monoclonal antibodies too, some of them are in advanced stages of development and some of them are in the intermediary stages of development"

New manufacturing unit and investments

Moving ahead, the company now does not want to leave any stone unturned in its biological venture. It has already made some significant investments in establishing a research unit for biosimilars namely the Lupin Biosimilars Research organization and new biological entities.

This is not all. As a stepping stone to its biological dreams, Lupin is now setting up its own manufacturing unit in Pune which is likely to be commissioned in the coming months. While the Lupin Biosimilars Research organization in Pune is fully operational, the manufacturing and technical arms are being currently ramped up. Lupin has developed several biosimilars as well as delivery platforms for proteins and completed pilot work on two monoclonal antibodies of global potential.

"We set up a manufacturing unit which will be commissioned in the course of the next three months in Pune. Here, we are

going to take up the clinical manufacturing of the proteins we have developed already and then put them for regulatory approval. It is a CGMP facility," added Dr Sharma.

When the manufacturing facility is ready, it would offer facilities for any clinical production or contract manufacturing services which overseas companies may require. Thus the setting up of its technological and manufacturing arm is not just an extension but a catalyst to further Lupin's biologics strategy both in India and overseas markets.

Disease segment of prime importance for Lupin in biologicals will be cancer, cardiovascular and rheumatoid arthritis. Lupin aims to reach all key global markets including the US, Europe, India, Brazil, Mexico, Turkey, Saudi Arabia, Argentina and Russia.

Investments

As far as investments go, funds and finances could go up to the tune of Rs 250 crore for Lupin's entire biological initiative with the entire amount being raised from internal accruals alone. However it is here that Lupin wants to take it up one at a time. "Obviously in trying to respect the economics of the business, we have kept it in a manner that we do not invest too much money upfront and invest as and when required. We have not allocated any separate budget but whatever initiative is taken, we look at it as a return on investment ranging between 25-30 percent. Unless that return on investment is insured we do not take a step ," confirmed Dr Sharma

Dr Sharma, who is spearheading the company's biological initiatives has a different mantra to keep the business up and running . He quipped, "What drives us is output not input. I am an advocate of concentrating more on output than input. It would make economic sense to have a situation where 50 people can create a Rs 500 crore business; a four acre plot generating Rs 400 crore business rather than making huge investment and getting nothing out of it." The same goes with its manpower investments too. In the span of two years, the company ramped up its workforce to over 35 and now with the setting up of its manufacturing unit and technological arm, it intends to beef up its total workforce to 100 and above which will be divided into research, manufacturing and Q/A. Lupin is looking at focusing on the right number of high quality people which will be determined more by the needs of the business.

Strategy

Venturing into the manufacturing is in line with the overall blueprint of Lupin's broad strategy. The company's business model consists of four components which is in-licensing products (wherein the company has already in-licensed products for biologics in the market); having its own manufacturing plant; scouting partners for taking an early stage product into clinical development including co development in India; and last, forging marketing alliances. "Our technology and manufacturing strategies are going to be different as this is altogether a different science. But the new strategy for technology and manufacturing will dovetail into our main line strategy for putting the product into the market. So we are starting with a new technology platform which is biologicals, starting with biosimilars moving into New Biological Entities for which we will enter into codevelopment and in licensing for early deals," added Dr Sharma.

Looking at the macro level, getting into an acquisition or an alliance with a "strategic fit" has always been Lupin's core strategy and it intends to emulate the same in its biotech model as well. "We do not acquire for the sake of becoming big but we are acquiring for the sake of adding strength to our base model. This can be done only by two methods. One is to acquire in the market you want to enter which is difficult to enter in an organic way or you acquire a technology platform to add to your business. It is this that will be applied to our biopharmaceuticals model as well," Dr Sharma said.

Lupin's manufactured products is estimated to be out in the market by the end of 2010 It is a prerequisite in the company's agenda that the products are first launched in India and then in overseas markets. In the process, the company will start developing partnerships. Partnerships will go concurrent.

Looking into the future

The share of biologics in Lupin's total revenues would be minuscule in the next one year, despite in-licensing deals and marketing alliances. The company is looking at a business turnover of Rs 100 crore from this business in the initial years and gradually increase the share of revenues from the biologics business to 10 percent over the next seven-eight year's time.

On a final note, Dr Sharma added optimistically, "I can confidently say, that we have gone into the biologics space at the right time. The regulatory pathway for biosimilars is just up in the US . It will take another 3-4 years before it gets settled into a well defined pathway. By then our technology and manufacturing would have graduated to a higher level by then which makes work easier for us and help us ink further alliances. I am pretty much excited about that."

Nayantara Som