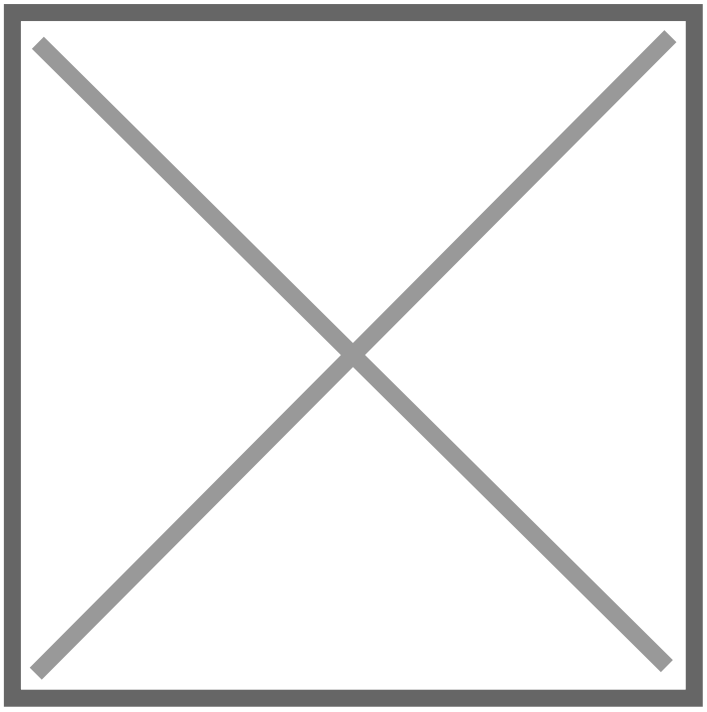
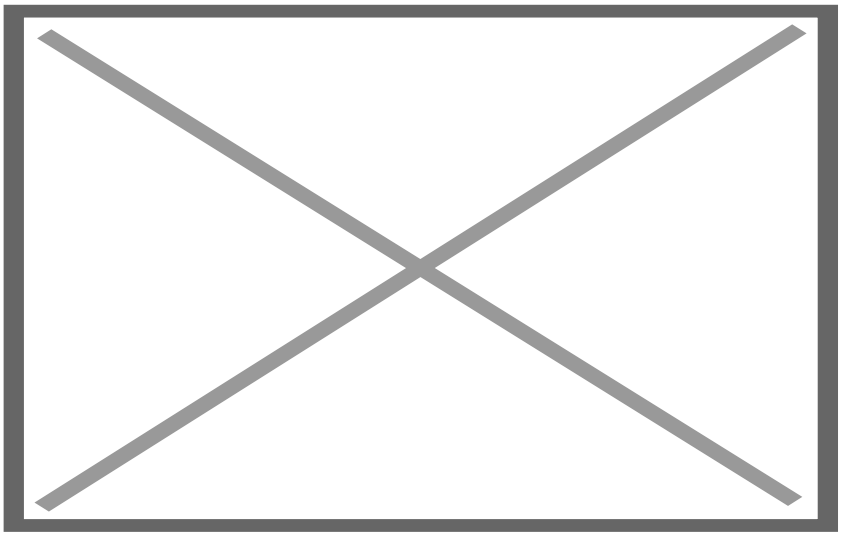
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New Entrant, Quick Development

04 November 2004 | News





Intas Pharmaceuticals Ltd, a fast growing pharmaceutical company with an annual turnover of Rs 381 crore (financial year 2003-04), has entered the biotechnology space by launching recombinant human Granulocyte Colony Stimulating Factor (G-CSF) in August this year.

With experience in marketing bio-generics and hepatitis B vaccines in the domestic market, Intas Pharmaceuticals entered the biotech field in 2000 with a view to emerge as a research based manufacturer of quality biopharmaceuticals and become a significant global player in the bio-generics market. And it set up Indus Biotherapeutics Ltd, a wholly owned subsidiary of Intas dedicated to biotech R&D. The group has invested over Rs 35 crore in developing research and manufacturing facilities.

Indus Biotherapeutics Ltd has successfully developed from lab scale-to-clinic recombinant human G-CSF for Intas Pharmaceuticals, which is marketed by Intas Pharmaceuticals under the brand name Neukine. Indus is a DSIR approved R&D company.

The team at Indus consists of 35 young researchers educated in premier institutes and having doctoral or postdoctoral experience in India, the US, Europe and Japan. It has shown that it has the capabilities to transform biotechnology discoveries into quality therapeutic products in a short time and in a cost-effective manner. It also provides contract research services to companies and groups seeking to develop recombinant products, with capabilities and expertise for development of up-stream fermentation / cell-culture based process, down-stream purification of proteins, protein characterization and analysis, stability testing, animal toxicity studies, handling multi-centric clinical trials, etc..

Intas Pharmaceuticals has a state of art manufacturing plant at Moraiya near Ahmedabad for manufacturing recombinant therapeutic proteins. The facility, covering 20,000 square feet area is capable of producing gram quantities of recombinant proteins under GMP conditions. It has the cGMP and process development expertise that is critical to successful manufacturing of complex pharmaceuticals and biologics.

At present, Intas is working on developing two-three generic recombinant biopharmaceutical products and many more are in the pipeline. These products are expected to lose patent protection soon and are being developed for global biogeneric markets. The product development meets the quality requirements laid down by the US and European regulatory authorities.

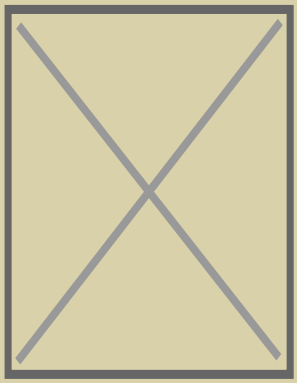
Besides Neukine, there are two more products-EPO and Interpheron alfa 2b (both recombinant therapeutic products)-which are under clinical trial stage and another four rDNA products that are under development stage. The company focuses on recombinant proteins based products mainly in the oncology and nephrology segments. For manufacturing, it has used cell culture and fermentation technology. Intas intends to make its products available in pre filled syringes and depending upon the nature of the products, these would made available in the liquid or lyophilized forms in vial as well.

With a committed approach and continuing focus on research and innovation, it has succeeded in bringing international standards in setting up a highly sophisticated manufacturing plant acclaimed as one of the finest in South East Asia. This plant is WHO approved and meets US FDA standards. Its pharma plant, also at Ahmedabad, has received approvals from many regulatory authorities like MCA (UK), TGA (Australia), MEB (Netherlands), MCC (South Africa), AFI (Belgium), Anvisa (Brazil) and FDA (Nordic Countries).

To take an early lead in the biotechnology space, Intas is actively collaborating with several research labs in the Europe and the US, turning laboratory scale technologies into commercially viable, cGMP compliant manufacturing processes. Indus Biotherapeutics is also working towards active tie-ups with several leading research labs and institutions in India. Recently, Intas has entered into a tie up with Avasthagen, a research focused biotechnology company from Bangalore. "Such tie-ups between two like-minded organizations and commitment of the management to focus on R&D will definitely pay the fruits for Intas in the coming years," say key officials in the company.

Narayan Kulkarni

"We Plan to Release One Product Every Six Months"



Dr Urmish Chudgar, a practising haemato-oncologist who is passionate about biotechnological development for better human health, is the director, Intas Pharmaceuticals Ltd. He is the man behind the biotech initiatives at Intas Pharmaceuticals. At Indus Biotherapeutics Ltd, a wholly owned subsidiary of Intas dedicated to biotech R&D, he plays a key role in strategic development, business growth and team building. He details out his company's interest in biotechnology and its future plans.

When did Intas initiate its biotech activities and what were the reasons for the same?
We started planning our entry into biotechnology in 1999 and actually initiated the activities in the middle of 2000. Biotechnology is a growing area within pharmaceuticals internationally, as more than 50 percent of the products are in early stage of development today and will become marketed products over the next 10-15 years. And these are biotechnology based. We expect that entering biotechnology at this stage will put us in a position to be a part of this phenomenon. Biotechnology will be an important component of the company's growth in the coming years and fits in well with our strategy of increasing international operations and adding specialized capabilities within the organization.

You have biologicals (vaccines), contract research (Indus Biotherapeutics) and recombinant products in pipeline (besides Neukine)? What is your core area of focus?
Currently our focus is on recombinant products. We launched Neukine, recombinant G-CSF a few months back and we have a rich pipeline of products that we expect to bring to the market at regular intervals. Two of our products, EPO and interferon alpha, are in advanced stages of development.

What is your marketing strategy for recombinant biologicals as companies are finding it difficult to market their products?
We don't perceive any unique difficulty in marketing biopharmaceutical products per se. Every product has its own challenges. Intas has a strong presence amongst the speciality segments like oncology, cardiology, nephrology, neurology and gastroenterology, which are some of the high growth segments. All our major biotherapeutic offerings are for such speciality segments, wherein we will have a natural advantage due to our existing strengths.
Biotechnology products are complex products and we are confident that our offering of well characterized, quality products will find acceptance. One particular feature of biotech products is that they are usually high priced and affordability is an issue. We keep this factor in mind and try to provide products at an acceptable price level.

What is your R&D investment in biotechnology and turnover from these core areas?
We have invested upwards of $10 million in our biotechnology venture. Since this is our year of entry into the market, we expect the revenues to cross $1 million this year, and grow at a CAGR of over 50 percent over the coming five-six years. We expect a major portion of the revenues to come through exports.

When are you going to launch your biotechnology products in the regulated market outside India?
We have a focused strategy of starting with the Indian market, expanding to non-regulated market and then moving to the regulated market. We plan to target the regulated markets by about 2007.

What are your current capabilities in vaccines and biologicals?
We have in-house capability in the vaccines area but as of now we are not focusing on vaccines.

Are there any major hurdles that you are concerned with in biotechnology?
Developing biotechnology products is a slow and long process involving a number of scientific, financial and regulatory challenges, but there are no specific hurdles. We are quite happy about the recent initiatives taken by the government to rationalize regulatory procedures. We also hope that the government will ensure equally stringent scrutiny of imported biopharmaceutical products, as is applied to indigenously developed products, to provide a level field to research-based domestic manufacturers.

What are your future plans?
We are going to build excellence in product development and manufacturing. We are committed to bringing to the market one product about every six months. Starting with generic products, we will gradually move towards innovative products and having our own intellectual property. We intend to build these capabilities by strengthening in-house R&D as well as working through a network of domestic and international collaborations.