'We are growing our biosimilars capacity sixfold'

After slowing in the past couple of years, pharmaceutical major Lupin is back on the growth track in the US. It sees scope for its complex generics pipeline and is betting on first-to-file (FTF) opportunities for that market to ensure a reasonable market share. Set to enter the European market with biosimilars, it is now enhancing its manufacturing capacity sixfold at a greenfield plant in Pune. It's the Japanese market where it sees single-digit growth owing to the pricing regime. Lupin Managing Director **NILESH D GUPTA** explains the firm's strategies and says it is open to acquisitions in the US market, In a chat with **Sohini Das**. Excerpts:

The US is back on growth track. So, what is the way forward?

A few years ago, the US was about 45 per cent of our sales and now it is around 30 per cent. We had crossed $1 billion in revenue in the US about two-and-a-half years ago. Against that, we are at $800 million plus now. But we are back on the growth path. The last two years had seen a decline. This year, we had budgeted a single digit growth and clearly we are delivering on that plan. For complex generics, not more than three-four players will make it to the finish line. The truly complex products will not see the same degree of commoditisation. We are also very clear that we are not walking away from the plain vanila generics. If we are there on day 1 (in the US market), we will have sizeable market share. We would focus on first to file (FTF) opportunities, and Para III, we will file 25-30 products every year. We did 30-35 oral solids every year, we now do 15-20 products. The biggest part of the growth will come from injectables, inhalation products and biosimilars. For the next five years, in oral solids we see single-digit growth. Inhalation will be the biggest growth driver in the near term.

What role will Gavis play in your US growth?

Gavis is completely enmeshed in the Lupin structure. We do not call out Gavis separately anymore. There are products from Gavis that have moved to India and vice versa. Gavis timing was the most unfortunate, valuations were the highest and the opioid crisis had not kicked in. The FDA has now come down on the opioid crisis in a very meaningful way. We have evolved the portfolio over time. We would want to do more complex ones in controlled substances.

With multiple plants with official action indicated (OAI) classification from the USFDA, how does it affect future product approvals?

Three areas shine out in complex generics — inhalation, injectables, and biosimilars. The inhalation facility is all fine. It was inspected last year. The injectable facility is a new one and has never been inspected. We have not yet filed to the USFDA from that facility and same for biosimilars facility. None of these are impacted. So, complex generics facilities are those that are either not inspected or have gone through completely fine. Indore, Goa and Mandideep are all oral solids facilities and that's where we have the OAIs. We have four OAIs now, nothing to be proud of. OAIs hold up approvals and generics business are built on new products. We hope that at least two of these OAIs we should reverse by the end of the year. There is a few months of work that we need to do before we offer them for re-inspection.

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Why do you think there has been a flurry of OAIs off late for Indian players?

So far as classification of an OAI is concerned, this is a new practice. In the old practice, you had to have pretty much a warning letter when a facility would be classified as OAI. Typically, before the FDA would classify an inspection, it would go through the entire review process, then a warning letter would be issued. Then, it would be classified as OAI. In the new practice, within 90 days you get a determination. The whole process is supposed to be faster, including classification and approval. I attend every FDA inspection that happens. I could get a lot of insight into people.

Now that you are looking at launching biosimilars in Europe, are you building capacities?

We are doing a major capacity expansion for biosimilars by growing it sixfold. At Pune, we are doing a greenfield set up adjoining to the existing site. This would be dedicated only to biosimilars and active pharmaceutical ingredients (APIs). The facility will be ready next year to launch biosmilars in Europe.

After a series of acquisitions till 2017, you have slowed down. Any plans for inorganic growth?

If you go back 15 years, Lupin was a company that had more revenue from APIs than from finished products. We had no business in the US and India was mostly acute (therapy) drugs. Exports were only 10 per cent of our total revenues. From there came the expansion phase – we build the US business. We were primarily into APIs in the US and we started finished products. We started Japan, South Africa, Australia, Brazil, and Mexico. To ensure we had substantial on-shore presence in these markets, this geographic expansion needed acquisitions. We are done with the geographical footprint expansion about three years ago. The acquisition priority now remains US specialty drugs and India. In India we would be interested in acquisitions in dermatology or urology where we do not have much presence.

How has the price control regime and push for generic generic changed the domestic market strategy?

I would not attribute the market growth or degrowth to the national list of essential medicines alone. It's for a bunch of other factors as well. Jan Aushadi and generic generic play are taking bigger bites of the market in terms of volumes. We are still getting 3-4 per cent increase for price controlled products. We participate in government tenders. We don't supply to Jan Aushadhi at this point of time.

The Japan market has seen price control getting stringent. What is the outlook?

The people who exited the Japan market are the peripheral players. If you are below $30-40 million, then one does not have the scale or efficiencies and it does not make commercial sense. We are the No. 5 player in that market and its 14 per cent of our revenues. The market has changed to a more generic generic market. The focus has to be on efficiencies — R&D and manufacturing — at the right costs and then commercialisation. We manufacture a lot of products for our Japan market at our Goa plant. From a volume perspective, the market keeps growing at 10 per cent. From a value perspective, it's a single digit growth at best. The main reason is price cuts.