Date	:	July 26, 2016
Publication	:	Mint

KIRAN MAZUMDAR-SHAW/BIOCON

Latin America, Middle East are key EMs for our biosimilars

By Reema Tendulkar & Sonia Shenoy
CNBC-TV18

INTERVIEW

Biocon chairman and managing director Kiran Mazumdar-Shaw attributes the company's improved quarterly earnings to the performance of the biologics business and better margin contribution from other verticals as the company moves into the value-added business. "Our insulin and biosimilar Trastuzumab in emerging markets are the reasons why we are seeing very good margin growth and sales growth and of course as you know our biologics business has grown 53% on a like for like basis compared to last year," she said in an interview. Edited excerpts:

How do you foresee the rest of FY17 with respect to Biocon's revenues as well as margins?

As a company we don't give guidance but what I can say is that this quarter is a reflection of improved earnings largely due to the performance of our biologics business and we are also seeing a better margin contribution from our other verticals as we move into the value-added business. So, we are beginning to benefit a lot from biologics. Our insulin and biosimilar Trastuzumab in emerging markets is also a reason why we are seeing very good margin growth and sales growth and of course as you know our biologics business has grown 53% on a like-for-like basis compared to last year. You are also seeing that we are beginning to report segmentally in terms of small molecules, biologics and research services and branded formulations.

Can you also tell us about the geography-wise break-up of biosimilars' growth? Which are the emerging markets that have done well and also if you can give us which biosimilars have performed well this time around—whether it is Trastuzumab or even insulin glargine?

I cannot give you very detailed break-up in terms of geographies but all I can say is Latin America (LATAM) and Middle East are really the key emerging markets for our biosimilars and in this not just insulin glargine but insulin itself, recombinant human insulin and of course more recently Trastuzumab are also doing very well and emerging markets are becoming extremely important for these biosimilars, not just now but in the long term as well. Of course the most important realisation from our biosimilars portfolio will be when we see the US and European market opening up for us. We have just started the regulatory review process for Pegfilgrastim where we have sought marketing authorisation from European Medicines Agency (EMA) and soon this will be followed by a submission to US Food and Drug Administration (FDA) but as you know we also have other submissions to make both at EMA and US FDA for our Trastuzumab and Adalimumab and of course insulin glargine. So, this is a very important inflection point for Biocon's business. Having said that there is greater credibility being established for Biocon's biosimilars and you can see from the quality of data that we have submitted for our biosimilar Trastuzumab to the American Society of Clinical Oncology (ASCO) that we are becoming more and more confident of the way we actually address these very interesting and large opportunities.

Hemant Mishra/Mint

Market scope: *Kiran Mazumdar-Shaw.*

Since we are talking about insulin glargine, I just had a follow up on what the initial demand trends are in Japan post the launch, and you have also launched in Malaysia. So, what are the sales looking like over there and where else do you plan to launch?

Let me give you the right optics on insulin glargine. We have just announced that biosimilar glargine was launched in Japan only on 15 July. So, it is early days yet. What I could tell you is that Eli Lilly, which actually launched their biosimilar glargine ahead of us, has already basically seen a garnering of almost 20% of the Japanese market. So, we hope that Fujifilm Pharma can also garner a sizeable market share in the coming years. Having said that another important aspect of the launch of insulin glargine is that it is interchangeable. So, that actually gives us a good opportunity to garner that share and the market size is around $140 million in Japan and it will all sort of pan out in the coming years as to see how biosimilars do vis-à-vis the innovators and what kind of discounting the innovators will respond with. So, these are early days yet. Now, in terms of glargine we are already present in Mexico and many other emerging markets and there we are seeing very strong performance of biosimilar glargine, especially after the Japanese approval. So, we will open up more emerging markets as we go forward. The most important news that everyone will be tracking is when we submit our dossiers in Europe and US, and that as we have indicated will happen this fiscal. So, that is an important piece of optics for glargine. In terms of Trastuzumab as I have already mentioned, the ASCO data basically has given optics on the quality of our dossier that is going to be filed with US FDA and EMEA later this fiscal. We have launched and got approval of Trastuzumab in some of the emerging markets and we expect that also to do well. So, I will probably leave it to market developments to really show up on how these products will do over the coming quarters.

Let me ask you about your first biosimilar filing that you have done with the European authorities in partnership with Mylan. Could you give us some more detail, when is the approval likely to come for the same, what would be the market size, what is the deal with respect to revenue sharing with Mylan, what is the Mylan deal pipeline looking like?

Actually Pegfilgrastim dossier has been accepted and being reviewed and it could take anywhere between one year to maybe 18 months to get final approval and we therefore are excited to enter the European markets along with these timelines.

Now, Mylan is really going to be responsible for commercialising this product in Europe and US and in terms of the market opportunity this is again a $3-4 billion opportunity between Europe and the US and really it is up to Mylan to make sure that we garner as much as we can of these two addressable market opportunities. In terms of the arrangements that we have with Mylan certainly it is a profit-share arrangement that we have and of course as far as Biocon is concerned we also will be supplying the product for these markets. So, that is the arrangement that we have.

Can you throw a little more colour on the R&D expenses. They were lower this quarter but I have noticed that generally it tends to be a lumpy expense. One quarter is high, one quarter is low. On an average what would the R&D spends be, say over the next one to two years?

We basically indicated that R&D expenses are going to be in the range of about 12-14% of biopharma sales which means if you look at the numbers that we are reporting, it just means excluding research services the rest of the business will be the biopharma business per se and it will basically amount to 12-14% of this business. If you were to compare it on a year-on-year (Y-o-Y) basis it is very comparable. So, there hasn't been a decline of R&D spends on a Y-o-Y basis but if you were to compare it between Q4 FY16 and Q1 FY17 there is a small decline. But as you said this is a lumpy spend because you spend on R&D based on your clinical trials, based on various other research requirements of developing these products.