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

quarterly earnings to the performance of the biologics business and better margin contribution from other verticals as the company moves into the valueadded 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?

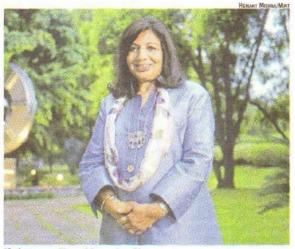
guidance but what I can say is also doing very well and emergthat this quarter is a reflection of ing markets are becoming improved earnings largely due to extremely important for these the performance of our biologics business and we are also seeing a better margin contribution from our other verticals as we from our biosimilars portfolio move into the value-added business. So, we are beginning to European market opening up for benefit a lot from biologics. Our us. We have just started the reguinsulin and biosimilar Trastuz- latory review process for Pegfilumab 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 Food and Drug Administration

INTERVIEW

basis compared to last year. You iocon chairman and man- are also seeing that we are aging director Kiran beginning to report segmentally Mazumdar-Shaw attrib- in terms of small molecules, bioutes the company's improved logics 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 As a company we don't give more recently Trastuzumab are biosimilars, not just now but in the long term as well. Of course the most important realisation will be when we see the US and grastim where we have sought marketing authorisation from European Medicines Agency (EMA) and soon this will be followed by a submission to US



Market scope: Kiran Mazumdar-Shaw.

(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 and large opportunities.

glargine, I just had a follow up on years. Having said that another where between one year to oping these products.

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 maraddress these very interesting ket. So, we hope that Fujifilm Pharma can also garner a sizea-Since we are talking about insulin ble market share in the coming

to garner that share and the lines. market size is around \$140 milsubmit our dossiers in Europe that we have. 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 that also to do well. So, I will probably leave it to market over the coming quarters.

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 deal pipeline looking like?

has been accepted and being trials, based on various other reviewed and it could take any- research requirements of devel-

important aspect of the launch maybe 18 months to get final of insulin glargine is that it is approval and we therefore are interchangeable. So, that actu- excited to enter the European ally gives us a good opportunity markets along with these time-

Now, Mylan is really going to lion in Japan and it will all sort of be responsible for commercialispan out in the coming years as to ing this product in Europe and see how biosimilars do vis-à-vis US and in terms of the market the innovators and what kind of opportunity this is again a \$3-4 discounting the innovators will billion opportunity between respond with. So, these are early Europe and the US and really it days yet. Now, in terms of glarg- is up to Mylan to make sure that ine we are already present in we garner as much as we can of Mexico and many other emerg- these two addressable market ing markets and there we are opportunities. In terms of the seeing very strong performance arrangements that we have with of biosimilar glargine, especially Mylan certainly it is a profitafter the Japanese approval. So, share arrangement that we have we will open up more emerging and of course as far as Biocon is markets as we go forward. The concerned we also will be supmost important news that every- plying the product for these marone will be tracking is when we kets. So, that is the arrangement

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 guarter 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 emerging markets and we expect biopharma sales which means if you look at the numbers that we are reporting, it just means developments to really show up excluding research services the on how these products will do rest of the business will be the biopharma business per se and Let me ask you about your first it will basically amount to 12-14% of this business. If you were to compare it on a year-onyear (Y-o-Y) basis it is very comparable. So, there hasn't been a decline of R&D spends on a to come for the same, what would Y-o-Y basis but if you were to be the market size, what is the compare it between Q4 FY16 deal with respect to revenue shar- and Q1 FY17 there is a small ing with Mylan, what is the Mylan decline. But as you said this is a lumpy spend because you spend Actually Pegfilgrastim dossier on R&D based on your clinical