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'We expect a turnaround in branded formulations in FY18'

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Biocon chairperson and managing director Kiran Mazumdar-Shaw. HEMANT MISHRA/MINT

Kiran Mazumdar-Shaw, chairperson and managing director of Biocon, said the firm is well poised to be a front runner in biosimilars. The acceptance of trastuzumab by the US drugs regulator is a milestone, she said, adding that the Malaysian facility would help Biocon address insulin supply challenges. Edited excerpts of an interview:

Revenue growth was spectacular, 29% on the top line. I wanted to focus on the biologics segment, that is insulins, as well as your biosimilar business, that is showing good growth. What is the trajectory going ahead, what kind of growth numbers can we look at because this year itself on a year-on-year (y-o-y) basis, it is a whopping 60%?

We have just announced that our Malaysia facility has been commercialized, has commenced commercial operations. This means that going forward Malaysia will be able to contribute to insulin sale. We have always been very challenged, with complete utilisation of our India facility, so this will add to our future sales in insulins. The offtake agreement that we signed with Malaysia is a big milestone for us. So this is a very important announcement that we have made but in addition to that what we also wanted to continue to do is to basically deliver on our other biologics. Our trastuzumab sales have been ramping up and we have also announced the acceptance of our biosimilar trastuzumab dossier by US FDA (Food and Drug Administration). That is another significant milestone for us. This coming fiscal is going to be a very important fiscal for us because there are potential approvals that we can expect in many emerging markets and possibly even from European Medicines Agency (EMA). So this is going to be a very exciting time for Biocon and Mylan. We expect that our biologics' performance is going to continue to ramp up in the years ahead.

Can you tell us how much do you think the Malaysian facility could contribute by way of revenues in the coming calendar year now that you have started the commercialisation of it and, secondly, you made a reference to some of the potential approvals from EMA etc, could you give us some more details on that?

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I can only comment on the fact that we have disclosed the offtake agreement value, which is 300 million ringgit, which in dollar terms translates to approximately $75 million over a three-year period extendable by an additional two years, but suffice to say that there are other opportunities for commercial supplies from Malaysia coming from emerging markets and we are on track to be inspected by some of these emerging market regulators after which we can start supplying from Malaysia to these markets as well. This is a very important signal because Malaysia will cater to some of the challenges we have had of catering from India. So I think these are very important signals that I can share with you at this point in time. In terms of regulatory approval, it is very difficult for me to make any comments because regulatory approvals are very sensitive. We are just hoping that we might get some approvals later this year from EMA but that is up to regulatory reviews and approvals thereof.

You were talking about trastuzumab. That is clearly the big talking point and that is what analysts are looking at very closely but Roche has gone ahead and they have started trials... the street is a bit worried. Will that be eating into market share? What is your take on the same?

There is going to be a lot of analyst and market speculation but it remains to be seen what impact it will have on trastuzumab because trastuzumab is a very important molecule. There are going to be a lot of pricing discussions around any new molecule and I think trastuzumab continues to be a very important therapy for breast cancer patients and depending on what the data looks like for other molecules—I am very confident that trastuzumab will continue to have a very important market opportunity as a biosimilar.

You are also gearing up for the commercial launch of your cholesterol lowering pill, Crestor generic. We know it has got a huge opportunity but how much could Biocon realise, any early estimates of that now?

I would say it is not going to be as large an opportunity as it has been for other companies that have had 180-day exclusivity. We were not the first-to-file in terms of Rosuvastatin generic. So I would say that it is just an opening of our generic's innings. It is not going to be significant in terms of revenues or profitability but the fact is that we are supplying Rosuvastatin active pharmaceutical ingredients (API) to many of these companies for the US market. So as a company I don't think this is going to be a huge needle mover in terms of generics business but just that it is the first off the table so to speak.

I wanted to ask you about the Middle East. I remember quite a few quarters ago that was a bit of a niggling worry. So what is happening on that front, have things recovered? Just looking through your numbers, your branded formulation sales, that is up only 18%. Eighteen percent is not a small number but in comparison to everything else, that seems it is a bit of a drag, so what is the trajectory out there?

Branded formulations has been a challenging business for us largely on account of leadership issues. We have put into place some of these concerns. We have a good head of branded formulations who has just assumed his responsibilities a few months ago. So we are expecting a turnaround to happen next fiscal. So yes, a bit disappointing in terms of branded formulations but in the overall scheme of things, there is so much going on in the business that branded formulations will take some time to pick up.