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KIRAN MAZUMDAR-SHAW/BIOCON

Syngene is set to continue growth momentum

INTERVIEW

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CNBC-TV18

Syngene International has delivered good business, said Kiran Mazumdar-Shaw, chairman and managing director, Biocon Ltd. Syngene is Biocon's research services subsidiary.

The contract research and manufacturing organisation has invested robustly in some of its anchor client businesses. Its clinical business has also begun to gain traction, she added.

In March, Japan agreed to market and sell Biocon's biosimilar insulin Glargine from the first half of FY17. Shaw said this move will help the company enter large emerging markets like South Africa, Brazil, Russia and Turkey. She expects these markets to give Biocon sales upwards of $100 million from FY18. During the Q4 of FY16, Biocon spent ₹100 crore at a net level in R&D, and Shaw says she doesn't expect this mark to go any higher. Biocon's R&D team is working on the second phase of the development of oral insulin (IN-105), and Shaw hopes that it will become an approved product in the next 2-3 years.

I wanted to ask you about Syngene and the scorching pace at which we have seen the growth this time—32% growth on the topline. What led to that and is that something that you can sustain through the course of FY17?

Syngene has had a very strong run thus far because all its basic strategic growth drivers are really driving good business and as you know, Syngene has been investing in some of its anchor client business very robustly and this is panning out very well for Syngene. The Bristol-Myers Squibb (BMS) business continues to drive good growth, followed by Baxter, Abbott and Amgen. So they are getting good traction on this kind of large business opportunity. But, added to that are some of these very differentiated offerings in the area of chemical synthesis and a large-scale manufacturing opportunity that are beginning to start realising and driving good growth.

Their clinical services business is also beginning to gain some traction and as you know, Syngene enjoys an impeccable track record in terms of regulatory approvals from the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and other international agencies and all this has augured very well for Syngene and there is a tremendous amount of confidence that pharmaceutical companies and non-pharma companies are buying into in terms of Syngene's research services model. So, I feel that Syngene is well poised to really carry on with a strong growth momentum.

I was actually more interested in what you can do with Glargine. That is what the analysts and experts are kicked about. You have crossed the first big hurdle, now it is a quantum leap. But, give us some numbers for this quantum leap. What does it mean for new geographies, what does it mean in terms of revenues for FY17-FY18?

Let me answer this question in two parts. First and foremost, as you know, the Japanese approval means we can actually start marketing this product this fiscal and our partners FUJIFILM Pharmaceuticals have indicated that this should happen in the first half of this fiscal. So, we will see our product in the Japanese market this fiscal which is a great milestone for us.

Weighing opportunities: *Kiran Mazumdar-Shaw, chairman and managing director, Biocon Ltd.*

But as you very rightly said, this also opens up many doors for us. In many large emerging markets which were thus far not accessible because they would not just accept Indian data and the Indian dossier, we are now going to be able to realise our entries into South Africa, Turkey, Russia and many other large emerging markets—where we believe the opportunity is significant.

In addition to that, we are also all set to submit our dossiers to both EMA and US FDA this fiscal and that of course, will require a review period, so we will not be in the market this fiscal, but that basically, will be another big event to watch out for because that again, signals our inevitable entry into these very important markets.

As a large global opportunity, you do know that Glargine is the second biggest blockbuster category drug in the pharmaceutical market. And, this is an opportunity, an addressable market size of around $8 billion. And of course, Biocon and Mylan will play very aggressively to see what part of this addressable market they can garner.

You told us in detail about your plans for Glargine and the fact that it is on the edge of getting permissions from US FDA as well as emerging markets. I was looking for slightly more clarity in terms of numbers, visibility. In FY17 and at least FY18, what can this do to the stock, to the company?

As you know, we are addressing a very large global opportunity. Insulin Glargine, as an opportunity is upwards of $8 billion as an addressable market. But most parts of this market opportunity is going to open up in FY18 and beyond.

So, if I was to basically focus on the market opportunity, ahead of that opportunity, then I would say that we are really looking at Japan and some of the key emerging markets like South Africa, Brazil, Russia and another key emerging markets like Turkey, etc.

Now, collectively, these could offer Biocon an opportunity of upwards of $100 million and that is the kind of addressable market that we are trying to realise over the next two years just ahead of the US, European opportunity which could be significant thereafter.

So, we are very well-positioned in the insulin space to be a big player.

And you know we are betting very big on this because we have invested big time in Malaysia, India, and we think that considering the fact that there are very few players in the biosimilar insulin space, where really Lilly and Biocon are the only players apart from the originators, we have a huge opportunity going ahead.

I wanted to ask you about the R&D (research and development) costs. It is one of the highest that you have recorded in quarters gone by indicating that yes, you are looking at more research and development down the line in terms of your pipeline. How much can we expect in terms of an average run rate in terms of R&D costs and where exactly are they being utilised?

The quarter spend has been the highest to date. We have spent ₹100 crore at a net level and ₹152 crore at a gross level and this almost reflects between 15 and 23% of bio-pharma revenues which is a very significant spend in R&D. We expect this is a sort of 'hit the top of the spend' rate that we anticipate.

So, I do not think you will see a much higher spend in R&D rates going forward because as you know, we are sort of coming to the end of big-ticket spends on many of our biosimilar programmes. As you know, we have indicated that we will be submitting our dossiers for many of our big ticket spends—Glargine, Pegfilgrastim, Trastuzumab, Adalimumab—in FY17.

So, you can basically get some sort of optics on how these R&D spends have been surging over the last few quarters. So, going ahead, you are likely to see these levels being sustained but equally, I do not think you are going to see much greater spends in R&D going forward. Having said that, you must realise that these are very important investments for Biocon because these are going to deliver very high growth opportunities for Biocon going forward.

And as I keep reiterating, the return on investment on these kinds of investments is going to be significant for Biocon—starting with the Japanese approval, which, you saw, has gone down very well with investors.