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KIRAN MAZUMDAR-SHAW

The growing share of biosimilars revenue is doing wonders for our business

With approvals and commercialised biosimilars in markets such as the US and EU, Biocon is confident of achieving its targets for FY19. In an interview with **Srinath Srinivasan**, its Chairperson and Managing Director **Kiran Mazumdar-Shaw** talks about the additions to the company's portfolio by which it is setting store

AS ASIA'S LEADING BIOPHARMA ENTERPRISE, BIOCON HAS BUILT GLOBAL CREDIBILITY WITH ITS SCIENTIFIC EXPERTISE, POSITIONING IT AHEAD OF THE CURVE ABOUT THE FIRST WAVE OF BIOSIMILARS FOR PATIENTS WORLDWIDE

Given the strong sales growth in Biologics, are you confident of meeting the $200-mn revenue target for the business in FY19?

We continue to stand by our guidance. The approvals and commercialisation of our biosimilars in the US, EU and key emerging markets have translated into accelerated revenue growth for the business. Having logged ₹1,066 crore (around $153 million) of Biologics revenue in the first nine months of FY19, we believe we are on way to meeting our $200-million revenue guidance for FY19.

What is the status of developed market approvals for your key biosimilar products?

As Asia's leading biopharmaceutical enterprise, Biocon has built global credibility with its scientific expertise and technological capabilities, positioning it ahead of the curve about the first wave of biosimilars for patients worldwide.

Biocon and its partner Mylan received EU approvals for Fulphila (biosimilar Pegfilgrastim) and Ogivri (biosimilar Trastuzumab) in the third quarter

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of FY19. Ogivri was also approved in Australia and Fulphila in Canada. Fulphila has been approved in the EU, Canada and Australia and commercialised in the US. Ogivri has been approved in the US, EU and Australia. Semglee, our Insulin Glargine, is now approved in Australia and commercialised in the EU.

How is the increasing contribution of biosimilar sales aiding your operating margins?

The higher contribution of biosimilars to overall revenues has significantly improved the quality of our earnings. Biocon's year-to-date earnings for FY19 have more than doubled over last year, driven largely by the higher-margin biosimilars business. The Biologics segment's EBIT margins saw a huge improvement in Q3FY19, going up to 30%. This saw the consolidated EBITDA margin expanding to 26% in Q3FY19 from 23% a year earlier.

What progress have you made in the pipeline of novel drugs?

Our existing novels portfolio has diverse assets. In addition to the orally delivered Insulin Tregopil, we have included monoclonal antibodies against novel targets like CD6, and against established targets like CD20 and EGFR.

Our novel anti-CD6 monoclonal antibody, Itolizumab, has moved ahead on its clinical development trajectory. Our partner Equillium, which acquired the US and Canadian rights to the asset, is planning to initiate a phase 1b/2 clinical trial for EQ001 (Itolizumab) in early 2019. In our internal discovery programme, we have advanced towards creating a pipeline of bispecific fusion antibodies that exploit recent understanding of the role of checkpoint inhibitors.

How is the small molecules business tackling pressure from generics commoditisation in the US?

Our small molecules business grew 27% y-o-y in Q3FY19 and 20% y-o-y in the first nine months of FY19. The strong performance in Q3 was led by higher sales of our core APIs to Europe, Latin America and India-based customers that use our drug substances to formulate products for the US market and robust growth in the US Generic formulations business.

Our generic formulations business grew sevenfold in Q3FY19, led by the successful launch of Atorvastatin Calcium tablets in the US and increased penetration of our Rosuvastatin and Simvastatin formulations launched earlier.

WHILE OUR MATURE APIs PORTFOLIO IS DELIVERING GOOD GROWTH, THE NEWER PORTFOLIO OF GENERIC FORMULATIONS IS BEGINNING TO MAKE AN IMPACT

How are you pushing growth and profitability in the branded formulations business?

The branded formulations business, of which sales in India and the UAE are a part, reported revenue growth of 36% y-o-y in Q3FY19. We have always focused on creating large anchor brands comprising specialty molecules in chronic therapy segments. This strategy is working well, with the top 10 brands of our India portfolio growing 26% y-o-y in Q3FY19. As a specialty products company, 70% of our overall India business is now accounted for by biologics/biosimilars products. In the UAE too, the business reported strong growth.

How much do you expect to spend on R&D in FY19?

The first nine months of FY19 saw our net R&D expenses grow 20% y-o-y to ₹198 crore and gross R&D, 10% y-o-y to ₹314 crore, primarily on account of increased spending in the biosimilars and insulin analogs development programmes. As guided earlier, we expect full-year gross R&D spends to be in the range of 12-15% of revenues ex-Syngene.