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Biocon's Malaysia facility on path to break even in FY19

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Biopharmaceutical major Biocon, which recently posted a fivefold net profit growth at ₹3.55 billion for the quarter ended September 30, riding on exceptional income, is on the path of breaking even at its Malaysian insulin facility in the current financial year.

The Bengaluru-based firm said Malaysia site was making good progress in receiving approvals for both the facility and products from various regulatory agencies globally, including European Medicine Agency and TGA, Australia. "This will help us aiming for operational break-even at Malaysia, after excluding R&D expenses in FY19," said Arun Chandavarkar, chief executive officer and joint managing director, Biocon.

In FY18, Malaysia had reported an operational loss of $5 million at a standalone level, when excluding the impact of R&D. Chandavarkar said the company was also making good progress in generating additional clinical data to support the manufacturing site change of insulin Glargine from Bengaluru to Malaysia. Biocon is also not anticipating any delay on the approval and launch time of Glargine in the US market, likely by early 2020, as all required activities agreed upon with the Food and Drug Administration (FDA) is in line according to the company.

Insulin Glargine is the first biosimilar from India to be approved and launched in Japan. It has also received regulatory approvals in the developed markets of EU and Australia.

Meanwhile, Biocon's US partner Equillium is working on clinical data for a rare disease (acute graft-versus-host disease (aGVHD)). This assumes significance as the Biocon-Mylan's cancer drug Pegfilgrastim faces increased competition in US.

According to an IIFL report, Coherus BioSciences, a California-based biotechnology firm, has received US FDA approval for its drug Udenyca (Pegfilgrastim). This is a copy of Amgen's drug Neulasta and is a competition to Fulphila (Biocon-Mylan's Pegfilgrastim biosimilar).