Q&A
with the CFO

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Financial **Endurance**

Adjusting for the impact of a decrease in licensing income in FY18, Biologics segment revenues grew by 28% during the year.

How will you describe the overall financial performance of Biocon this year?

During the year FY18, consolidated revenue grew 6% to ₹43,359 million (vs ₹40,787 million in FY17). Revenue growth was primarily led by the Research Services business, which grew 19% to ₹14,231 million (vs ₹11,925 million in FY17). Biologics business at ₹7,702 million, reported growth of 10% from ₹7,018 million in FY17. However, adjusting for the impact of a decrease in licensing income in FY18, Biologics segment revenue grew by 28% during the year. Branded Formulations business, which includes sales in India and UAE, grew 11% to ₹6,115 million (vs ₹5,489 million in FY17). Revenue from the Small Molecules business decreased 8% to ₹15,077 million (vs ₹16,405 million in FY17).

Earnings before Interest, Taxes, Depreciation and Amortization (EBITDA) declined 9% to ₹10,353 million (vs. ₹11,366 million in FY17) and Net Profit decreased 39% to ₹3,724 million (vs. ₹6,121 million in FY17). The overall profitability for FY18 was largely impacted due to pricing pressures in the generics business, lower licensing income in biologics, planned shutdown of biologics fill finish plant for requalification post regulatory audits and inclusion of fixed and operating costs relating to the Malaysia facility.

Revenue:	EBITDA	Profit for the year	R&D Spends Gross:
43,359	10,353	3,724	3,804
₹ Million	₹ Million	₹ Million	₹ Million

In FY19, we expect gross R&D spends to be approximately 15% of revenues, ex-Syngene.

With Biocon receiving approvals for biosimilars in large markets like U.S. and EU, do you expect a significant ramp-up in Biologics segment revenue? How will biosimilar sales in developed markets aid revenue growth and margins in the consolidated P&L statement in FY19?

FY18 witnessed significant progress of our global biosimilars pipeline, as we received approvals in the U.S. for Trastuzumab and in the EU for Insulin Glargine. We also received multiple approvals in the emerging markets through various partners. We expect a significant portion of Biologics revenue growth in FY19 to come from the emerging markets on the back of recent and expected approvals. We also expect launch of biosimilars in developed markets during FY19.

Higher sales of products in FY19 will help boost Biologics segment margins which will be partly offset by increased R&D expenses on biosimilars and novel biologics. At the consolidated level, we expect our core margins percentage, i.e. EBIDTA margins net of licensing, forex gain/ loss and R&D expenses, to be broadly similar to core margins percentage in FY18.

You had guided for fixed expenses of around USD 48 million for the Malaysia facility in FY18. Is this likely to change this year? When do you expect the facility to break even?

At the beginning of FY18, we had guided that fixed expenses, including depreciation and finance costs related to the Malaysia plant, totaling approximately USD 48 million annually would be charged to the P&L account. With an offset of a portion of these costs through product sales in Malaysia and other emerging markets and utilization of facility towards R&D activities, we had expected a loss at the Malaysia standalone level. In FY18, Malaysia reported an operational loss of USD 5 million at a standalone level, excluding R&D expenses for Insulin products, which are also booked in the legal entity P&L. In FY19, we project fixed expenses to be USD 50 million on account of an increase in operating expenses. During FY19, we expect to receive additional facility and Insulin product approvals from various regulatory agencies globally while our partner Mylan is expected to launch Insulin Glargine in Europe and Australia. As a result of these, we expect an operational breakeven in Malaysia in FY19, when excluding R&D expenses.

Do you expect the trend of soft realizations on the licensing income front to continue?

Licensing income relates to upfront or milestone payments received from the licensing of our Biologics and Small Molecule products globally and is dependent on the number and the timing of new products being developed. Over the last few years, a significant portion of licensing income accrued from Small Molecule products, recombinant human Insulin (rh-Insulin), Trastuzumab and Insulin Glargine dossiers. These products have already been licensed in major markets till FY17 and, as a result, the licensing income has reduced from ₹1,451 million in FY17 to ₹228 million in FY18. Given the current development pipeline, we expect licensing income in FY19 to be around similar levels as FY18.

What is your estimate for R&D spends in FY19? Does this factor in the expenses due to new biosimilar programs with Sandoz?

In FY18, gross R&D expenses were ₹3,804 million, representing 14% of our revenues from operations, ex-Syngene. In FY19, we expect gross R&D spends to be approximately 15% of revenues, ex-Syngene. The increase in R&D expenses will primarily be on account of advancements in our Small Molecules and Novel Molecules pipeline.

R&D activities for Small Molecule APIs and Generic Formulations are expected to pick up in FY19 compared to the slow pace in the last two years. On the Novel Molecules front, a Phase II/III clinical study for Insulin Tregopil is being conducted in India on Type 2 diabetes

We plan to fund our capex through a combination of internal accruals, additional debt, partial monetization of our stake in Syngene and contribution from our partner, Mylan.

patients, dosing for which commenced in FY18. In addition to this, we expect to initiate a multiple ascending dose study in Type 1 patients, in partnership with U.S. based JDRF in FY19. In addition to these two clinical programs, we also expect spends towards other Novel Molecules in our portfolio.

R&D spends on biosimilar molecules are expected to be at the same level as in FY18. The new biosimilar molecules that we have added to the pipeline with Sandoz are in early stages of development. The R&D expenses for these molecules will increase significantly once they enter the clinic in the coming years.

Will you continue to capitalize R&D spends? How can investors track capitalized R&D spends for the Company?

In accordance with requirements of Ind-AS 38: Intangible Assets, product development costs are capitalized as intangible assets based on the recognition parameters by the Company. We disclose such R&D spends capitalized on a quarterly basis as part of the financials fact sheet. While we do not provide break up of the amount being capitalized at the molecule level, total capitalization can be tracked on the balance sheet as 'Intangible assets under development' under non-current assets.

With biosimilars approvals coming in developed markets, do you plan to make fresh investments in capacity expansion in FY19? How do you plan to fund this capex?

In FY18, we initiated construction of our second antibodies facility in Bengaluru to cater to the biosimilars pipeline in line with our projected capacity requirements. This facility will entail an investment of approximately USD 200 million and the cash outflow will be in two phases, spread over four years.

In addition to the above, we have also planned for upgradation of existing assets at the end of their useful life largely in our insulins drug substance facility in Bengaluru.

Excluding Syngene's capex and capitalized R&D/ intangible assets, we expect cumulative capex spend in FY19 and FY20 to be approximately ₹14 billion.

We plan to fund this through a combination of internal accruals, additional debt, partial monetization of our stake in Syngene and contribution from our partner, Mylan.

Going forward, will Biocon continue to fund its high-margin Biologics business from the revenue generated from its Small Molecules business? Or you will have to look at alternate sources?

Thus far, cash flows from the Small Molecules business have funded our biologics programs. Going ahead, however, we would like the Biologics business to be self-funded.

Operating cash flows from the Biologics segment will ramp up once our biosimilar products are commercialized in the U.S. and EU. We will also consider raising equity capital by unlocking value of our biosimilars business at an appropriate time. These factors coupled with additional debt to fund the capex will significantly reduce dependency of funding from the traditional Small Molecules business.