Q3’FY25 Q&A

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Radiopharmaceuticals

Q1. Can you talk about growth in Ruby-Fill®?

Answer: Ruby-fill® is a best in class Positron Emission Tomography (PET) radiopharmaceutical product used for Cardiac imaging through a non-invasive procedure of the myocardium, to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease. Our product is superior due to longer shelf life leading to more scans per generator, better and consistent image quality due to the patented saline push feature and multiple safety features.

Our Ruby-fill® franchise has been witnessing strong growth. We have witnessed strong installations in Q3'FY25. Overall, we expect to continue to gain market share in the US cardiac PET market.

Q2. Can you talk about the sales of SPECT product portfolio in Q3'FY25?

Answer: We continue to maintain strong position in our SPECT portfolio. We are happy with the offtake of our new products. We expect the new products to reach their normalised market share within a couple of years.

Q3. What is the timeline of the MIBG Launch? What is the patient recruitment status & expected date of result?

Answer: MIBG is targeting paediatric patients with high-risk Neuroblastoma. Neuroblastoma is a type of cancer that forms in certain types of nerve tissues. The incidence of Neuroblastoma in the US market is estimated at 800 new cases per year and the relapse / refractory cases are estimated at 400 per year.

MIBG clinical trials are progressing well. We have completed the dosing of Phase two trials. Launch timelines are subject to regulatory approvals and we expect the launch of MIBG to happen in CY 2026 for relapse / refractory cases, post US FDA approval.

Q4. Can you give us some more colour on the product pipeline?

Answer: We have a very strong pipeline of products in SPECT (Addressable Market at approx. USD 50 million) & PET (Addressable Market at approx. USD 500 million) categories in the medium term. On top of it, in the therapeutic, we are working on MIBG.

Q5. Can you explain Q3'FY25 Radiopharmaceutical results?

Answer: Q3'FY25 revenue grew 10% YoY to Rs. 265 Cr. on the back of growth in Ruby-Fill ® and new product Sulphur Colloid. Q3'FY25 EBITDA flat YoY at Rs. 125 Cr. due to change in product mix however overall 9M'FY25 EBITDA increased YoY by 5% to Rs. 370 Cr.

Radiopharmacy

Q6. What are the growth levers in this business, particularly, can you talk about USD 50 million investment that you plan to make in this business?

Answer: The PET Imaging market is growing rapidly on the back of new products so there is a need to position the company in this growing PET imaging market.

In that regards, we are pleased to share that we have started the commercial distribution of PYLARIFY®, which is an industry leading prostate cancer diagnostic imaging agent, through two of our PET radiopharmacies.

We also announced USD 50 million investment to expand our PET radiopharmacy network to nine (9) sites and therefore positioning us to secure long-term contracts with the leading PET radiopharmaceutical manufacturers. These new PET radiopharmacies shall be fully operational in FY28 and shall start to contribute significantly to the top line and bottom line. We expect a RoCE in excess of 20% on our investment.

Q7. Can you explain Q3'FY25 Radiopharmacy results?

Answer: Q3'FY25 revenue grew 13% YoY to Rs. 576 Cr. on the back of increase in volume from new products, however revenue growth got impacted by Industry wide Technetium shortage. Q3'FY25 EBITDA stands at Rs. 5 Cr., lower YoY due to Industry wide Technetium shortage during the period. 9M'FY25 EBITDA increased by 35% YoY to Rs. 24 Cr.

Allergy Immunotherapy

Q8. What are the growth levers in this business? Particularly, how do you plan to grow outside US business?

Answer: We have three growth levers in place.

1. US Venom growth: As you are aware, we are the sole player in this segment in the US, we will grow by expanding the segment through increased customer awareness.

2. Grow revenues in US Non-venom: We are leveraging our position in the venom segment to increase customer wallet share through portfolio selling.
3. Outside US Markets: Our strategy is to enter new markets in Europe, MEA and APAC, particularly for Venom products. Each market requires a different regulatory strategy. We plan to invest in select markets with lower upfront investment. We plan to build market by market either through strategic partnerships, where our partner would hold market authorisation or build a local presence and hold market authorisation.

Q9. Can you explain Q3'FY25 Allergy immunotherapy results?

Answer: In Q3'FY25, Revenues grew by 7% on YoY basis to Rs. 171 Cr. Q3'FY25 EBITDA stands at Rs. 48 Cr. Q3'FY25 EBITDA margin decreased YoY due to weakness in exports and production challenges for specific SKU's. Production challenges have been solved and normalized production has resumed. We anticipate outside US sales to gradually improve. We expect EBITDA margins to revert to normalised levels, starting from Q4'FY25.

CDMO Sterile Injectable

Q10. Can you talk about the overall demand scenario in the sterile fill and finish market?

Answer: The global CDMO Sterile fill and finish market is expected to grow from USD 13 billion in 2023 to USD 20 billion by 2027 at a CAGR of 11%. The demand drivers include an increasing number of injectables in the development pipeline driven by biologics and an increase in loss of exclusivities.

As big pharma is focused on internalising only select capabilities, this increase in demand is being outsourced to specialised CDMO Sterile fill and finish companies.

The drug shortages in the injectables in the US are signalling that the demand still runs higher than the supply of the capacity and therefore there is a need of significant new capacity.

The Biosecure Act and the Catalent acquisition by Novo Holding shall further widen the gap between demand and supply in the US. In particular, a recent McKinsey report highlighted a 6.8Bn demand vs. 6.1Bn supply specifically for sterile vials – a 700 Mn. sterile vial shortfall.

Q11. What is the project status of the expansion project in Spokane? What is the maximum revenue potential for Line 3 & 4 and how much time it shall take to fill up the lines?

Answer: The capacity expansion program in Spokane, Washington, USA is on track with respect to time and cost. We are pleased to share that we have successfully completed Media-Fills at Line 3. The technology transfer programs are underway. The commercial production at Line 3 is expected to start post approval by FDA in late FY26 or early FY27.

The revenue potential for Line 3 and Line 4 combined is estimated at USD 160 to 180 million. Typically, as seen in the Industry, it takes four years to reach optimal capacity utilisation post commercialisation. As we are seeing shortages in the US Injectables market, we are making an effort to fill up the new capacity much faster than the industry average timeline. Also, we expect to clock higher than normalised EBITDA margins on the incremental revenue from Line 3 and Line 4 on the back of improved pricing due to newer technology and lower incremental overheads.

The technology transfer programs that have started at Line 3, shall generate cash inflow. We shall apply for FDA approval in FY26 and post the approval, commercial production shall start.

Q12. When did Montreal facility restart operations?

Answer: Pursuant to the USFDA audit observations and in light of recently issued new and stringent cGMP guidelines for sterile fill and finish manufacturing facilities, we implemented corrective and Preventive actions (CAPA's) in our manufacturing set up at Montreal facility. Once the CAPA implementation was complete, we restarted sterile injectables operations successfully in middle of Q3'FY25 and are stable now. We plan to return to production for ophthalmic line in H1'FY26.

Q13. Can you explain Q3'FY25 CDMO Sterile Injectables results?

Answer: Q3'FY25 revenue is stable YoY at Rs. 306 Cr. Montreal facility restarted operations in this quarter and operated for partial quarter. EBITDA grew by 38% YoY to Rs. 51 Cr. Q3'FY25 EBITDA margins increased YoY however decreased QoQ due to semi-annual shutdown.

CRDMO – Drug Discovery

Q14. We have seen an impressive revenue growth in Drug Discovery services? Can you talk about it the growth trajectory going forward?

Answer: We are bullish on the mid and long term prospects of the CRO industry in India due to talent availability & gradual shifting of demand due to the preference for friend "sourcing" locations due to Biosecure ACT. We are increasing our partnership with large Pharma companies doing, leveraging our infrastructure, capacity and capabilities expanded during last two years. As a testament, we on boarded three large pharmaceutical companies in last one year.

We are well prepared to further scale up Infrastructure and scientific talent to take advantage of the upcoming in CRO demand. We expect revenue growth to continue on the back of our large pharma strategy and the industry tailwinds.

Q15. Can you talk about the partnership with Pierre Fabre?

Answer: We have announced a strategic partnership with Pierre Fabre, France. Under this partnership, Jubilant Biosys Innovative Research Services Pte Limited, Singapore ('JBIRSPL'), subsidiary of Jubilant Biosys Limited, a wholly owned subsidiary of the company has executed the transaction definitive agreements with Pierre Fabre SA, and its affiliate entities ("PF"), for JBIRSPL to acquire 80% equity capital in JASMIN (new company incorporated in France, as a Société par Actions Simplifiée (SAS), 100% owned by Pierre Fabre). Jasmin shall acquire Pierre Fabre's R&D Centre (Including R&D Site and R&D activities) at Saint Julien, France upon closing of the transaction.

This strategic partnership will enable Jubilant Biosys to expand its footprint in Europe in areas like Biologics (mAbs) and Antibody Drug Conjugate (ADC), in addition to its existing services including integrated drug discovery services from India.

Q16. Can you explain Q3'FY25 CRDMO Drug Discovery results?

Answer: In Q3'FY25, the Drug Discovery business revenue grew by 32% to Rs. 150 Cr and EBITDA grew by 27% to Rs. 39 Cr. Q3'FY25 revenue increased sharply YoY due to increase in revenue from new contracts from large Pharma customers.

CRDMO – API

Q17. Can you explain Q3'FY25 CRDMO API results?

Answer: The API business reported revenues of Rs. 142 Cr., growth of 3% YoY. Q3'FY25 EBITDA stands at Rs. 20 Cr. EBITDA margins improved by 620 basis points YoY to 14%

due to cost optimisation and improvement in product mix. Industry wide pricing pressure still continues.

Generics

Q18. Can you explain Q3'FY25 generics results?

Answer: After becoming profitable in Q2'FY25, the profitability improved in Q3'FY25. Overall 9M'FY25 EBITDA margin stands at 8%. The success of turnaround strategy is based on continuous quality improvement, reduction in overall cost and scaling up profitable products. Q3'FY25 revenues remained stable YoY at Rs. 200 Cr. Reported EBITDA stands at Rs. 30 Cr.

Q19. Can you tell us your plans for new product launches?

Answer: We plan to launch six to eight products per annum in our US and non-US international markets. There are 33 ANDAs in the approval pipeline for the US. We have got approval for 3 ANDAs in FY25.

In line with our communication, we are ramping up exports to the US markets from our Roorkee facility in a meaningful and gradual manner. We have also started supply of products from our Contract manufacturing partners to the US market in line with our plan.

Q20. Can you talk about USFDA audit at Solid dosage formulation facility at Salisbury?

Answer: Company's subsidiary, Jubilant Cadista Pharmaceuticals Inc., solid oral formulations facility at Salisbury, Maryland, USA was inspected by the United States Food and Drug Administration (USFDA) in Jan'25. USFDA has issued five observations with no repeat observations. Jubilant Cadista will submit an appropriate action plan to the USFDA on these observations within stipulated time.

Going forward, the said facility is not expected to manufacture any products as it has closed manufacturing operations as was referenced in the previous disclosure dated April 18, 2024.

Prop Novel Drugs

Q21. What is the status of clinical trials of your lead programs JBI-802 and JBI -778?

Answer: We continue to dose patients in global clinical trials involving both of our lead programs, Phase II trial for JBI-802 for Essential Thrombocythemia (ET) and select Myeloproliferative Neoplasms (MPN), and Phase I trial for JBI -778 for non-small cell lung cancer (NSCLC) and high grade Glioma.

For JBI-802, Phase 1 clinical data established safety and further, dose dependent platelet effect was seen in the clinic at higher doses, establishing application in Essential Thrombocythemia (ET) and other Myeloproliferative Neoplasms (MPNs). In light of these, we have started a phase II clinical trial to treat ET and MPN patients with thrombocytosis (high platelets). The phase I trial also showed anti-tumour response in two lung Cancer patients with a good safety profile. One Non-small cell lung Cancer patient with STK11 mutations, having progressed on prior doublet IO therapy, showed a confirmed partial response (tumour reduction). Generally, the survival rate is very low in such cases, however, the patient has responded well to JBI-802 monotherapy and continues to be on treatment for over a year. Therefore, additional investigator led clinical trials in NSCLC and post MPN AML are being discussed with multiple institutions to obtain a larger patient data.

Q22. Why the EBITDA losses has reduced in 9M'FY25 as compared to 9M'FY24?

Answer: We are focussed on 2 key clinical stage projects only and are investing in a calibrated manner with many trials done outside US.

Consolidated Financials

Q23. Can you talk about exceptional items in Q3'FY25 ?

Answer: Q3'FY25 exceptional items mainly includes expenses pursuant to temporary suspension of manufacturing operations for remediation of OAI at CMO Montreal.

Q24. What is the outlook for revenue and EBITDA for Q4'FY25?

Answer: In 9M'FY25, Revenue grew by 7% on a YoY basis to Rs. 5,306 Cr., EBITDA grew by 24% YoY basis to Rs. 873 Cr. and Net debt to EBITDA improved from 2.5x in Mar'24 to 1.4x in Dec'24.

In Q4'FY25, we shall continue to work on these three financial priorities, which is to continue the revenue growth momentum, to expand EBITDA margins and improve net debt / EBITDA.

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