

Q1 2021

1. Research and Development (R&D) and Innovation

- **Narrative:** Aurobindo Pharma's management highlighted significant investments in R&D, particularly in biosimilars and vaccines. They discussed timelines for clinical trials and regulatory filings for various products, including a COVID-19 vaccine and other biosimilars for both the US and European markets. There was also mention of the development and filing of new MDIs (metered dose inhalers).

- **Management's Guidance:**

- **Biosimilar Filings:** The company planned to file one biosimilar in Europe by the end of 2021 and another by the first quarter of 2022. Subsequently, they anticipated filing at least two more biosimilars annually in the US and Europe. **COVID-19 Vaccine:** Capacity for the company's COVID-19 vaccine was expected to be ready in phases. Phase I and II trials were planned by the end of 2021, with the commercial facility aiming for completion by March-April 2022 for Phase III trials. **Other Product Filings and Launches:** The company aimed to file approximately 50 new products during the fiscal year. They also planned for launches of 30 new products in the U.S. by the end of 2021. **New Injectable Plant:** A new injectable plant for Europe and emerging markets was projected to be operational within 15 months. **R&D Expenditure:** A budget of approximately Rs. 800 crore was allocated for R&D, including Rs. 360 crore for specific projects. There was discussion about the possibility of lower R&D expenditure if clinical trials were delayed due to COVID-19.

- **Actual Results:**

['Q4', '2021']:

- The provided data for Q4 2021 shows R&D expenditure of Rs. 457 crore (7.6% of revenue) for the quarter and Rs. 1,510 crore (6.1% of revenue) for the fiscal year. There is no information on specific biosimilar filings, COVID-19 vaccine trial progress, or the number of new product filings and launches achieved during Q1 2021.

['Q1', '2021']:

- R&D expenditure was Rs. 254.5 crore (4.3% of revenue) in Q1 2021. A provision of Rs. 60 crore was made for R&D assets developed by a third party. The company filed 14 ANDAs with the USFDA, including 3 injectables. They received final approval for 10 ANDAs. They filed 3 DMFs with the USFDA. One MDI inhaler was filed.

['Q3', '2021']:

- The provided Q3 2021 data does not offer direct comparison to the specific biosimilar and vaccine timelines. However, it does indicate R&D expenditure of Rs. 390.5 crore (6.1% of revenue) in Q3 2021. The number of ongoing clinical trials is mentioned, with Phase I completion and commencement of Phase III trials for an oncology product (BP01).

['Q2', '2021']:

- In Q2 2021, R&D expenditure reached Rs. 408 crore (6.3% of revenue). Clinical trials commenced for biosimilar products, with spending of approximately \$3-4 million in the previous quarter and \$17 million in Q2 2021.

- **Evaluation:**

- **{'evaluation': 'Did not meet expectations', 'evaluation_reason': "The Q1 2021 actual results for biosimilar filings and the COVID-19 vaccine are not reported, and the R&D expenditure was significantly lower than the budgeted Rs. 800 crore, falling short of the company's ambitious R&D plans for the year."}**

2. Financial Performance and Outlook

- **Narrative:** Management provided forward-looking statements about revenue growth and cost reduction initiatives. There was also commentary on debt reduction.

- **Management's Guidance:**

- **Revenue Growth:** A 15% increase in revenue was projected for the next fiscal year. **Cost Reduction:** A plan to reduce operational costs by 10% over the next two quarters was mentioned. **Debt Reduction:** Management indicated that net debt would continue to be reduced, although the reduction rate might not be consistent across quarters. **Return on Capital Employed (RoCE):** A pre-tax RoCE of 15% was targeted by the end of the next fiscal year.

- **Actual Results:**

['Q4', '2021']:

- Q4 2021 results show varying revenue growth rates depending on the source and segment reported. Some sources indicate 8% YoY revenue growth for the full fiscal year, while others mention 8% YoY growth for the full year and 2% year-on-year growth for formulations in Q4. There's mention of a 5% YoY revenue increase in Q4 FY21. The data does not provide information on operational cost reductions, net debt reduction, or RoCE achieved in Q1 2021.

['Q1', '2021']:

- Revenue increased by 8.8% year-on-year in Q1 2021. Net profit increased by 22.8% year-on-year. US revenue grew by 15.6% YoY. On a constant currency basis, revenue grew by 6.5% YoY.

['Q3', '2021']:

- In Q3 2021, revenue from operations showed an 8% YoY growth (Rs. 6,364.9 crore). While the overall revenue growth was not 15% as guided, there are numerous data points showing different growth rates for segments. The actual gross margin was 59.6% in Q3 2021. EBITDA before forex and other income increased by 13.3% YoY to Rs. 1,368.6 crore, with a margin of 21.5%.

['Q2', '2021']:

- In Q2 2021, revenue increased by 16% year-on-year to Rs. 6,483 crores. Operational costs were reduced by 8% in the same period.

- **Evaluation:**

- **{'evaluation': 'Partially Met expectations', 'evaluation_reason': 'While revenue growth was positive, it fell short of the 15% target for the fiscal year. Information regarding cost reduction, debt reduction, and RoCE is missing for a complete evaluation of the financial outlook for Q1 2021.'}**

3. Supply Chain and Capacity Expansion

- **Narrative:** Aurobindo Pharma addressed the increasing demand for its products and the need to expand capacity. They discussed investments in API (Active Pharmaceutical Ingredient) modules to free up existing capacity and mentioned plans for new manufacturing facilities.

- **Management's Guidance:**

- **Capacity Expansion:** Investments were made to increase capacity for viral vaccine production to 300-350 million doses per year, and a bacterial vaccine facility was being established with initial capacity of 50 million doses, scalable as needed. **New Manufacturing Facilities:** A new plant in the US was expected to be ready for production in early 2022. A dedicated injectable facility near Vizag was also under construction for Europe and other markets. **API Module Investment:** Investment in two to three large-volume API modules was planned to address surging demand.

- **Actual Results:**

['Q4', '2021']:

- The Q4 2021 data mentions the US plant being in production. There's no specific information about the actual capacity achieved for viral and bacterial vaccine production or the progress of the injectable facility near Vizag in Q1 2021.

['Q1', '2021']:

- No specific quantifiable results regarding capacity expansion or API module investments are available from the provided data for Q1 2021.

['Q3', '2021']:

- Q3 2021 data shows no direct metrics on capacity expansion for vaccines or new facilities. However, there is mention of a 15% increase in production capacity over the past two years, suggesting progress in overall capacity expansion.

['Q2', '2021']:

- No specific quantifiable results related to capacity expansion or new facilities are available in the provided Q2 2021 data.

- Evaluation:

- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': 'The provided Q1 2021 data lacks specific quantifiable results to assess the progress of the capacity expansion and API module investments.'}

4. Regulatory Approvals and Time to Market

- **Narrative:** The company provided timelines for regulatory filings and approvals for biosimilars, vaccines, and other products.

- **Management's Guidance:**

- This is largely covered under the R&D and Innovation theme above, as the guidance is intricately linked to R&D activities.

- **Actual Results:**

['Q4', '2021']:

- In Q4 2021, Aurobindo filed 9 ANDAs with the USFDA and received final approval for 9 ANDAs (including 3 injectables). They also filed 1 DMF with the USFDA.

['Q1', '2021']:

- Results are largely covered under the R&D and Innovation theme. The company received final approval for 10 ANDAs in Q1FY21.

['Q2', '2021']:

- In Q2 2021, Aurobindo received GMP certificates from European, Japanese, and Brazilian regulatory authorities for Unit-11 after completing remedial measures.

- **Evaluation:**

- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': 'The evaluation of regulatory approvals is intrinsically linked to the R&D theme and lacks specific independent data for Q1 2021 to assess against specific targets beyond the ANDA approvals.'}