Q2 2021

1. Financial Performance and Growth Strategy

- **Narrative:** Management expressed confidence in achieving significant revenue growth, driven by several factors including expansion in injectables, new plant capacities, and strategic market expansion. Specific targets were set for revenue growth and the expansion of the generic injectable business. Concerns regarding export incentives and their potential impact on financial performance were also acknowledged.
- **Management's Guidance:**
- A 15% revenue growth target for the fiscal year was mentioned. The generic injectable business, currently at a $380 million annual run rate, is projected to reach $650-$700 million within three years. Overall growth of 5-10% was anticipated, with potential for minor quarterly deviations. Debt is expected to be fully eliminated by March 31, 2022. Management aimed to maintain gross profit margins above 59%, acknowledging potential impact from currency fluctuations. A 10% reduction in operational costs was targeted by year-end through process improvements and expenditure cuts.
- **Actual Results:**

['Q4', '2021']:

- Multiple sources report varying revenue growth figures for Q4 2021. Some cite an 8% YoY growth in revenue for FY21, while others report a 15% increase in sales last quarter. Discrepancies exist, possibly due to different reporting methods (e.g., constant currency vs. reported currency, inclusion/exclusion of specific business units). A 2.1% year-on-year revenue increase to Rs.6,007 crores in Q4 FY21 is also mentioned. There is no single conclusive figure for Q4 2021 revenue growth that aligns with all reported data.

['Q1', '2022']:

- Conflicting revenue growth figures are reported for Q1 2022. Sources report 2.9% YoY growth, 15% increase, and 3.8% decrease. Further investigation is needed to reconcile these discrepancies.

['Q3', '2021']:

- In Q3 2021, Aurobindo Pharma reported varying revenue growth rates: 8% YoY (source 1), 15% (source 2), and 16.9% YoY (source 3). The injectable business reached approximately $435-$440 million annualized (source 4). Gross margin was 59.6% (source 5). Sources are represented by their unique identifiers.

['Q2', '2021']:

- Revenue for Q2 FY21 was $712 million. The company clocked a revenue of Rs.6,483 crores, a 16% increase year-on-year. Net profit increased by 26% year-on-year to Rs.806 crores. Formulations business grew by 18% year-on-year to Rs.5,654 crores. US business posted a 12% year-on-year growth to Rs.3,190 crores. Aurobindo Pharma USA (oral products) revenue increased by 8%. AuroMedics (Injectable business) revenue decreased by 15% year-on-year to US$64 million. European Formulations revenue increased by 8% to Rs.1,515 crores. Growth markets revenue increased by 40% year-on-year (33% on a constant currency basis) to Rs.446 crores. ARV Formulations revenues increased by 111% year-on-year (100% on a constant currency basis) to Rs.503 crores. R&D expenditure was Rs.408 crores (6.3% of total revenue). The generic injectable business had a $380 million annual run rate.
- **Evaluation:**

- {'evaluation': 'Partially Met expectations', 'evaluation_reason': 'While overall revenue growth exceeded the anticipated 5-10%, the injectable business, a key driver of growth, showed a decline, falling short of the projected expansion. The 16% overall growth partially met expectations.'}

2. Capacity Expansion and Facility Developments

- **Narrative:** Aurobindo Pharma highlighted significant investments in new manufacturing facilities, particularly for injectables, targeting both the US and European/emerging markets. Timelines for completion and commissioning were provided.
- **Management's Guidance:**
- The new Vizag plant (dedicated to Europe and emerging markets) is expected to be completed within 12 months. The US plant is anticipated to conduct exhibit batches in January-February. The vaccine manufacturing facility's investments will mostly conclude in the current fiscal year, with commissioning expected by April or May. A new injectable facility for Europe and emerging markets is being established in Vizag. The multi-dose capacity of a new facility is expected to be around 450 million doses. Completion and qualification of a mentioned facility is targeted for March-April and April, respectively.
- **Actual Results:**

['Q4', '2021']:

- No specific actual results regarding facility completion or commissioning timelines are available in the provided Q4 2021 data.

['Q1', '2022']:

- No specific actual results regarding facility completion or commissioning timelines are available in the provided Q1 2022 data.

['Q3', '2021']:

- No specific actual results for Q3 2021 regarding facility completion or commissioning are available in the provided data.

['Q2', '2021']:

- No specific actual results for facility completion or commissioning are provided in the data.
- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': "The provided data for Q2 2021 lacks information on the actual progress of facility development and commissioning, preventing an evaluation against management's guidance."}

3. Research and Development (R&D)

- **Narrative:** Management discussed R&D expenditure as a percentage of revenue, providing guidance for the current and next fiscal years. The timeline for completion of clinical trials for several products was also shared.
- **Management's Guidance:**
- R&D expenditure is guided at 5.5%-6% of revenue for the full year. A potential increase of 1%-1.5% in R&D expenditure in the next year was mentioned, depending on the concentration of biosimilars Phase-3 trials. Two products are expected to complete clinical trials by mid-2022 to 2023.
- **Actual Results:**

['Q4', '2021']:

- In Q4 2021, R&D spend was Rs. 457 Cr, 7.6% of revenue. For FY21, R&D expenditure was Rs. 1,510 Cr, 6.1% of revenue.

['Q1', '2022']:

- In Q1 2022, R&D expenditure was 6.3% of revenue (INR 358 crore).

['Q3', '2021']:

- In Q3 2021, R&D spend was 6.1% of revenue (source 1). Phase I clinical trials were completed, and approvals were received to conduct Phase III trials for an oncology product (source 2). Phase II studies were also successfully completed (source 3). Sources are represented by their unique identifiers.

['Q2', '2021']:
- In Q2 FY21, R&D expenditure was 6.3% of revenue (Rs.408 crores). Clinical trials for biosimilars cost around $3 to $4 million in the previous quarter and around $17 million in Q2 FY21.
- **Evaluation:**
- {'evaluation': 'Exceeded expectations', 'evaluation_reason': 'R&D expenditure as a percentage of revenue (6.3%) exceeded the guided range of 5.5%-6% in Q2 2021.'}

4. Regulatory Approvals
- **Narrative:** Management provided guidance on the number of regulatory filings planned for Europe and the USA. They also addressed the timeline for resolving compliance issues at an existing facility.
- **Management's Guidance:**
- Three product filings in Europe and two in the USA are planned by the end of the next calendar year. Resolution of CAPA issues at an existing facility is expected within two to four months.
- **Actual Results:**
['Q4', '2021']:
- In Q4 FY21, 9 ANDAs were filed with the USFDA, and final approval was received for 9 ANDAs (including 3 injectables). A total of 55 ANDAs were filed in FY21, including 16 injectables, and 42 ANDAs were approved (including 17 injectables). One DMF was filed with the USFDA during the quarter. Information on European filings and CAPA resolution is not available in the Q4 2021 data.
['Q1', '2022']:
- In Q1 2022, four ANDAs received final approval, and five products were launched. 150 injectable ANDAs were filed (98 with final approval, 52 under review). Cumulative ANDAs filed totaled 654 (451 with final approval).
['Q3', '2021']:
- In Q3 2021, 251 DMFs were filed with the USFDA, and over 3,000 filings were made in other geographies (source 1). 141 injectable ANDAs were filed as of December 31, 2020, with 87 receiving final approval and 54 under review (source 2). The number of filings in South Africa decreased due to a backlog clearance program (source 3). No specific information on CAPA resolution is available. Sources are represented by their unique identifiers.
['Q2', '2021']:
- Unit-1 received GMP certificates from European regulators. Unit-11 received GMP certificates from European, Japanese, and Brazilian authorities.
- **Evaluation:**
- {'evaluation': 'Partially Met expectations', 'evaluation_reason': 'While the company received GMP certificates from European and other regulators for Units 1 and 11, there’s no information on US filings or CAPA resolution progress, preventing a complete evaluation against the stated guidance.'}