Q3 2023

1. Research and Development (R&D) Pipeline and Spending
- **Narrative:** Management highlighted the maturation of its Biosimilars pipeline, with three products in Phase III clinical trials. One is nearing completion, and two others are in progress with significant recruitment already achieved. A significant investment (USD 250 million) is planned for the Penicillin G project.
- **Management's Guidance:**
- R&D expenditure for the fiscal year is projected to be between 6% and 6.5% of revenue. Clinical expenditure for Biosimilars is expected to continue for at least another 6-7 quarters.
- **Actual Results:**
['Q1', '2024']:
- R&D spend was Rs 388 crore in Q1FY24, 5.7% of revenue. There is mention of an ongoing two plus one dosing trial in about 550 children.
['Q2', '2024']:
- In Q2 2024, R&D expenditure was Rs. 300 crores (approximately USD 36 million), representing 4.2% of revenue. Multiple clinical trials were ongoing, including advancement of BP11 into a global Phase 3 study and completion of Phase 1 and 3 studies for BP01 and BP02 respectively.
['Q4', '2023']:
- Research & Development spend was Rs 410.7 crore in Q4FY23 (6.3% of revenue). One biosimilar clinical trial (Trastuzumab) completed the treatment phase in 690 subjects.
['Q3', '2023']:
- R&D spend in Q3 FY23 was Rs 415.2 crore (6.5% of revenue), up from Rs 275.6 crore (4.8% of revenue) in Q2 FY23. Biosimilars contributed significantly to this increase, with expenditure rising from Rs 75 crore in the previous quarter to Rs 180 crore in Q3.
- **Evaluation:**
- {'evaluation': 'Met expectations', 'evaluation_reason': "R&D spending in Q3 FY23 reached the high end of the projected range (6.5% of revenue), and biosimilar spending increased significantly as anticipated, aligning with management's guidance for continued investment over several quarters."}

2. Regulatory Approvals and Commercialization Timeline
- **Narrative:** Management discussed the anticipated timelines for regulatory approvals and subsequent commercialization of several products. This includes an antibody product, a PCV vaccine, and a monoclonal antibody targeting India, Emerging Markets, Europe, and the US.
- **Management's Guidance:**
- The antibody product is expected to have at least one quarter of sales in the next fiscal year, contingent on Q2 approval. The PCV vaccine's commercialization is planned for two quarters after receiving the manufacturing license (anticipated in April-May). Filing for the monoclonal antibody is slated for July in India and Emerging Markets, September with the European Medicines Agency, and December with the USFDA. The first US biosimilar approval is anticipated in 2025.
- **Actual Results:**
['Q1', '2024']:
- No specific actual results for regulatory approvals or commercialization timelines are provided in the Q1 2024 data.
['Q2', '2024']:
- Actual results regarding specific approvals and commercialization timelines for the antibody product, PCV vaccine, and monoclonal antibody in Q2 2024 are not explicitly provided in the data. However, data indicates some progress on the regulatory front with completed licensure trials and filings for BP13 and BP14. Additionally, a submission to the CHMP for one product and pending assignment of rapporteurs for a second are mentioned.
['Q4', '2023']:
- The provided data does not contain actual results for this theme in Q4 2023. Information on approvals and launches is available but does not directly correlate to the specific management guidance timelines.
['Q3', '2023']:
- No specific actual results for approvals or commercialization timelines are provided in the data for Q3 2023.
- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': "The provided Q3 2023 data lacks information on actual regulatory approvals or commercialization progress for the mentioned products, preventing an assessment against management's guidance."}

3. Financial Performance and Growth Projections
- **Narrative:** Management provided revenue growth targets for various segments and discussed expectations for future cash flow generation. Specific projections were made for Biosimilars, formulations, and the impact of new product launches.
- **Management's Guidance:**
- A 15% revenue increase in the Biosimilars segment is targeted by the end of the next fiscal year. A 10% growth in the formulations segment is anticipated for FY23. Double-digit sequential growth is expected in Q4 and Q1 of the next fiscal year. Conservative estimates project approximately USD 50 million in annual revenue from new products, potentially higher. The Penicillin G project (USD 250 million) is expected to generate cash flow starting in FY25, with positive cash flow anticipated in FY24 as well. Another projection suggests a revenue target of $121-$125 million for the next financial year.
- **Actual Results:**
['Q1', '2024']:
- Revenue from operations was Rs 6,851 crore, a 9.9% YoY increase. US revenue increased by 11.2% YoY and 8.5% QoQ to Rs. 3,304 crores. Growth Markets revenue increased by 12.9% YoY. ARV business revenue was Rs 190 crore. Formulation business grew 6.6% QoQ to Rs. 5,817.2 crores. API business revenue was 1,033.3 crores, a 14% YoY increase. Eugia Injectable US business revenue increased by 11.7% YoY and 11.4% QoQ to USD 80.1 million. Global Eugia Pharma Speciality sales were USD 122 million. Europe Formulations revenue was 1,836.8 crores, an 18.6% YoY increase. Net cash position, including investments, was USD 178 million.
['Q2', '2024']:
- In Q2 2024, Aurobindo Pharma reported a 25.8% year-on-year revenue increase to Rs 7,219 crore (approximately USD 870 million). US revenue (excluding Puerto Rico) reached USD 409 million, a 31% YoY and 7% QoQ increase. Net profit increased by 83.6% year-on-year to Rs 752 crores (approximately USD 90 million). EBITDA before forex and other income grew to Rs 1,403 crore (approximately USD 169 million), reflecting a margin of 19.4%.
['Q4', '2023']:
- Revenue from operations reached 6,473.0 crores in Q4FY23, an 11.4% year-over-year increase. US revenue increased by 11.6% YoY and 1.4% QoQ to Rs. 3,044.5 crores. EBITDA before forex and other income grew by 2.8% year on year to Rs. 1,002.2 crores. Net Profit increased to Rs. 505.9 crores.

['Q3', '2023']:
- In Q3 FY23, revenue was Rs 6,407 crore, a 6.7% increase YoY and 11.6% QoQ. US revenue increased by 9.3% YoY and 13.8% QoQ to Rs 3,001.2 crore (46.8% of consolidated revenue). Formulation business grew by 9.2% YoY and 14.3% QoQ to Rs 5,452 crore. API business revenue was Rs 955 crore (15% of total revenue). European formulation revenue reached Rs 1,701 crore, a marginal 4% YoY increase and 12.2% QoQ increase. Growth market revenue increased by 26% to Rs 499 crore. ARV business revenue was Rs 251 crore, a 61% YoY increase (47% in dollar terms).
- **Evaluation:**
- {'evaluation': 'Partially Met expectations', 'evaluation_reason': "While overall revenue showed growth exceeding the YoY guidance for FY23 formulations (9.2% vs 10%), the Biosimilars segment's performance and the overall revenue target for the next financial year cannot be evaluated based solely on Q3 data. Further data is needed to assess the full year performance against the annual targets."}

4. New Product Launches and Market Expansion
- **Narrative:** Management outlined plans for numerous new product launches and expansion into new geographical markets. This includes specialty products and ANDAs.
- **Management's Guidance:**
- The launch of 10 new specialty products is planned within the next two quarters. Approximately 40 ANDAs are expected to be commercialized over the next 12 months. An immunology biosimilar is planned for the US market by 2025-2026. Commercialization in EMEA is anticipated before the end of the next fiscal year for at least one product, with a second product launch possible in Q1 or Q2 of the following fiscal year. Similar timelines are projected for Canada.
- **Actual Results:**
['Q1', '2024']:
- 19 ANDAs received final approval and 15 products were launched in Q1 FY24. As of June 30th, 2023, there were 613 final ANDA approvals in the US.
['Q2', '2024']:
- Specific numbers of new product launches and ANDA commercializations in Q2 2024 are not detailed in the provided data.
['Q4', '2023']:
- 26 ANDAs received final approval and 10 products were launched during Q4.
['Q3', '2023']:
- No specific actual results for new product launches or market expansion are provided in the data for Q3 2023.
- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': "The Q3 2023 data lacks details on new product launches or market expansion, preventing assessment against management's guidance."}

5. Supply Chain and Capital Expenditure
- **Narrative:** Management addressed the timing of capital expenditures related to various projects.
- **Management's Guidance:**
- The arrival of materials for various projects is expected between April and June, with installation slated for July to September. Commissioning of several projects is anticipated to begin by March 31, 2024.
- **Actual Results:**
['Q1', '2024']:
- No specific actual results related to supply chain or capital expenditure timing are provided in the Q1 2024 data.
['Q2', '2024']:
- The provided data does not offer specific information on the completion status of these projects in Q2 2024. However, it does mention high capacity utilization for formulations suggesting supply chain is managing demand.
['Q4', '2023']:
- The provided data does not contain actual results for this theme in Q4 2023.
['Q3', '2023']:
- Freight costs saw significant reduction in Q2 and Q3. Civil works for a project were 75-80% complete, with purchase orders exceeding Rs 1,500 crore issued for mechanical and electrical components.
- **Evaluation:**
- {'evaluation': 'Met expectations', 'evaluation_reason': "The progress on civil works (75-80% complete) and significant purchase orders suggest the project is on track to meet the anticipated commissioning date by March 31, 2024, aligning with management's guidance on timing."}