Q4 2022

1. Research and Development (R&D)
- **Narrative:** Aurobindo's R&D expenditure as a percentage of revenue is expected to decrease from a historically high level to around 6% going forward. The company targets 20 filings and 20 launches annually. Specific timelines are provided for biosimilar filings and launches, with some projects expected to extend into 2024 or even 2025. There's an 80%+ confidence level in a complex injectable, but success isn't guaranteed until fully achieved. One oncology biosimilar is in global phase III trials, with filing expected in Q4 of the next fiscal year.
- **Management's Guidance:**
- R&D expenditure as a percentage of revenue will be around 6% going forward. 20 filings and 20 launches are targeted annually. Filing for an oncology biosimilar is expected in Q4 of the next fiscal year. Filing for another product is expected in late 2023 or early 2024 due to extensive clinical trials. Another product's clinical trial is expected to conclude in 2023-2024, with potential filing in Q4 2023-2024 or as early as Q3.
- **Actual Results:**
['Q2', '2023']:
- In Q2 2023, R&D expenditure was 4.8% of revenue (Rs 276 crore). A Phase III trial for an oncology biosimilar completed randomization of all subjects.
['Q3', '2023']:
- In Q3 FY23, R&D expenditure was 6.5% of revenue (Rs 415.2 crore), exceeding the projected 6%. A key driver was increased biosimilar investment (Rs 180 crore compared to Rs 75 crore in the previous quarter).
['Q1', '2023']:
- In Q1 2023, R&D expenditure was 5% of revenue.
['Q4', '2022']:
- In Q4 2022, R&D spend was 7.4% of revenue (Rs 431 crore). An immunology asset advanced to Phase 1 clinical trials.
- **Evaluation:**
- {'evaluation': 'Did not meet expectations', 'evaluation_reason': 'The R&D expenditure of 7.4% exceeded the guided 6%, and while an immunology asset advanced, no specific filings mentioned in guidance were completed in Q4 2022.'}

2. Regulatory Compliance
- **Narrative:** Aurobindo anticipates submitting exhibits for Depo products in FY23, with potential filing in FY24 (best-case scenario). Regulatory processes for various products (including a bacterial vaccine) are expected to commence in Q3-Q4 of the current year.
- **Management's Guidance:**
- Exhibits for Depo products will be submitted in FY23, with potential filing in FY24. Indian regulatory processes for certain products will be initiated in Q3-Q4 of the year.
- **Actual Results:**
['Q2', '2023']:
- In Q2 2023, the number of ANDA filings was reported as 756 as of September 30, 2022. A decrease in South Africa filings was also noted due to SAHPRA backlog clearance.
['Q3', '2023']:
- No specific Q4 2022 results related to the management guidance on Depo products or other regulatory submissions are provided in the Q3 2023 data. Information on ANDA approvals and filings is present, but does not directly address the management guidance provided.
['Q1', '2023']:
- In Q1 2023, management reported receiving final approval for 10 ANDAs and launching 7 products. Further information on specific Depo product submissions or other regulatory processes initiated in Q3-Q4 was not available in the provided Q1 2023 data.
['Q4', '2022']:
- In Q4 2022, final approval was received for 3 ANDAs, and 4 products were launched. 14 ANDAs were filed, including 3 injectables. A total of 727 ANDAs were with the USFDA cumulatively, with 505 having final approval. The second oncology biosimilar was submitted to the EMA.
- **Evaluation:**
- {'evaluation': 'Partially Met expectations', 'evaluation_reason': 'While the guidance regarding Depo product submissions and filings in Q3-Q4 is not directly addressed in the Q4 2022 results, the company did make progress on other regulatory filings and approvals, exceeding expectations in some areas.'}

3. Financial Performance
- **Narrative:** The company aims for 10% revenue growth in the next fiscal year through portfolio expansion and new market entry. Double-digit growth is expected for the injectables business, particularly specialty products (Oncology, hormonal, and general injectables). A 15% reduction in operational costs is targeted by year-end. The company hopes to increase EBITDA margin from 10-11% to 14-15%. For the specialty business, revenue is projected to reach $650-700 million by FY24.
- **Management's Guidance:**
- 10% revenue growth is targeted for the next fiscal year. Double-digit growth is expected for the injectables specialty business in the next year. 15% reduction in operational costs is targeted by year-end. EBITDA margin increase from 10-11% to 14-15% is hoped for. Specialty business revenue is projected to reach $650-700 million by FY24.
- **Actual Results:**
['Q2', '2023']:
- In Q2 2023, revenue was Rs. 5,739 crores, a decrease of 3.4% year-on-year. US revenue decreased by 11% YoY and QoQ. European revenue declined by 2.1% QoQ. EBITDA before Forex and other income was Rs. 836.9 crores. Net profit decreased to Rs. 409.4 crores for the quarter. One source reported a 15% increase in sales over the past year, while others reported 8% revenue growth in Q2 FY23.
['Q3', '2023']:
- In Q3 FY23, revenue increased by 6.7% YoY and 11.6% QoQ. Formulation business grew 9.2% YoY and 14.3% QoQ. US revenue increased by 9.3% YoY and 13.8% QoQ. EBITDA margin before Forex and Other income was 14.9%, exceeding the target range. Specific data on operational cost reduction is not explicitly provided in the Q3 2023 data.
['Q1', '2023']:
- In Q1 2023, revenue increased by 9.4% QoQ. EBITDA margin was 15.5%. Further details on operational cost reductions were not directly available in the Q1

2023 data.
['Q4', '2022']:
- In Q4 2022, revenue from operations declined by 3.2% QoQ to Rs 5,809 crores. Net profit decreased by 28.1% YoY and 4.7% QoQ to ■576 Crores. US revenue decreased by 4.5% YoY to Rs. 2,728 crore. EBITDA before Forex and Other income was Rs 974.4 crore, with an EBITDA margin of 16.8%. API business revenue increased by 15% YoY to ■913 crore.
- **Evaluation:**
- {'evaluation': 'Did not meet expectations', 'evaluation_reason': 'Q4 2022 showed a decline in overall revenue and net profit, falling short of the projected 10% growth. While the EBITDA margin exceeded expectations, this was not sufficient to offset the overall negative financial performance.'}

4. Market Position
- **Narrative:** Aurobindo is focusing on Oncology but has advanced an Immunology asset into Phase 1 trials, with potential for global Phase 3 trials by Q3-Q4, aiming for a top-three filing position by 2024-2025. There are no plans to expand in the oral side for at least three years. A product launch in the Indian market is expected in Q1 2023.
- **Management's Guidance:**
- Potential launch of a product into the Indian market in Q1 2023. Aiming to be in the top three to file an immunology product by 2024-2025. No plans to expand in the oral side for at least three years.
- **Actual Results:**
['Q2', '2023']:
- No specific Q2 2023 results directly address market share changes or competitive ranking in relation to the provided guidance. However, data on addressable market size for ANDAs related to the Eugia group was provided (US$ 25.82 Bn) in Q2 2023.
['Q3', '2023']:
- The Q3 FY23 data does not contain information directly related to the market launch in India, market share, or the competitive position in immunology.
['Q1', '2023']:
- In Q1 2023, management stated that they are number one in the US by prescription volume. Information regarding the Indian market launch or progress on the immunology asset was not directly provided in the Q1 2023 data.
['Q4', '2022']:
- A product launch in the Indian market occurred in Q1 2023.
- **Evaluation:**
- {'evaluation': 'Met expectations', 'evaluation_reason': 'The Indian market launch, although occurring in Q1 2023, met the expectation set for a launch in Q1 2023.'}

5. Innovation and Pipeline
- **Narrative:** Aurobindo is on track to launch three new biosimilar products by the end of 2023. Significant launches are expected to drive future growth. A new plant is starting production, focusing on dermatology, MDIs, and patches; filings for several products are underway.
- **Management's Guidance:**
- Launch of three new biosimilar products by the end of 2023. Production start at a new plant focusing on dermatology, MDIs, and patches by the end of the year.
- **Actual Results:**
['Q2', '2023']:
- In Q2 2023, management reported approximately 20 product launches for the year.
['Q3', '2023']:
- The Q3 FY23 data doesn't provide specific details on the number of biosimilar launches or the commencement of production at the new plant.
['Q1', '2023']:
- In Q1 2023, management reported launching 7 products in the US market. Information on the three biosimilar launches or the new plant's production start was not available in the provided Q1 2023 data.
['Q4', '2022']:
- In FY22, there were 11 launches.
- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': "The Q4 2022 data provides information on FY22 launches, not on the progress towards the three biosimilar launches targeted for 2023 or the new plant's status."}

6. Supply Chain Management
- **Narrative:** Significant capital expenditure (around ■1500 crores) is related to injectables, oral, and derma plants in the US. The oral plant is expected to be commissioned before the end of FY23, while the injectable plant might spill over to the next year. Vizag plant capacity will increase to 425 million tablets/capsules per month next year.
- **Management's Guidance:**
- Oral plant commissioning before FY23 end; injectable plant potentially spilling over to next year. Vizag plant capacity increase to 425 million tablets/capsules per month next year.
- **Actual Results:**
['Q2', '2023']:
- In Q2 2023, it was reported that approximately 55% of manufacturing had been moved to India. Details on the commissioning of the US oral and injectable plants and the Vizag plant capacity increase were not available. A 140,000 square feet manufacturing footprint with 10 KL capacity bioreactors for internal programs was mentioned. This may relate to the new plant but is not explicit confirmation of its completion or capacity.
['Q3', '2023']:
- The Q3 FY23 data mentions progress on the new plants (75-80% civil works completed, purchase orders issued for >■1500 crore), but doesn't confirm commissioning of the oral plant or provide an update on the injectable plant's timeline. There's no information on Vizag plant capacity increase. However, there is mention of significant freight cost reduction in Q2 and Q3.
['Q1', '2023']:
- In Q1 2023, management indicated an increase in production capacity over the last year to meet growing demand. Specific details on the commissioning of the oral and injectable plants or the Vizag plant capacity increase were not provided in the Q1 2023 data.
['Q4', '2022']:

- In Q4 2022, Vizag plant capacity was approximately 325 million tablets or capsules per month. Significant inventory reduction occurred over the past six months.
- **Evaluation:**
- {'evaluation': 'Did not meet expectations', 'evaluation_reason': 'The Vizag plant capacity increase to 425 million tablets/capsules per month was not achieved by the end of Q4 2022. There is no information on the commissioning of the oral plant.'}