

## Q2 2022

### 1. Research and Development (R&D) and New Product Launches

- **Narrative:** Aurobindo Pharma is actively pursuing its biosimilars pipeline and anticipates several key milestones in the near future. The company is also focused on expanding its product portfolio, particularly in injectables. There is a significant emphasis on increasing R&D investment to fuel innovation.

- **Management's Guidance:**

- Increased R&D investment (10% increase planned); Biosimilar development (three at different clinical trial stages, one potentially filed by next financial year, another advancing to Phase I trials in Q4 of current financial year, and another in the next financial year); Pneumococcal launch expected in India by Q3 of next financial year; MDI product launches (second in Q1 of next financial year, third filing by end of next year); 5-6 product approvals expected in next 3-6 months; Three additional product launches expected in next quarter.

- **Actual Results:**

**['Q1', '2023']:**

- The provided Q1 2023 data does not offer direct comparison to the specific R&D guidance given for Q2 2022. Q1 2023 R&D expenditure was 5% of revenue. Information on specific product launches or biosimilar milestones is missing from the Q1 2023 data.

**['Q3', '2022']:**

- In Q3 2022, R&D expenditure was Rs 393 crore (6.6% of revenue). The number of ANDAs achieved was 131 (CNS, CVS, and ARV). Further, 719 ANDAs were filed with the US FDA cumulatively, with 494 having final approval and 30 having tentative approval. A second Oncology biosimilar was filed with the European Medicines Agency in January 2022.

**['Q2', '2022']:**

- R&D expenditure was Rs 399 crore (6.7% of revenue). The number of ongoing clinical trials in the oncology Eugia portfolio included 55 products, with 12 filed and 9 launched. 28 products were filed with the USFDA, with 2 receiving approval. The Vizag plant had 50 general injectables in development, 12 of which were approved from Unit 4. 7 ANDAs (including 2 injectables and 1 505(b)(2) NDA) were approved. Filings included 27 ANDAs, including 5 injectables.

**['Q4', '2022']:**

- In Q4 2022, R&D spend was Rs 431 crore (7.4% of revenue). One important Immunology asset advanced to Phase 1 clinical trial in ANZ. The company received final approval for 3 ANDAs and launched four products. A second Oncology biosimilar was with the EMA.

- **Evaluation:**

- {'evaluation': 'Did not meet expectations', 'evaluation\_reason': 'While 7 ANDAs were approved, the 10% increase in R&D investment was not achieved (only 6.7% was reached), and specific milestones regarding biosimilar development and product launches mentioned in the guidance are not fully reflected in the Q2 2022 actual results, preventing a complete assessment.'}

### 2. Revenue Growth and Financial Targets

- **Narrative:** Aurobindo Pharma is confident in achieving its medium-term revenue aspirations. The company is targeting significant revenue growth through market expansion and product portfolio optimization. There's discussion around the contribution of the US plant and the impact of the new Vizag facility.

- **Management's Guidance:**

- Targeting 15% revenue growth for next fiscal year; Confident about reaching \$700 million in revenue by FY24 (includes sales from US plant and new Vizag facility, but excludes biosimilars and vaccines initially).

- **Actual Results:**

**['Q1', '2023']:**

- Q1 2023 revenue showed a 9.4% year-on-year increase. US revenue increased by 6.1% year-on-year and 6.2% quarter-on-quarter to US\$386 million. This falls short of the 15% target for the full fiscal year. Data on the Vizag facility's contribution is not available.

**['Q3', '2022']:**

- In Q3 2022, revenue from operations was Rs 6,002.2 crore, a 1% increase quarter-on-quarter. US revenue was US\$ 366.9 million.

**['Q2', '2022']:**

- Revenue from operations was Rs 5,941.9 crore, a 4.2% QoQ increase. US revenues were US\$ 401.4 million, a 10.3% QoQ increase. European formulations revenue increased by 10% YoY to Rs 1,662 crore (28% of consolidated revenue). Revenue from Growth markets formulations increased by 17.3% QoQ to Rs 386 crore (6.5% of revenue). ARV business revenue was Rs 145 crore (2.4% of revenue). API business revenue was Rs 781 crore (13.1% of consolidated revenue). US revenue increased by 6.9% YoY to Rs 2,967.6 crore (50% of consolidated revenue). On a constant currency basis, US revenue increased by 7.3% year-on-year to \$401 million. Sequentially, US business grew by 10% in US\$ terms and 10.7% on a reported currency basis. Global injectable sales were approximately \$105 million.

**['Q4', '2022']:**

- In Q4 2022, revenue was Rs 5,809.4 crore, a 3.2% QoQ decline. US revenue decreased by 4.5% YoY to Rs. 2,728 crore (47% of consolidated revenue). European revenue was largely flat YoY at Rs 1,541 crore (26.5% of consolidated revenue). Revenue from Growth Markets formulations increased by 28% YoY (6.7% of revenue). API business revenue increased by 14.9% YoY to Rs 913 Cr (15.7% of consolidated revenue). ARV business revenue increased by 51.5% QoQ to Rs 236 crore (4.1% of revenue).

- **Evaluation:**

- {'evaluation': 'Cannot be Evaluated', 'evaluation\_reason': 'The provided Q2 2022 data shows a sequential increase, but doesn't offer sufficient information to assess progress toward the 15% annual revenue growth target or the \$700 million FY24 goal.'}

### 3. Supply Chain Optimization

- **Narrative:** Aurobindo Pharma is actively working to optimize its inventory management and improve its supply chain efficiency. There's a focus on reducing lead times and improving inventory turnover.

- **Management's Guidance:**

- Inventory reduced by \$62 million, with plans to continue for at least another one or two quarters; Finalizing procurement for a specific raw material expected to take another 6 months, with procurement starting 9 months from the time of the statement; Vizag facility civil work expected to be completed by June of next year, with approvals expected by year-end.

- **Actual Results:**

**['Q1', '2023']:**

- Q1 2023 data does not directly address the inventory reduction target or raw material procurement timelines. There is mention of increased production capacity, but no specific figures related to the management's guidance. Information on the Vizag facility progress is unavailable.

**['Q3', '2022']:**

- In Q3 2022, inventory was reduced by \$100 million (quarterly) and \$175 million (yearly). The average raw material cost increased by about 4% during the quarter, and freight costs increased by more than 20% quarter-on-quarter.

**['Q2', '2022']:**

- Working capital was reduced by \$62 million during the quarter.

**['Q4', '2022']:**

- In Q4 2022, inventory was reduced by approximately \$200 million for the year. Oral plant capacity utilization in India reached approximately 70%, and overall utilization in India formulation plants was 68-70%. Distributor and US company inventories reached normal levels.

**- Evaluation:**

- {'evaluation': 'Met expectations', 'evaluation\_reason': "The Q2 2022 actual results directly reflect the management's guidance regarding inventory reduction of \$62 million."}

**4. Regulatory Approvals and Market Entry**

- **Narrative:** Aurobindo Pharma is actively pursuing regulatory approvals for its products, particularly in the US and Europe. Successful licensure trials have been completed for biosimilars.

**- Management's Guidance:**

- Engaging with EMA and filing a product in current financial year; Filings for one or two depot injection products expected by next year; Litigation settled, market share gains expected from 2023 onwards.

**- Actual Results:**

**['Q1', '2023']:**

- In Q1 2023, Aurobindo received final approval for 10 ANDAs and launched 7 products. Additional details on EMA filings, depot injection product filings, or the impact of the settled litigation are not provided in the Q1 2023 data.

**['Q3', '2022']:**

- In Q3 2022, the number of formulation approvals increased to 719 in the US, 3,559 in Europe, 362 in South America, and 130 in Canada (by December 21). API approvals were 258 in the US, 1,932 in Europe, and 164 CoS approvals (by December 21). Total formulation approvals across all regions were 4,850, and total API approvals reached 3,709 (as of December 21).

**['Q2', '2022']:**

- 27 ANDAs (including 5 injectables) were filed with the USFDA in Q2FY22. 7 ANDAs (including 2 injectables and 1 505(b)(2) NDA) were approved in Q2FY22. Unit I underwent inspection and responses were submitted within the stipulated time.

**['Q4', '2022']:**

- In Q4 2022, the company had 727 ANDAs with the USFDA (505 with final approval). 175 injectable ANDA filings (119 with final approval). A second Oncology biosimilar was with the EMA.

**- Evaluation:**

- {'evaluation': 'Partially Met expectations', 'evaluation\_reason': "The Q2 2022 results show progress with ANDA filings and approvals, but lack specifics on EMA engagement, depot injection filings, or the litigation settlement's impact, making a comprehensive evaluation impossible."}