

Q3 2022

1. Financial Performance

- **Narrative:** Management provided mixed signals regarding financial performance in Q3 2022. While some statements suggest a bottoming out of performance and anticipation of improvement, others indicate continued challenges and muted growth in certain areas. There's a strong emphasis on future revenue targets, both organic and inorganic.

- **Management's Guidance:**

- A revenue growth target of 15% by the end of the fiscal year is mentioned. A revenue target of \$500 million by the end of the fiscal year is also stated. A three-year goal of reaching 1,000 crore sales is mentioned, with a strategy including both organic and inorganic growth. A \$650-700 million run rate for the injectable business in FY24 is anticipated. Q3 is considered the bottom, with expectations of stabilization or improvement thereafter. Double-digit growth is expected for the next year. A steady and muted growth in Europe for FY23 is anticipated, with a pickup expected from FY24 onwards. The US injectable business is expected to improve in the coming weeks. A significant portion of the anticipated growth in the injectable business over the next two years will come from the US (75:25 US:Other markets ratio). A plan to cut operating costs by 10% in the upcoming quarter is mentioned. A goal to cut operational expenses by 15% in the next two quarters is set.

- **Actual Results:**

['Q2', '2023']:

- In Q2 FY23, Aurobindo reported consolidated revenue of Rs. 5,739 crores (a 3.4% YoY decrease). US revenue decreased by 11% YoY and QoQ to Rs. 2,638 crore (46% of consolidated revenue). European revenue declined by 2.1% QoQ to Rs. 1,516 crore (26.4% of consolidated revenue). The API business posted a revenue of Rs 969 Cr (a 6.9% QoQ increase, 16.9% of consolidated revenue). Growth Market formulations revenue increased by 4.9% QoQ (7.9% of revenue). ARV business revenue was Rs 164 crore (2.8% of revenue). Aurobindo Pharma USA revenue decreased by 19% YoY in USD terms. Eugia US (injectable business) revenue decreased by 27.6% YoY to \$49 million. Net profit for the quarter was Rs 409.4 crore. US revenue in Q2 FY23 was \$331 Million.

['Q1', '2023']:

- In Q1 2023, Aurobindo reported revenue from operations at Rs 6,235.9 crore, a 9.4% increase quarter-over-quarter. US revenue increased by 10.8% year-over-year and 8.9% quarter-over-quarter to Rs. 2,971 crore (47.7% of consolidated revenue). European formulation revenue decreased by 2.2% year-over-year to Rs 1,548 crore. API business revenue increased by 11.6% year-over-year to Rs 906 crore. EBITDA before Forex and Other income was Rs 964.7 crore, with an EBITDA margin of 15.5%. Net profit decreased by 9.6% quarter-over-quarter to INR 520.5 Cr.

['Q3', '2022']:

- Revenue from operations was Rs 6,002.2 crore (1% QoQ increase). US revenues were US\$ 366.9 million. US Formulations revenue decreased by 4.4% YoY to Rs. 2,745.2 crore (46% of consolidated revenue). Europe revenue increased by 1.4% YoY to Rs 1,694 crore (28% of consolidated revenue). API business revenue was Rs 1,010 crore (16.8% of consolidated revenue), showing 48% YoY growth. Growth Markets formulations revenue was largely flat YoY, growing 2.8% QoQ to INR 397 Cr (6.6% of revenue). ARV business revenue was Rs 156 crore (2.6% of revenue). Net profit was Rs 604.3 crore. EBITDA (before forex and other income) was Rs 1,016.3 crore, with an EBITDA margin of 16.9%. Formulation business declined 3.3% QoQ to Rs. 4,992 crores (83% of total revenue). Auromedics (injectable business) revenue decreased by 7% YoY to 63.2 million. R&D expenditure was Rs 393 crore (6.6% of revenue). Net cash including investments at the end of December 2021 was ~US\$ 211.1 million. The average Forex rate was Rs. 73.68. Net working capital reduced by \$137 million due to inventory reduction. Price erosion impacted revenue by approximately 45 million in Q3. Freight costs increased by around 8.5 million.

['Q4', '2022']:

- Revenue from operations declined by 3.2% QoQ to **■**5,809.4 crore in Q4 FY22. US revenues were US\$ 363.3 Million. API business revenue increased by 15% YoY to **■**913 crore. Net profit decreased by 28.1% YoY and 4.7% QoQ to **■**576 Crores. The formulation business declined by 1.9% QoQ to **■**4,896 crores. US revenue decreased by 4.5% YoY to Rs. 2,728 crore. Europe revenue was largely flat YoY at Rs 1,541 crore. Growth Markets formulations revenue increased by 28% YoY. The net working capital was reduced by about \$98 million for the quarter and \$126 million for the year, mainly due to inventory reduction. Overall volume increased by 6%, but pricing pressure continued. Aurobindo USA revenue decreased by 5% YoY; Auromedics (injectable) revenue increased by 4% YoY to \$70 million; European formulations revenue decreased by 0.8% YoY; Growth Markets revenue increased by 28% YoY; ARV business registered a 51.5% QoQ growth, but a 52% YoY decline. EBITDA before Forex and Other income was Rs 974.4 crore (16.8% margin). Net profit was Rs 576.1 crore. The average raw material cost increased by about 9% during the quarter, and freight costs were up by more than 10% YoY and QoQ. The average raw material cost increased by 18% year-on-year, and freight costs by 42%.

- **Evaluation:**

- {'evaluation': 'Did not meet expectations', 'evaluation_reason': 'While Q3 showed some positive aspects like API growth and a slight QoQ revenue increase, overall, the results fell short of the ambitious growth targets set by management for the fiscal year, particularly in the US formulations and injectables segments.'}

2. Research and Development (R&D)

- **Narrative:** Aurobindo is progressing with its biosimilar pipeline, with a key oncology biosimilar anticipated to be filed in the next financial year.

- **Management's Guidance:**

- Three more biosimilars are in different stages of phase III clinical trials. One oncology biosimilar, currently in phase III trials, will potentially be filed in the next fiscal year (Q3-Q4 timeframe).

- **Actual Results:**

['Q2', '2023']:

- In Q2 FY23, Aurobindo completed randomization of all 690 metastatic breast cancer subjects in its Phase 3 efficacy trial comparing its biosimilar to the innovator's product. R&D expenditure was Rs 276 crore (4.8% of revenue).

['Q1', '2023']:

- In Q1 2023, R&D expenditure was INR 310 Cr (5% of revenue).

['Q3', '2022']:

- R&D expenditure was Rs 393 crore (6.6% of revenue).

['Q4', '2022']:

- In Q4 of the last fiscal year, a key Immunology asset advanced to Phase 1 clinical trial in ANZ. A second Oncology biosimilar was filed with the EMA, as expected. R&D spend was Rs 431 crore (7.4% of revenue).

- **Evaluation:**

- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': 'The Q3 2022 actual results only report R&D expenditure; there is no information on the progress of the biosimilar pipeline, including the filing of the oncology biosimilar, making it impossible to assess whether expectations were met.'}

3. Regulatory Compliance

- **Narrative:** The company is facing ongoing regulatory challenges, particularly concerning Unit 1, which is under a warning letter.

- **Management's Guidance:**

- Aurobindo is working to resolve the issues with the FDA and aims to do so within the next year. Injectable launches will be subject to inspections and approvals.

- **Actual Results:**

['Q2', '2023']:

- No specific actual results regarding regulatory compliance were provided for Q2 FY23 in the given data. However, the number of ANDA filings was mentioned as 756 as of 30th September 2022.

['Q1', '2023']:

- In Q1 2023, Aurobindo received final approval for 10 ANDAs and launched 7 products. Unit VII (SEZ) Oral Formulations had 172 approvals, with 13 new filings. Regarding Unit Seven, management informed the stock exchange that it had been classified as VAI, and Unit 5 had been cleared.

['Q3', '2022']:

- The company filed 719 ANDAs with the US FDA cumulatively, with 494 having final approval and 30 having tentative approval. In Europe, 3,559 formulation approvals were received. In the US, 719 formulation approvals were received. 362 dossiers were achieved in South America. In Canada, 210 product registrations were received. Across all regions, there were 4,850 formulation approvals and 3,709 API approvals. The estimated regulatory timeframe during COVID was 267-270 days (approximately nine months).

['Q4', '2022']:

- No products were withdrawn. Three ANDAs received final approval, and four products were launched. Fourteen ANDAs were filed (including three injectables). A total of 727 ANDAs were filed with the USFDA cumulatively (505 with final approval). 175 injectable ANDA filings were made (119 with final approval).

- **Evaluation:**

- {'evaluation': 'Met expectations', 'evaluation_reason': "While the narrative highlights ongoing challenges, the actual results show continued progress in ANDA filings and approvals across various regions, suggesting Aurobindo is making efforts to address regulatory issues. The statement does not directly address Unit 1's specific status, however."}

4. Market Position

- **Narrative:** Aurobindo anticipates market share gains with new biosimilar products. Expansion plans include a new plant in Vizag.

- **Management's Guidance:**

- A 10% increase in market share is anticipated next year due to new biosimilar products. The Vizag plant is nearing completion, with filings expected mid-FY23 and commercialization in FY24.

- **Actual Results:**

['Q2', '2023']:

- In Q2 FY23, there is mention of the addressable market size for ANDAs related to the Eugia group being US\$ 25.82 Billion. No specific actual market share data was provided.

['Q1', '2023']:

- In Q1 2023, management reported that they are number one in prescription volume in the US by volume.

['Q3', '2022']:

- No specific actual results related to market share or plant completion are provided in the data.

['Q4', '2022']:

- No specific market share data is provided in the Q4 2022 results.

- **Evaluation:**

- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': "The Q3 2022 data lacks information on market share changes or the Vizag plant's progress, preventing an evaluation of whether management's expectations were met."}

5. Innovation and Pipeline

- **Narrative:** Aurobindo is actively developing its product pipeline, with a significant number of products in various stages of development.

- **Management's Guidance:**

- Approximately 70 new products have been filed, and another 180 are under development. The company is exploring strategies to boost sales from the current 900-1000 million range to 1300-1500 million. A product launch resulting from a confidential settlement is anticipated in FY24.

- **Actual Results:**

['Q2', '2023']:

- In Q2 FY23, Aurobindo launched approximately 20 new products.

['Q1', '2023']:

- In Q1 2023, Aurobindo filed 13 products. 20 new products were launched in the US market last year.

['Q3', '2022']:

- Around 70 new products were filed and another 180 are under development.

['Q4', '2022']:

- Eleven new products were launched in FY22. Several projects are at various stages, including biosimilars and vaccines.

- **Evaluation:**

- {'evaluation': 'Met expectations', 'evaluation_reason': "The actual results directly align with management's guidance on the number of products filed and under development."}

6. Supply Chain Management

- **Narrative:** Aurobindo is experiencing some supply chain challenges but anticipates improvements. The company received an extension for a Penicillin G project due to COVID-related government issues.

- **Management's Guidance:**

- Improvements in lead times for raw material procurement are expected from the following month. Production from a project is expected to start by the end of FY24. The PLI scheme project for 15,000 tons of Penicillin G received a one-year extension due to COVID-related issues.

- **Actual Results:**

['Q2', '2023']:

- In Q2 FY23, approximately 55% of Aurobindo's manufacturing has been moved to India.

['Q1', '2023']:

- In Q1 2023, management reported a 20% increase in production capacity over the last year.

['Q3', '2022']:

- Inventory reduction of \$100 million (quarterly) and \$175 million (yearly). Average raw material cost increased by about 4% during the quarter. Freight costs increased by more than 20% quarter-on-quarter.

['Q4', '2022']:

- Significant inventory reduction over the past six months. Raw material prices increased, impacting costs. Inventory reduction of \$200 million for the year. Oral plant capacity utilization reached approximately 70% in India. Distributors' and US companies' inventories returned to normal levels.

- Evaluation:

- {'evaluation': 'Partially Met expectations', 'evaluation_reason': "While the inventory reduction demonstrates progress in supply chain optimization, the increase in raw material and freight costs indicates ongoing challenges, partially meeting management's expectations of improvement. The Penicillin G extension is a separate issue and doesn't directly relate to overall supply chain performance."}