

Q1 2025

1. Research and Development (R&D)

- **Narrative:** Aurobindo's R&D efforts are focused on ophthalmic products, with clinical trials underway. Progress is described as "pretty slow" but there is confidence in completion.

- **Management's Guidance:**

- Completion of the Indian clinical study by the end of 2025, enabling filing in India and emerging markets by Q3-Q4 2025. Clinical study closure in June 2026, with subsequent filing with the EMA and FDA in Q2 FY26. Completion of the large European study by mid-2026, aiming for EMA and FDA filing in Q3 FY26.

- **Actual Results:**

['Q2', '2025']:

- In Q2 2025, a Phase 1 PK/PD clinical study was completed. A Phase 3 clinical study in metastatic breast cancer subjects was completed and met clinical endpoints. Dossiers increased from 348 in March 2020 to 416 in September 2024. Approvals increased from 639 in March 2020 to 848 in September 2024. Registrations increased from 185 in March 2020 to 266 in September 2024. Total R&D (incl. depreciation) spend was Rs. 410 Crore (5.3% of sales).

['Q1', '2025']:

- R&D expenditure for Q1 2025 was Rs. 339 crores (4.5% of revenue). The Denosumab trial in Europe completed patient recruitment in May. The Tocilizumab biosimilar phase three trial in India was completed. Recruitment for an oncology product was 80% complete.

- **Evaluation:**

- {'evaluation': 'Did not meet expectations', 'evaluation_reason': "While some trials were completed in Q1 2025, the overall progress against the management's detailed timelines for clinical study completion and subsequent filings with regulatory bodies in 2025 is not reflected in the Q1 2025 actual results. The provided data doesn't show achievement of the projected milestones."}

2. Regulatory Compliance

- **Narrative:** Aurobindo is navigating regulatory hurdles, particularly with the FDA. There's cautious optimism regarding resolving FDA-related issues. Multiple filings are planned with the FDA and other regulatory bodies.

- **Management's Guidance:**

- Expectation to meet regulatory requirements within the current clock stop period, with approvals anticipated in two quarters. Planned FDA filing within the next four to eight weeks for one product. Planned filing for another product (India and emerging markets only) within the next three to four months. Anticipation of three to four US filings during the year, with revenue generation expected from FY26 onwards. Cautious optimism about resolving FDA issues and increasing sales momentum from Q2 FY25 onwards.

- **Actual Results:**

['Q2', '2025']:

- In Q2 2025, Aurobindo filed 10 ANDAs with the USFDA and received approval for 8 products. They launched 14 products. A Marketing Authorization (MA) was received for Trastuzumab in India. 14 DMFs were filed in peptides. The number of filings in South Africa decreased from 436 (March 2020) to 348 (March 2021) due to SAHPRA backlog clearance.

['Q1', '2025']:

- As of June 30th, Aurobindo had 838 ANDAs filed with the US FDA, with 668 having final approval and 26 tentative approvals. Remediation actions related to the Eugia-3 plant impacted Q4 FY24 and Q1 FY25.

- **Evaluation:**

- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': "The provided Q1 2025 actual results describe the current state of ANDA filings and the impact of Eugia-3 remediation, but there's no specific Q1 2025 management guidance on FDA approvals or filings to compare it against."}

3. Financial Performance

- **Narrative:** Aurobindo projects continued revenue growth, with specific targets and expectations for various regions and product lines. EBITDA margin targets are reiterated. There's commentary on remediation costs related to Eugia-3.

- **Management's Guidance:**

- Strong performance in the European market, on track to achieve €880 million plus for FY25. Confidence in achieving the overall internal EBITDA margin target of 21%-22% for FY25. Cautious optimism regarding regular injectable business moving up from Q2 FY25 onwards. Expectation of approximately \$600 million plus in revenue for the year. Continued revenue of around 8 million per quarter for the current financial year. Expectation that remediation costs for Eugia-3 will be significantly lower in Q2 FY25 (around \$2 million) compared to Q1 FY25. Gross margin maintenance at 21%-22%, with absolute margin ramp-up. Overall gross margin projected around 27-28%. Revenue impact from Eugia-3 remediation expected to end.

- **Actual Results:**

['Q2', '2025']:

- In Q2 2025, revenue was ■ 7,796 Cr (8.0% YoY growth). Net profit was ■ 817 Cr (8.6% YoY growth). The US market experienced 4.3% YoY growth, Europe 19.0% YoY growth, and Growth Markets 44.0% YoY growth. Total Formulations increased by 11.3% YoY. Consolidated Sales (Ex-Puerto Rico) grew 9.3% YoY and 3.0% QoQ. US revenue (excluding Puerto Rico) was US\$ 421 Mn (2.9% YoY increase, 1.1% QoQ decrease). EBITDA was ■ 1,566 Cr (11.6% YoY growth). Base business revenue grew 7% QoQ. Base EBITDA margin was around 21%, with double-digit QoQ growth in absolute EBITDA. Gross Profit increased by 15.1% from Q2FY24 to Q2FY25. Gross Margin increased by 366 bps.

['Q1', '2025']:

- Revenue increased by 10% year-on-year in Q1 FY25 to Rs. 7,567 crores. US revenue was \$426 million (marginally impacted by seasonality), European revenue was €221 million, and growth market revenue was \$85 million. Formulation business (excluding Puerto Rico) grew 15% year-on-year to Rs. 6,475 crores. API business revenue increased 6% year-on-year to Rs. 1,092 crores. Net profit increased 61% year-on-year to Rs. 919 crores. EBITDA margin was 21.4%. Remediation costs for Eugia-3 were approximately \$9 million in Q1 FY25. Gross margin was 59.4%, up from 53.9% in the previous year's Q1.

- **Evaluation:**

- {'evaluation': 'Met expectations', 'evaluation_reason': "The Q1 2025 actual results show that the EBITDA margin (21.4%) met the management's guidance range (21%-22%). While full-year revenue targets are not yet achievable in Q1, the revenue growth shows progress toward those goals. The Eugia-3 remediation costs were high, but the management guidance indicated that would decrease in Q2, so the Q1 results are not necessarily a failure to meet expectations."}

4. Market Position

- **Narrative:** Aurobindo is focusing on the commercialization of Pen-G, aiming for significant ramp-up.

- **Management's Guidance:**

- The company is on track for significant ramp-up of Pen-G commercialization from October 2024.

- **Actual Results:**

['Q2', '2025']:

- No specific Q2 2025 actual results for Pen-G commercialization are provided in the data.

['Q1', '2025']:

- Pen-G sales were impacted in Q1 FY25 due to various reasons at the Pen-G plant, resulting in zero sales for three months.

- **Evaluation:**

- {'evaluation': 'Did not meet expectations', 'evaluation_reason': 'The actual results show zero sales for three months of Q1 2025, clearly falling short of the anticipated "significant ramp-up" from October 2024.'}

5. Supply Chain Management

- **Narrative:** Aurobindo is addressing supply chain challenges, particularly concerning raw material procurement and manufacturing ramp-up for specific products. There's mention of plans for sourcing from China.

- **Management's Guidance:**

- Expectation to produce approximately 20 batches in one month and 30 in the following month, leading to significant ramp-up from October. Plan to begin small-volume sourcing from China in November-December, with ramp-up between January and March of the next year (Q4 FY25). Full-fledged volumes are expected to start in FY26.

- **Actual Results:**

['Q2', '2025']:

- No specific Q2 2025 actual results related to supply chain management are provided in the data.

['Q1', '2025']:

- No specific actual results for supply chain management are provided in the data for Q1 2025. The first commercial product for BFS was shipped to China through a JV partner.

- **Evaluation:**

- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': 'The Q1 2025 actual results only mention one shipment to China, which is insufficient information to assess the overall progress against the management's broader guidance on production targets and sourcing plans from China.'}