Q2 2024

1. Research and Development (R&D)
- **Narrative:** Aurobindo's R&D spending in Q2 2024 was lower than projected due to the completion of major clinical trials in June. The company anticipates a return to higher spending (Rs. 350-400 crore) in Q3 2024 as new phases of clinical trials begin. They also estimate R&D expenditure of Rs. 750-800 crore in the second half of the fiscal year.
- **Management's Guidance:**
- Q3 2024 R&D expenditure: Rs. 350-400 crore; Second half of FY24 R&D expenditure: Rs. 750-800 crore; Completion of BP08 Phase 3 clinical study: April/May 2024; Phase 3 trials for a new product: First subject dosing expected in the next quarter; Filing of three biosimilars (Pegylated filgrastim, Filgrastim, and Trastuzumab) before the end of January 2024.
- **Actual Results:**
['Q1', '2025']:
- In Q1 2025, R&D expenditure was Rs. 339 crores (4.5% of revenue). Multiple clinical trials reached significant milestones: Denosumab trial completed patient recruitment in European sites; Tocilizumab biosimilar Phase 3 trial completed in India; and an oncology product reached 80% patient recruitment.
['Q4', '2024']:
- Actual Q4 2024 R&D expenditure was Rs. 392 Crore (5.2% of sales). The completion of Phase 3 clinical studies for Omalizumab biosimilar (meeting PK/PD endpoints), and Trastuzumab biosimilar (completed licensure trials and filed with EMEA) are mentioned. Also, a Phase 3 trial for a product in 690 metastatic breast cancer subjects successfully met clinical endpoints.
['Q2', '2024']:
- R&D expenditure for Q2 2024 was Rs. 300 crore, representing 4.2% of revenue. Various clinical trials were completed (BP01, BP02) and others were ongoing (BP11).
['Q3', '2024']:
- In Q3 2024, R&D expenditure was Rs. 398 crore. BP02 Oncology Phase 3 clinical study was completed successfully. BP11 Respiratory Phase 1 study completed, Phase 3 ongoing. Updates were given on the pneumococcal vaccine trial.
- **Evaluation:**
- {'evaluation': 'Met expectations', 'evaluation_reason': 'While Q2 R&D spending was lower than the projected Q3 spending, management clearly stated that this was due to the completion of major clinical trials and that higher spending was anticipated in subsequent quarters, aligning with their overall guidance.'}

2. Regulatory Compliance
- **Narrative:** Aurobindo is actively engaged in the regulatory filing process for its products. They expect to complete filings in major markets within 8-10 weeks and anticipate an FDA filing in the next quarter, pending scientific advice. A CHMP audit for Filgrastim and Peg filgrastim is expected in Q1 of the next year.
- **Management's Guidance:**
- Completion of regulatory filings in major markets: within the next 8-10 weeks; FDA filing: Expected in the next quarter, pending scientific advice; CHMP audit for Filgrastim and Peg filgrastim: Expected in Q1 of the next year.
- **Actual Results:**
['Q1', '2025']:
- As of June 30th, Aurobindo had 838 ANDAs filed with the US FDA, with 668 having final approval and 26 having tentative approval. Remediation actions related to the Eugia-3 plant impacted Q4 FY24 and Q1 FY25.
['Q4', '2024']:
- In Q4 2024, Aurobindo filed 11 ANDAs with the USFDA, received approval for 17 ANDAs (including 4 specialty & injectable products), and launched 7 products. A Type 2 meeting on PEGylated Filgrastim was completed. Auro Peptides facility passed a US FDA inspection with zero observations. The company had 830 ANDAs filed with the USFDA, of which 658 had final approval and 27 had tentative approval.
['Q2', '2024']:
- As of September 30, 2023, Aurobindo had 817 ANDAs filed with the U.S. FDA, with 628 final approvals and 32 tentative approvals. BP13 and BP14 completed licensure trials and are in the filings phase. One product was submitted to the CHMP, with a second awaiting rapporteur assignment. The China plant received EU GMP approval.
['Q3', '2024']:
- In Q3 2024, 7 ANDAs were filed with the USFDA and approval was received for 16 products (including 7 specialty and injectable products). BP13 and BP14 Oncology completed licensure trials and were filed with EMEA. Further information is available on filings in South Africa and FDA approval for a product was received. Filings from the Vizag plant were mentioned.
- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': 'The Q2 2024 actual results provide a snapshot of the regulatory landscape but do not directly address the timeframe for completing filings in major markets or the FDA filing, making a complete evaluation impossible based solely on the provided data.'}

3. Financial Performance
- **Narrative:** Aurobindo expects to achieve its internal target of a 20%+ EBITDA margin for the year. The company anticipates continued growth in its generic injectable business in the US market, with a potential increase in quarterly revenue from USD 80 million to USD 90 million. They also project USD 560 million in global revenue for Eugia Specialities in FY24. The China plant is expected to begin revenue generation by the end of Q4 FY24 or early Q1 FY25. ARV business quarterly sales are projected to be around USD 25 million (plus or minus five). Strategic CapEx is expected to be in the range of USD 100-150 million for biosimilars. The company aims for a 20% gross margin. Net cash is expected to be between $0 and $50 million by year-end.
- **Management's Guidance:**
- Achievement of 20%+ EBITDA margin target for the year; Eugia Specialities global revenue for FY24: USD 560 million; Generic injectable business revenue in the US: Potential increase from USD 80 million to USD 90 million per quarter; China plant revenue generation: End of Q4 FY24 or early Q1 FY25; ARV business quarterly sales: Approximately USD 25 million (plus or minus five); Strategic CapEx for biosimilars: USD 100-150 million; Gross margin target: 20%; Net cash by year-end: Between $0 and $50 million; Pen-G project capitalization: Q4; Biosimilar plant full commissioning: FY26 or early FY26, revenue streams in calendar year 2026 or fiscal year 2027.
- **Actual Results:**
['Q1', '2025']:

- Overall revenue increased by 10% year-on-year in Q1 2025 (Rs. 7,567 crores or approximately $915 million). US formulation revenue grew by 12% year-on-year to $426 million; European formulation revenue increased by 8% year-on-year to Rs. 1,982 crores (€221 million); Growth market revenue increased by 49% year-on-year to Rs. 709 crores ($85 million). ARV formulation business revenue increased by 14% year-on-year to Rs. 229 crores ($27 million). EBITDA margin was 21.4%, in line with expectations. Gross margin was 59.4%. The Pen-G plant experienced sales disruptions in Q1 2025, impacting revenue. Net profit increased by 61% year-on-year to Rs. 919 crores.

['Q4', '2024']:

- In Q4 2024, Aurobindo reported revenue from operations at Rs 7,580 Crore (17.1% YoY increase). US revenue (excluding Puerto Rico) was USD 432 million (20.4% YoY increase, -4.2% QoQ decrease). Specialty & Injectables revenue in the US was ~USD 104 Mn (24% of total US revenue). Global Specialty & Injectables revenue was ~USD 143 Mn. EBITDA before Forex and Other income was Rs 1,687 Crore (22.3% margin). Net profit after minority interest was Rs 909 Crore (79.6% YoY growth, -2.9% QoQ decrease). Gross margin was 59.6% for the quarter and 56.5% for the year.

['Q2', '2024']:

- Revenue from operations was Rs 7,219 crore (a 25.8% YoY increase). US revenues (excluding Puerto Rico) were USD 409 million. EBITDA (before forex and other income) was Rs 1,403 crore, representing a 19.4% margin. Gross margin was 55.2%. Net profit was Rs 752 crore. ARV business revenue was USD 30 million. Net cash at the end of June was approximately $180 million, and approximately $130 million at the time of the report, with a $50 million reduction attributed to acquisition financing.

['Q3', '2024']:

- In Q3 2024, revenue from operations was Rs 7,352 Crore, a 14.7% YoY increase. US revenues (excluding Puerto Rico) were US$ 451 Mn. Net Profit after minority interest was Rs 936 Crore. EBITDA before Forex and Other income was Rs 1,601 Crore, a margin of 21.8%. Gross profit was 4,201 crore. Net profit margin was 12.7%. Eugia revenue information is available.

- **Evaluation:**

- {'evaluation': 'Partially Met expectations', 'evaluation_reason': 'While the ARV business exceeded expectations and net cash was significantly higher than predicted, the EBITDA margin of 19.4% fell short of the 20%+ target. The gross margin of 55.2% was also below the stated 20% target. The data is insufficient to evaluate the Eugia revenue.'}

4. Innovation and Pipeline

- **Narrative:** Aurobindo plans to launch 40 new products over the next 12 months. They expect a second wave of product launches in 2026/27 for one specific product.
- **Management's Guidance:**
- Launch of 40 new products: Over the next 12 months; Second wave of launches for a specific product: 2026/27.
- **Actual Results:**

['Q1', '2025']:

- No Q1 2025 actual results are provided in the data for this theme.

['Q4', '2024']:

- In Q4 2024, Aurobindo launched 7 products including 1 Specialty & Injectable product. They also commercialized 4 manufacturing plants.

['Q2', '2024']:

- No specific actual results for Q2 2024 were provided in the data.

['Q3', '2024']:

- 21 products were launched during the quarter, including 4 specialty and injectable products. Another source mentions 10 new product launches in the US market.

- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': 'No Q2 2024 actual results on product launches are available to assess progress against the 40-product launch target.'}

5. Supply Chain Management

- **Narrative:** Aurobindo's Pen-G and 6-APA plants are under installation and expected to be operational from Q4 FY24 or Q1 FY25. Potential partnerships related to these plants are expected from 2027 onwards.
- **Management's Guidance:**
- Pen-G and 6-APA plant operation: Q4 FY24 or Q1 FY25; Potential partnerships related to plants: From 2027 onwards.
- **Actual Results:**

['Q1', '2025']:

- The Pen-G plant experienced sales disruptions impacting Q1 2025 revenue.

['Q4', '2024']:

- In Q4 2024, Aurobindo was manufacturing approximately 47 billion units of formulation.

['Q2', '2024']:

- No specific actual results for Q2 2024 were provided in the data related to plant operations. However, there was mention of high capacity utilization for formulation.

['Q3', '2024']:

- Information on Vizag plant capacity and its role as a backup for Eugia III is provided. Additional information about product lines is also available.

- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': 'The provided data lacks specific information on the progress of the Pen-G and 6-APA plant installations during Q2 2024, preventing an evaluation of whether the timeline was met.'}