Q3 2024

1. Research and Development (R&D)
- **Narrative:** Several clinical trial timelines are mentioned. The completion of a Phase 3 clinical study is anticipated (a7241e367d8b7af32c2238acea35c318). Recruitment for another trial is expected to conclude by October 2024, with submissions to regulatory bodies in Q2 or Q3 of the following fiscal year (67b7d58880d2349f92becbd68c33fc0c). Another trial's completion is expected in May 2024, with subsequent filings (eba0401512a062dd133b36a436ca479d). A product launch is anticipated in July 2024, pending no unforeseen hurdles (6cb3e8248cd268a8763a346c8528ded6).
- **Management's Guidance:**
- Several clinical trial timelines are mentioned. The completion of a Phase 3 clinical study is anticipated (a7241e367d8b7af32c2238acea35c318). Recruitment for another trial is expected to conclude by October 2024, with submissions to regulatory bodies in Q2 or Q3 of the following fiscal year (67b7d58880d2349f92becbd68c33fc0c). Another trial's completion is expected in May 2024, with subsequent filings (eba0401512a062dd133b36a436ca479d). A product launch is anticipated in July 2024, pending no unforeseen hurdles (6cb3e8248cd268a8763a346c8528ded6).
- **Actual Results:**
['Q1', '2025']:
- In Q1 2025, Aurobindo completed recruitment for its Denosumab trial in European sites (e033c7a89b118e50c990db883ba90403). They also completed a Phase 3 clinical trial in India for their Tocilizumab biosimilar (46e57a52d8cea8f855ad94aa0ecfbd01). Recruitment for an oncology product reached approximately 80% completion (a009f99ebbc3bbc3a8a2dffd7ee01d22).
['Q4', '2024']:
- In Q4 2024, Aurobindo reported the successful completion of a Phase 3 clinical study in 690 metastatic breast cancer subjects (a0af34819ab9be6b1dccfed7346a47b0). Additionally, the Phase-III recruitment for their omalizumab biosimilar was completed across 40 European sites, encompassing 436 osteoporosis patients (65d2569e6b87b2287b07a887e7f5aafd). Three biosimilars completed licensure clinical trials and were filed (d54dfaa6595f46298d42000e73757e8d). Total R&D spend was Rs. 392 Crore (5.2% of sales) (1c969507f2d551f6ed57f1edb888dc2d, 018bcf074c4a92d319fc8abf84635e65).
['Q2', '2025']:
- In Q2 2025, a Phase 1 PK/PD clinical study was completed (c019b9995aa074644361b7686ea1a2b4). A Phase 3 clinical study in 690 metastatic breast cancer subjects was completed and met clinical endpoints (c019b9995aa074644361b7686ea1a2b4).
['Q3', '2024']:
- A Phase 3 oncology clinical study (BP02) was completed successfully in Q3 FY24 and met clinical endpoints. Another Phase 1 respiratory clinical study (BP11) was completed, with an ongoing Phase 3 study in Europe. A pneumococcal vaccine trial concluded, resulting in an SEC recommendation.
- **Evaluation:**
- {'evaluation': 'Met expectations', 'evaluation_reason': "The actual results for Q3 2024 show the successful completion of a Phase 3 oncology study and a Phase 1 respiratory study, aligning with the management's guidance of completing several clinical trials within the specified timeframe. The pneumococcal vaccine trial's successful conclusion further supports meeting expectations."}

2. Regulatory Compliance
- **Narrative:** Seven ANDAs were filed with the USFDA in Q3 FY24 (7aaa9cdcd119b295a52f03a9c3694b65). Efforts are underway to resolve compliance issues by March 31, 2024 (cb08119f2a8e62eb49dc70e0b189cedc).
- **Management's Guidance:**
- Seven ANDAs were filed with the USFDA in Q3 FY24 (7aaa9cdcd119b295a52f03a9c3694b65). Efforts are underway to resolve compliance issues by March 31, 2024 (cb08119f2a8e62eb49dc70e0b189cedc).
- **Actual Results:**
['Q1', '2025']:
- As of June 30th, 2024, Aurobindo had 838 ANDAs filed with the US FDA cumulatively, with 668 having final approval and 26 having tentative approval (24336a5714cdedb21a30e4ff36ac7abe). Remediation actions related to the Eugia-3 plant impacted Q4 FY24 and Q1 FY25 (b6033cacac59078621b2c3d0b3e42744).
['Q4', '2024']:
- In Q4 2024, Aurobindo filed 11 ANDAs with the USFDA (32787dbea95672de6254ed7a0ac70364) and received approval for 17 ANDAs, including 4 Specialty & Injectable products (32787dbea95672de6254ed7a0ac70364). As of March 31st, they had 830 ANDAs filed, with 658 having final approval and 27 tentative approvals (018bcf074c4a92d319fc8abf84635e65, 299b9684666d1677242ae3fd8fa71c24). The Auro Peptides manufacturing facility underwent a US FDA inspection with zero observations (a2ec8ef084db343b28af57663362605b). Management noted that while some ANDAs might be delayed, proactive actions were taken to ensure compliance (d18e3ce1e5687882c36d32546732b065). Remediation efforts were ongoing, with completion expected within 3-4 months (193a1666b58da939b4686bb4a0899378).
['Q2', '2025']:
- In Q2 2025, Aurobindo filed 10 ANDAs with the USFDA and received approval for 8 products (e1f0c637eff3718592d6bc93e1eb1c4b, 02526114f04485a67e50227aa3504a4d). They also launched 14 products (e1f0c637eff3718592d6bc93e1eb1c4b). A marketing authorization (MA) was received for Trastuzumab in India (257191118292dc1d76b60db2f033773b).
['Q3', '2024']:
- Seven ANDAs were filed with the USFDA in Q3 FY24. Approval was received for 16 ANDAs, including 7 specialty and injectable products. Licensure trials were completed and filings made with EMEA for two oncology products.
- **Evaluation:**
- {'evaluation': 'Exceeded expectations', 'evaluation_reason': 'Aurobindo not only met the target of filing seven ANDAs but also exceeded expectations by receiving approval for 16 ANDAs and making significant progress with EMEA filings for oncology products.'}

3. Financial Performance
- **Narrative:** A 20% profit increase is targeted for the next quarter (ce2129d5d04ef0f519a31fdb7342b440). A 15% revenue growth projection for the biosimilar segment is anticipated in the next fiscal year (56325c615496aaf1b226b0b3b0e64dbe). Maintaining a revenue run rate of $150 million+ in the coming quarters is the objective, with a potential $20 million impact in Q4 (0309d7c17162be191ebd3c0485e8c27d, 44e13d6b36ed6fcecb0dead7b7c1b5d8). A specific quarterly run rate is also mentioned, though impacted by a clawback (a8b3670cff9244d44d87dff1b6f56123). Further revenue generation is expected from new plants, starting in Q1/Q2 FY25 (343db7b91b121d131d18b4207c9213aa). Specific revenue projections are given for a particular product, ranging from $120 million to $180

million by 2028 (df8f632b774b38a7b3ac0dde9d87b559, 0e600e3ac4954493d2ceca3752211856). Cost reduction initiatives are mentioned, aiming for a 10% decrease in operational costs over the next two quarters (56325c615496aaf1b226b0b3b0e64dbe). An EBITDA margin of 20% is the target (0bdb21fa38c8012be4088faabf7b00e8). Further growth in gross profit margin is also anticipated (7e6eb27a360cb0dde2a12c0137352a8b).

- **Management's Guidance:**

- A 20% profit increase is targeted for the next quarter (ce2129d5d04ef0f519a31fdb7342b440). A 15% revenue growth projection for the biosimilar segment is anticipated in the next fiscal year (56325c615496aaf1b226b0b3b0e64dbe). Maintaining a revenue run rate of $150 million+ in the coming quarters is the objective, with a potential $20 million impact in Q4 (0309d7c17162be191ebd3c0485e8c27d, 44e13d6b36ed6fcecb0dead7b7c1b5d8). A specific quarterly run rate is also mentioned, though impacted by a clawback (a8b3670cff9244d44d87dff1b6f56123). Further revenue generation is expected from new plants, starting in Q1/Q2 FY25 (343db7b91b121d131d18b4207c9213aa). Specific revenue projections are given for a particular product, ranging from $120 million to $180 million by 2028 (df8f632b774b38a7b3ac0dde9d87b559, 0e600e3ac4954493d2ceca3752211856). Cost reduction initiatives are mentioned, aiming for a 10% decrease in operational costs over the next two quarters (56325c615496aaf1b226b0b3b0e64dbe). An EBITDA margin of 20% is the target (0bdb21fa38c8012be4088faabf7b00e8). Further growth in gross profit margin is also anticipated (7e6eb27a360cb0dde2a12c0137352a8b).

- **Actual Results:**

['Q1', '2025']:

- In Q1 FY25, Aurobindo reported a 10% year-on-year increase in overall revenue (c45761bf69733561e65706db60884c32, af88e0d66e55f334d5a955d3baf3c9ad). US formulation revenue grew by 12% year-on-year to $426 million (24336a5714cdedb21a30e4ff36ac7abe, af88e0d66e55f334d5a955d3baf3c9ad). Net profit increased by 61% year-on-year to Rs. 919 crores (af88e0d66e55f334d5a955d3baf3c9ad). The EBITDA margin was 21.4%, in line with expectations (af88e0d66e55f334d5a955d3baf3c9ad). Gross margin stood at 59.4% (44e21167abb8856b2d2ce953c4aff17e). A supply chain disruption impacted Q1 revenue by approximately $15-20 million (69d7a66ddb69637b702f161694a93042).

['Q4', '2024']:

- In Q4 2024, Aurobindo's revenue from operations reached Rs 7,580 Crore, a 17.1% YoY increase (1c969507f2d551f6ed57f1edb888dc2d). Net profit after minority interest was Rs 909 Crore (79.6% YoY growth, -2.9% QoQ decrease) (1c969507f2d551f6ed57f1edb888dc2d). US revenue (excluding Puerto Rico) was USD 432 Mn (20.4% YoY increase, -4.2% QoQ decrease) (32787dbea95672de6254ed7a0ac70364). EBITDA before Forex and Other income was Rs 1,687 Crore (22.3% margin) (ee8178da6c3090cf7db392f855ac9eac, 1c969507f2d551f6ed57f1edb888dc2d). Gross profit increased by 27.6% YoY, with a 490 bps YoY improvement in gross margin (de327a1a1571af775ec6379120f97c1c). The supply chain disruption resulted in a $20 million impact as projected (though specific citation connecting this to the actual impact is missing).

['Q2', '2025']:

- In Q2 2025, Aurobindo reported an 8% year-on-year revenue growth (7,796 Cr) and an 8.6% year-on-year net profit growth (817 Cr) (b0d0da0ae383df85b89f0b6e5c838679). The US market saw 4.3% YoY growth, Europe 19% YoY growth, and Growth Markets a 44% YoY increase (689010bf793af464fb0cc7a20586252d). Total formulations increased by 11.3% YoY (689010bf793af464fb0cc7a20586252d). Consolidated sales (excluding Puerto Rico) showed 9.3% YoY growth (689010bf793af464fb0cc7a20586252d). US revenue (excluding Puerto Rico) was $421 million (e1f0c637eff3718592d6bc93e1eb1c4b). The base business (excluding transient and long-term impacts) grew by 7% QoQ (e1f0c637eff3718592d6bc93e1eb1c4b). EBITDA was ■ 1,566 Cr, with 11.6% YoY growth (b0d0da0ae383df85b89f0b6e5c838679). Base EBITDA margin was around 21% (e1f0c637eff3718592d6bc93e1eb1c4b).

['Q3', '2024']:

- Revenue from operations was Rs 7,352 Crore, a 14.7% YoY increase. US revenue (excluding Puerto Rico) was US$ 451 Mn. Net profit after minority interest was Rs 936 Crore, with a YoY growth of 90.6% and QoQ growth of 23.7%. EBITDA before Forex and other income was Rs 1,601 Crore, reflecting a margin of 21.8%. Gross profit was 4,201 crore, a 20% increase YoY. The Eugia business achieved a quarterly revenue run rate exceeding $150 million.

- **Evaluation:**

- {'evaluation': 'Exceeded expectations', 'evaluation_reason': 'Aurobindo significantly exceeded the projected profit increase, achieving a substantial YoY growth in net profit and surpassing the targeted EBITDA margin. The Eugia business also exceeded the $150 million revenue run rate target.'}

4. Innovation and Pipeline

- **Narrative:** A second wave of product launches is anticipated in 2026/27 (bb38538c7ab73abc34f78889dad12229). News regarding manufacturing and commercial sales of certain products from a joint venture is expected in early fiscal year 2025 (fb638ea057b0e6f0170797bfd7d5f84c).

- **Management's Guidance:**

- A second wave of product launches is anticipated in 2026/27 (bb38538c7ab73abc34f78889dad12229). News regarding manufacturing and commercial sales of certain products from a joint venture is expected in early fiscal year 2025 (fb638ea057b0e6f0170797bfd7d5f84c).

- **Actual Results:**

['Q1', '2025']:

- In Q1 FY25, Aurobindo shipped its first commercial product for BFS in China through its JV partner (e7bc63d5521ec36a60711b0aa56b1fc2).

['Q4', '2024']:

- No specific actual results related to these aspects of the innovation pipeline are provided in the Q4 2024 data. However, the launch of 7 products in Q4, including one specialty and injectable product, demonstrates progress (32787dbea95672de6254ed7a0ac70364). The company also commercialized 4 manufacturing plants in March 2024 (1c969507f2d551f6ed57f1edb888dc2d).

['Q2', '2025']:

- In Q2 2025, Aurobindo launched 14 products (02526114f04485a67e50227aa3504a4d). There is no information available from the provided data to confirm information on the joint venture.

['Q3', '2024']:

- No specific actual results are provided in the data for this theme in Q3 2024.

- **Evaluation:**

- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': "The provided data lacks specific information on the innovation pipeline's performance in Q3 2024, making it impossible to assess whether expectations were met, exceeded, or not met."}

5. Supply Chain Management

- **Narrative:** A supply chain disruption is acknowledged, with an estimated impact of $20 million in Q4 and a projected recovery within 1-2 months (0bdb21fa38c8012be4088faabf7b00e8, f2307ad256c544b75579d5a60f1bc19a).

- **Management's Guidance:**

- A supply chain disruption is acknowledged, with an estimated impact of $20 million in Q4 and a projected recovery within 1-2 months

(0bdb21fa38c8012be4088faabf7b00e8, f2307ad256c544b75579d5a60f1bc19a).
- **Actual Results:**
['Q1', '2025']:
- The supply chain disruption continued to impact Q1 FY25, resulting in approximately a $15-20 million revenue impact (69d7a66ddb69637b702f161694a93042).
['Q4', '2024']:
- The provided Q4 data does not contain specific details about the resolution of the supply chain disruption, but the $20 million impact was apparently realized. The data does not offer a clear indication whether the 1-2 month recovery timeline was met.
['Q2', '2025']:
- The provided data does not contain actual results related to the supply chain disruption's impact or recovery timeframe in Q2 2025.
['Q3', '2024']:
- While a supply chain disruption was mentioned impacting Q4, there's no data in the provided actuals for its impact in Q3 2024. There is mention of backup manufacturing capacity.
- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': "The provided Q3 2024 data does not contain information on the supply chain disruption's impact during that quarter, preventing an evaluation of whether expectations were met."}