

Q1 2022

1. Regulatory Approvals and Filings

- **Narrative:** Aurobindo plans to file two products before March in Europe and the UK, with one filing expected the following month. They anticipate filing two additional products in the US during FY22-23. Furthermore, management plans to utilize funds to cover filing fees and exhibit batches for 45 additional products. The timeline for European approvals is approximately 210 days, while US approvals are estimated at 12-18 months depending on product complexity. One US inspection, deferred due to COVID, is expected by the end of the year or early next year, impacting six products launched through CMOs.

- **Management's Guidance:**

- Aurobindo's regulatory strategy focuses on timely filings and approvals across Europe, the UK, and the US. The company anticipates a significant number of filings and is proactively managing timelines and potential delays.

- **Actual Results:**

['Q3', '2022']:

- In Q3 2022, Aurobindo reported 719 ANDA approvals in the US, 3,559 in Europe, 362 in South America, and 130 in Canada, for a total of 4,850 formulation approvals. API approvals totaled 3,709 across all regions. A second Oncology biosimilar was filed with the European Medicines Agency in January 2022. The regulatory timeframe during COVID was estimated at 267-270 days (9 months).

['Q2', '2022']:

- In Q2 2022, Aurobindo filed 27 ANDAs (including 5 injectables) with the USFDA—their highest ever in a quarter. They received final approval for 7 ANDAs (including 2 injectables and 1 505(b)(2) NDA). Unit-wise ANDA approvals are also mentioned for various therapeutic areas. Further, they reported 681 approvals in the US, 3,507 in Europe, 361 in South Africa, and 203 in Canada by September 2021 for a total of 4,752 approvals. API approvals totaled 3,673.

['Q4', '2022']:

- No specific results for Q1 2022 regulatory filings are provided in the Q4 2022 data. However, Q4 2022 data shows total approvals for formulations reached 4,891 as of March 22, and total API approvals reached 3,884. Three ANDAs received final approval and four products were launched in Q4 2022.

['Q1', '2022']:

- Aurobindo received final approval for four ANDAs and launched five products in Q1 FY22. They filed 150 injectable ANDAs (98 approved, 52 under review) and a cumulative 654 ANDAs (451 with final approval). Exhibit batches were completed for over 32 products, with filings completed for 22 and approvals for 6. A US inspection, delayed from March 2020 due to COVID, was expected by year-end or early next year.

- **Evaluation:**

- **{'evaluation': 'Met expectations', 'evaluation_reason': "While the full extent of the year's filing plan isn't reflected in Q1 results alone, the Q1 data shows progress toward the stated goal of timely filings and approvals, with a significant number of ANDAs approved and in progress."}**

2. Financial Performance and Outlook

- **Narrative:** Aurobindo targets a 15% revenue increase by the fiscal year-end. Six ANDAs are ready for marketing, anticipated to generate approximately \$30 million annually. A previously acquired entity is expected to exceed last year's turnover of \$13 million. Management expresses confidence in achieving a long-term goal, despite quarter-to-quarter variations. There's also mention of aiming for a 60% gross margin (currently at 58%), although this is contingent on price erosion factors. A plan to reduce operational costs by 10% over the next two quarters is also mentioned. Finally, management, while cautious about providing specific guidance, expresses excitement about exceeding \$20 million in revenue for the current year from six outsourced molecules, and exceeding \$100 million in three years.

- **Management's Guidance:**

- Aurobindo projects strong revenue growth, driven by new ANDAs and acquisitions. The company aims for improved margins through cost reduction and anticipates significant revenue increases from outsourced molecules.

- **Actual Results:**

['Q3', '2022']:

- In Q3 2022, Aurobindo's revenue from operations was Rs 6,002.2 crore, a 1% QoQ increase. US revenue was 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). Growth Markets formulations revenue was largely flat YoY, growing 2.8% QoQ to INR 397 Cr (6.6% of revenue). API business revenue was Rs 1,010 Cr (16.8% of consolidated revenue), with a 48% YoY growth. ARV business revenue was Rs 156 crore (2.6% of revenue). The gross profit margin was 54.3% in Q3FY22, down from 59.6% in Q3FY21 and 57.8% in Q2FY22. EBITDA before Forex and other income was Rs 1,016.3 crore, with an EBITDA margin of 16.9%. Net profit was Rs 604.3 crore. Operational costs were reduced by 5% in the last fiscal year.

['Q2', '2022']:

- In 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 revenue increased 10% YoY to Rs 1,662 crore (28% of consolidated revenue). Revenue from Growth markets formulations increased 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 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. Net profit was Rs 696.7 crore. EBITDA (before forex and other income) was Rs 1,186.7 crore (20% margin).

['Q4', '2022']:

- Q4 2022 data shows a revenue of Rs 5,809 crores, with a 3.2% quarter-on-quarter decrease. This doesn't directly reflect the full-year 15% target, nor the individual projections for ANDAs or acquisitions. However, a 15% increase in sales was mentioned for the last quarter, indicating some success in revenue generation. The API business registered a 15% year-on-year growth in revenue. Information on gross margin and operational cost reduction is partially available, with a mention of operational cost reduction by 8% over the past year.

['Q1', '2022']:

- Revenue for Q1 FY22 was INR 5,702 crore, a 2.9% YoY increase. Net profit increased by 8.9% to INR 770 crore. US revenue declined 1.5% YoY, while Europe revenue increased 19.7% YoY. Revenue from growth market formulations increased 13.7% YoY. ARV business revenue decreased 30.3% YoY. API business revenue was INR 812 crore. The acquired entity exceeded \$6.5 million in turnover in the first half of the year.

- **Evaluation:**

- **{'evaluation': 'Did not meet expectations', 'evaluation_reason': "The 2.9% YoY revenue increase in Q1 fell significantly short of the 15% full-year target. While the acquired entity exceeded expectations, the overall financial performance in Q1 did not meet the company's ambitious guidance."}**

3. Product Launches and Pipeline

- **Narrative:** Aurobindo anticipates 30+ product launches annually. One to two products are expected to be added to the portfolio each year, depending on trial length. Two products are slated for launch in the following month, utilizing third-party units.

- **Management's Guidance:**

- Aurobindo maintains a robust product launch pipeline, aiming for a consistent flow of new products to the market.

- **Actual Results:**

['Q3', '2022']:

- No specific Q3 2022 results directly correlating to this guidance are provided in the data.

['Q2', '2022']:

- In Q2 2022, Aurobindo launched 6 products, including 3 injectables.

['Q4', '2022']:

- Q4 2022 data mentions 11 launches in FY22 and 5 new product launches in the year. This data doesn't specifically address Q1 2022 launches, but suggests the company maintained a consistent product launch pipeline.

['Q1', '2022']:

- Five products were launched in Q1 FY22.

- **Evaluation:**

- {'evaluation': 'Met expectations', 'evaluation_reason': 'The launch of five products in Q1 is a reasonable contribution toward the annual target of 30+, indicating the company is on track to meet its expectations for a consistent product launch pipeline.'}

4. Market Position

- **Narrative:** Aurobindo positions itself as the largest supplier by volume in a specific (unspecified) area and aims to maintain and expand this position due to a large portfolio.

- **Management's Guidance:**

- Aurobindo aims to solidify and expand its leading market position through its extensive product portfolio.

- **Actual Results:**

['Q3', '2022']:

- In Q3 2022, the total market size was US\$ 140.34 Bn. Many products were going off-patent, starting in May, and Aurobindo was present in most of those off-patented molecules. No quantifiable market share data is available.

['Q2', '2022']:

- In Q2 2022, Aurobindo's market share in injectables was approximately 20-22%.

['Q4', '2022']:

- Q4 2022 data offers limited direct evidence regarding market share. However, statements about customer satisfaction improvements suggest some success in maintaining customer relationships, which could indirectly contribute to market position. The mention of India plants achieving 70% capacity utilization and a statement about the US market representing a small portion of plant capacity provides some insight into the geographic distribution of sales and capacity utilization, but not direct market share data.

['Q1', '2022']:

- No specific quantifiable results regarding market share are available from the provided data for Q1 2022. However, 60-65% of their portfolio held top 1-3 market share rankings.

- **Evaluation:**

- {'evaluation': 'Met expectations', 'evaluation_reason': 'While precise market share figures are absent for Q1, the fact that a substantial portion of their portfolio maintained top rankings suggests the company likely met its goal of maintaining its leading market position.'}