Q3 2021

1. Research and Development (R&D)
- **Narrative:** Management discussed R&D expenditure as a percentage of revenue and the timeline for various clinical trials, particularly in oncology and immunology. There was also mention of utilizing facilities for COVID vaccine development.
- **Management's Guidance:**
- R&D expenditure is projected to be around 6.1% for the quarter, potentially lower on an annualized basis, but could reach 7.5% if multiple Phase-III biosimilar and vaccine trials commence. Clinical trials for various molecules (BP14, BP13, BP02, BP06) have specific completion timelines mentioned, ranging from late Q1FY22 to Q2FY22. Phase II/III trials for a product are expected to begin in Brazil by the end of the month (of the Q3 2021 reporting period), with data anticipated by July. The company expects to use its viral facility for COVID vaccine development in FY22.
- **Actual Results:**
['Q2', '2022']:
- In Q2 2022, R&D spend was Rs 399 crore, representing 6.7% of revenue. There's mention of 55 products under development in the oncology Eugia portfolio, with 12 filed and 9 launched.
['Q4', '2021']:
- In Q4 2021, R&D expenditure was Rs. 457 Cr, representing 7.6% of revenue. For the full fiscal year (FY21), R&D expenditure totaled Rs. 1,510 Cr, 6.1% of revenue.
['Q1', '2022']:
- In Q1 2022, R&D expenditure was INR 358 crore, representing 6.3% of revenue.
['Q3', '2021']:
- R&D spend was Rs. 390.5 crore (6.1% of revenue) in Q3 2021. Phase I for one product was completed, and approvals were received to conduct Phase III trials for BP01 (Oncology). Phase I and II studies were successfully completed for another product.
- **Evaluation:**
- {'evaluation': 'Met expectations', 'evaluation_reason': "The actual R&D expenditure of 6.1% of revenue matched the lower end of management's projected range (6.1% - 7.5%), and significant progress was reported on several clinical trials."}

2. Regulatory Compliance
- **Narrative:** Management addressed regulatory submissions and timelines for approvals, and also discussed revisiting compliance issues after normalcy returns.
- **Management's Guidance:**
- Regulatory submission of data is expected by July, with approval anticipated in the following fiscal year. A specific product completed Phase I and II studies, with Phase III anticipated in March 2021 and regulatory filing in Q4FY22. A revisit of compliance issues is planned for around March 2022.
- **Actual Results:**
['Q2', '2022']:
- In Q2 2022, 27 ANDAs (including 5 injectables) were filed with the USFDA, the highest ever quarterly filings. 7 ANDAs (including 2 injectables) and 1 505(b)(2) NDA received final approval. Unit I underwent inspection and the response was submitted within the stipulated time. There were also various other approvals mentioned across different regions.
['Q4', '2021']:
- In Q4 2021, 9 ANDAs were filed with the USFDA, and final approval was received for 9 ANDAs (including 3 injectables). A total of 55 ANDAs were filed in FY21 (including 16 injectables), with 42 approvals (including 17 injectables). 1 DMF was filed with the USFDA during the quarter. The number of filings in South Africa decreased from 436 (March 2020) to 348 (March 2021) due to SAHPRA backlog clearance.
['Q1', '2022']:
- In Q1 2022, final approval for four ANDAs was received, and five products were launched. A total of 150 injectable ANDAs were filed as of June 30, 2021, with 98 receiving final approval; 654 ANDAs were filed cumulatively, with 451 receiving final approval. USFDA audited Unit-1 for nine days, concluding in Q1 2022.
['Q3', '2021']:
- The provided data mentions 251 DMFs filed with the USFDA and over 3,000 filings in other geographies. 141 injectable ANDAs were filed as of December 31, 2020, with 87 receiving final approval and 54 under review. The number of filings in South Africa decreased from 436 (March 31, 2020) to 341 (December 31, 2020).
- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': "The Q3 2021 actual results provide general regulatory filing numbers but lack specific data to compare against the management's guidance on specific submissions and timelines mentioned in the narrative."}

3. Financial Performance
- **Narrative:** Management provided revenue growth projections and plans to reduce operational costs.
- **Management's Guidance:**
- Revenue growth of 15% is projected for the next fiscal year. The company aims to double external sales within 4-5 years, with a significant portion of this growth expected in fiscal year 25. Revenue is expected to reach $650 million to $700 million over the next 3 years from the current $380 million. Operational costs are planned to be reduced by 10% in the coming quarter.
- **Actual Results:**
['Q2', '2022']:
- In Q2 2022, revenue from operations was Rs 5,941.9 crore, a 4.2% QoQ increase. US revenues were US$ 401.4 Million, up 10.3% QoQ. Various other revenue figures are reported across different segments and geographies, showing mixed growth patterns. Net profit was Rs 696.7 crore.
['Q4', '2021']:
- There are multiple, sometimes conflicting, figures reported for revenue growth in Q4 2021 and FY21. Reports include 88% YoY growth, 8% YoY growth for FY21, 15% increase last quarter, 5% YoY growth in Q4 FY21, and 2.1% YoY increase to Rs. 6,007 crores in Q4 FY21. Further discrepancies exist regarding specific business segments (US, Europe, API, formulations).
['Q1', '2022']:
- In Q1 2022, revenue from operations was INR 5,702.0 Cr, a decrease of 3.8% from Q1FY21. However, other sources indicate a 2.9% YoY revenue growth. Net profit increased by 8.9% year-on-year to Rs.770 crores. US revenue declined by 1.5% YoY, while Europe revenue increased by 19.7% YoY. Some sources reported a 15% revenue increase.

['Q3', '2021']:
- Revenue from operations was Rs. 6,364.9 crore in Q3 FY21, an 8% YoY increase. Net profit after JV share and minority interest was Rs. 2,946.5 crore, a 317.7% YoY increase. US revenue grew by 6.8% YoY to Rs. 3,171.6 crore (49.8% of consolidated revenue); European revenue increased by 13.2% YoY to Rs. 1,671.2 crore (26.3% of consolidated revenue). Injectable business showed 6% sequential growth. Global generic Injectable sales were US$ 109 million in Q3FY21 and US$ 283 million for 9MFY21. Total revenue (including captive consumption) was US$ 206 million for Q3FY21 and US$ 632 million for 9MFY21. Gross profit margin was 59.6% in Q3FY21. EBITDA (before forex and other income) was Rs. 1,368.6 crore (21.5% margin), a 13.3% YoY increase. Reported EPS was Rs. 50.29.
- **Evaluation:**
- {'evaluation': 'Met expectations', 'evaluation_reason': 'While the 8% YoY revenue growth in Q3 2021 is lower than the projected 15% for the full fiscal year, it represents positive growth and provides a foundation for achieving the longer-term target.'}

4. Market Position
- **Narrative:** Management discussed expansion plans in Europe and the timeline for a new facility.
- **Management's Guidance:**
- The setup of a dedicated injectable facility in Europe is underway. This facility is expected to be completed in 15 months.
- **Actual Results:**
['Q2', '2022']:
- No specific data on European facility completion or market share changes is provided in the Q2 2022 data. However, there is mention of a 10% YoY increase in Europe revenue to Rs 1,662 crore in Q2FY22. There are also various other mentions of market position data, but none directly address the European facility.
['Q4', '2021']:
- Specific data on market share or ranking among competitors is not available in the provided Q4 2021 data, but there are mentions of increased exports to Europe and sourcing from India.
['Q1', '2022']:
- No specific results related to the European facility completion are available in the provided Q1 2022 data.
['Q3', '2021']:
- Global generic Injectable sales were reported, providing some indication of market performance.
- **Evaluation:**
- {'evaluation': 'Cannot be Evaluated', 'evaluation_reason': 'The Q3 2021 results do not provide information on the progress of the European facility construction, preventing evaluation against the 15-month completion target.'}

5. Innovation and Pipeline
- **Narrative:** Management discussed the number of products planned for launch and the size of their development pipeline.
- **Management's Guidance:**
- Approximately 4 product launches are targeted for the quarter. Around 12 to 15 injectable product launches are anticipated annually. A new plant will enable the immediate supply of 20 approved or filed products, with an additional 30 products to follow, totaling 50 products. 52 products are under development, planned for launch over the next 1-1.5 years.
- **Actual Results:**
['Q2', '2022']:
- In Q2 2022, 6 products (including 3 injectables) were launched. Further details on the number of patents filed and the diversity of the drug pipeline are provided, but not directly tied to the original guidance.
['Q4', '2021']:
- In Q4 2021, 19 products were launched, including 10 injectables.
['Q1', '2022']:
- In Q1 2022, three new products were launched. There were approximately 67 products in total, with 40 injectables and 27 non-injectables in the pipeline. Another source mentions a pipeline of 174 products under different dosage forms.
['Q3', '2021']:
- 11 products were launched during the year, with an expectation of another 3-4 before year-end. Approximately 20 products were filed or approved but not fully capitalized upon.
- **Evaluation:**
- {'evaluation': 'Partially Met expectations', 'evaluation_reason': "While the number of launches in Q3 2021 is not explicitly stated, the yearly total of 11-15 falls short of the implied quarterly target of 4 and the overall annual projection of 12-15 injectable launches, although the full year's performance is closer to meeting the expectations."}

6. Supply Chain Management
- **Narrative:** Management discussed capacity expansion plans and the timeline for these expansions.
- **Management's Guidance:**
- Capacity is being doubled from 220 million doses to 480 million doses by June 2021. Capacity expansion in Vizag is planned for large-volume products, expected to be completed within 1-1.5 years.
- **Actual Results:**
['Q2', '2022']:
- In Q2 2022, there's a mention of a $62 million reduction in working capital QoQ, indicating some success in supply chain optimization. However, there's no direct data on the completion of capacity expansion in Vizag or the overall increase in capacity.
['Q4', '2021']:
- In Q4 2021, there's mention of a capacity of 480 million doses in the new viral vaccine facility, but no specific data on whether this target was met by June 2021. There is also mention of supply chain disruptions two quarters prior to Q4 2021.
['Q1', '2022']:
- In Q1 2022, a new manufacturing plant became fully operational, increasing production capacity by 25%.
['Q3', '2021']:
- Production capacity increased by 15% over the past two years.
- **Evaluation:**

- {'evaluation': 'Did not meet expectations', 'evaluation_reason': 'The 15% increase over two years is significantly less than the targeted doubling of capacity by June 2021, indicating that the capacity expansion plan fell short of its initial goals.'}