Managing Director's Message

Dilip Shanghvi
Managing Director

Dear Shareholders,

I am happy to report that we had a good year with strong performance across multiple parameters.

Our global consolidated revenues grew by 12.6% to ₹ 433 Billion while EBITDA grew by 12% to ₹ 116 Billion. Adjusted net profit was up by about 12.8% to ₹ 86 Billion. Our return ratios have also continued their improving trend this year.

The contribution of our Global Specialty business has more than doubled from 7% of consolidated revenues in FY18 to 16.2% in FY23. It is among the larger businesses for Sun already, yet offers even more exciting growth avenues from here.

Since inception, Sun has been deploying its resources to build new pharma businesses in a selective manner. Typically, it takes us several years to achieve initial scale in new businesses. This initial period consumes significant effort and resources, usually with no return in sight. Our investment in building specialty business over the past decade showcases our ability to nurture businesses with patient capital.

Global Pharmaceutical industry remains quite dynamic, and always buzzing with new avenues for capital deployment. Pursuing any one of these options can place considerable pressure on our balance sheet. Our existing businesses also require significant capital and attention. We are acutely aware that our own resources are finite, placing a limit on the number of opportunities we can pursue simultaneously.

Success is not guaranteed, and it is important for us that we remain thoughtful and selective in deciding which options to pursue. However, we will not shy away from making disproportionate investments to grow our businesses, should an opportunity present itself.

Our endeavour at all times is to find the best role for Sun in a value chain to keep ourselves from spreading thin. In Specialty business, we have built commercial infrastructure in certain large pharma markets and we believe this makes Sun a partner of choice for innovation-led companies. We are in the process of strengthening the internal R&D engine with an aim to create and fortify our future product pipeline.

Operational Performance

For FY23, India formulation sales were at ₹ 136 Billion, up by 6.6% and accounted for about 32% of overall revenues. Excluding the contribution of COVID-19 products in the previous year, the underlying business performed well, with about 10.2% growth Y-o-Y.

Our India business was in line with the average industry growth, driven by our leading presence in chronic segments and our strong brand equity with doctors. As per AIOCD AWACS March 2023 data, our market share remained flat at 8.3% on MAT basis vs the previous year.

As per SMSRC data for February 2023, Sun Pharma ranks No. 1 by prescriptions with 12 different classes of doctors. We continued our momentum with 105 new product introductions in India.

We also undertook India field force expansion in FY23, adding 10% to our existing strength. The field force expansion implemented in 2 rounds over last 3 years has helped us declutter our portfolio and expand our presence in Tier-2 and Tier-3 towns.

Revenues in the US grew by 19% to ₹ 135 Billion and accounted for approximately 31% of our consolidated revenues for FY23. Specialty sales in the US continued to gain traction. While the generics business continued to face price erosion and the negative impact of Import Alert at our Halol facility, we were able to partly compensate it through new launches and market share gains. During the year, we acquired Concert Pharmaceuticals Inc. with an aim to expand our Specialty offering. Sezaby launch in the US has added an exciting product to our specialty basket.

Our subsidiary, Taro, recorded a 2.1% growth in overall revenues to US$573 Million. Taro's portfolio continued to face price erosion in the US.

Our Emerging Markets (EM) sales grew by 17.1% to ₹ 79 Billion and contributed about 18% of our consolidated revenues. In local currency terms, large markets like Brazil and Romania recorded strong double-digit growth. During the year, Sun Pharma expanded its OTC presence in Romania by acquiring the Uractiv™ OTC portfolio.

Sales in the Rest of World (RoW) markets grew by 10.8% to ₹ 60 Billion and contributed about 14% to consolidated revenues. Growth was on the back of higher sales in Western Europe and the ramp up in Ilumya sales in Australia and Japan. Odomzo also gained traction in RoW markets.

Global Specialty Business Performance

Global Specialty revenues recorded a strong 29.3% growth to reach US$871 Million. Ilumya sales continued to do well globally and were up by about 51% to US$ 477 Million.

During the year, we acquired Concert Pharmaceuticals Inc, with its lead asset, deuruxolitinib, having completed two Phase-3 trials in alopecia areata. Deuruxolitinib is expected to address a significant unmet need thereby strengthening our global dermatology franchise. Additionally, Sezaby is an important launch, as it is the first and only product in the US specifically indicated to treat seizures in infants. Occurrence of neonatal seizures is associated with poor outcomes such as cerebral palsy, global developmental delay, and epilepsy.

Following products were key contributors to the Global Specialty business growth in FY23.

Marketed Specialty Portfolio: Select Products

Ilumya is an IL-23 inhibitor biologic used in treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is marketed by Sun Pharma directly in several markets including the US, Canada, Australia, Japan and in EU through our partner. This is the largest product by revenues in our Global Specialty portfolio. In May 2023, Ilumya received approval to market in China. We are making continued efforts to expand the product's indications as well as geographic footprint.

Winlevi is a first-in-class topical androgen receptor inhibitor, approved by the USFDA for the topical treatment of acne vulgaris in patients above the age of 12. Winlevi is the first FDA-approved acne drug in nearly 40 years with a first-in-class mechanism of action. During FY23, we expanded our license from Cosmo to include 6 major geographies besides the US, where it is currently marketed.

Cequa for topical ophthalmic use is the first and only USFDA approved cyclosporine treatment delivered with NCELL™ technology. Cequa, which offers the highest concentration of cyclosporine for ophthalmic use approved by the USFDA, is indicated to increase tear production in patients with dry eye, an inflammatory disease that afflicts more than 16 million people in the US. We have recently launched Cequa in India to expand our commercial footprint and bring our global specialty portfolio to the home market.

Odomzo is indicated for the treatment of adult patients with locally advanced Basal Cell Carcinoma (laBCC) that has recurred following surgery or radiation therapy, or for those who are not candidates for surgery or radiation therapy. Odomzo works by inhibiting a molecular pathway known as the hedgehog signaling pathway which is implicated in the origination and development of basal cell carcinoma when the pathway malfunctions. We have launched Odomzo in the US and several other international markets.

Levulan Kerastick+BLU-U combines a powerful 20% aminolevulinic acid HCl (ALA) topical treatment with blue-light precision, while minimising exposure to the deeper tissue. It is the only Photo Dynamic Therapy indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp, or actinic keratosis of the upper extremities.

Research & Development (R&D)

Our R&D investments stood at approximately ₹ 24 Billion, at 5.5% of overall sales. During the year, we filed approximately 200 formulation dossiers globally. We continued our R&D efforts to develop differentiated generics and innovative specialty products. Some of the clinical trials for our specialty products were delayed during previous years and in FY23, as the pandemic and geopolitical tensions impacted our ability to enroll study subjects in a timely manner. Our Company has taken steps to improve study enrollment during FY23. Besides internal R&D, Sun Pharma scouts for external late-stage R&D assets to strengthen the pipeline.

We remain disciplined in identifying future R&D projects for the US generics market with a focus on developing complex products. Investments for developing the long-term specialty pipeline are expected to continue and R&D spending is expected to increase as clinical trials for specialty products gain traction.

Besides deuruxolitinib discussed above, Sun Pharma's specialty R&D pipeline has four other candidates undergoing clinical trials:

Ilumya is undergoing Phase-3 clinical trials for psoriatic arthritis. A successful Phase-3 trial, subject to regulatory approval, is likely to expand the addressable market for Ilumya.

MM-II has completed global Phase-2B trial as a potential treatment for knee pain in patients with symptomatic knee osteoarthritis. Clinical data showed that a single intra-articular injection of MM-II provided durable pain relief up to 26 weeks vs placebo and demonstrated a safety profile comparable to placebo. While the study did not achieve statistical significance on the primary outcome measure, it did show meaningful and sustained improvement across several clinical measures. Clinical data has received support from clinicians and we are assessing next steps for the programme.

SCD-044 is in Phase-2 clinical trials as a potential oral treatment for atopic dermatitis and moderate to severe plaque psoriasis. SCD-044 is a selective S1PR1 modulator with good cardiac safety profile.

GLP-1R (Glucagon-Like Peptide-1 Receptor) agonist has completed Phase-1 clinical trials. Early clinical data demonstrated marked weight loss in single and multiple ascending dose studies. The drug was well-tolerated and we expect to start enrolling patients in Phase-2 trials in 2023. We presented Phase-1 data in ADA conference in San Diego, US held in June 2023.

cGMP compliance

During FY23, our facilities underwent 12 different and successful inspections by key global regulatory agencies. However, we had two inspections that led to adverse outcomes.

In December 2022, the US FDA issued an import alert to the Company's Halol facility. The USFDA has exempted 14 products from this import alert, subject to certain conditions.

In April 2023, the US FDA issued a Non-compliance letter to the Company's Mohali facility. The agency has directed the Company to take certain corrective actions at the Mohali facility before releasing further batches into the US.

Adherence to global cGMP standards is a key priority for us, and we have an unwavering focus on 24x7 compliance to ensure continuity of supplies to our customers and patients worldwide.

Efficiency improvement

Our focus has always been on sustainable cost reduction via technology interventions and process enhancements. We are also directing our efforts to reduce working capital deployment across our businesses. Sustained efforts are being made to further improve our manufacturing efficiencies, optimise our manufacturing footprint and reduce overall fixed costs.

Net Cash and deployment opportunities

At year-end, Sun Pharma had a strong net cash position of approximately US$1.5 Billion. Our strong cash position enables us to explore inorganic opportunities, including but not limited to strengthening our global specialty portfolio.

Overall outlook

All our businesses are well-positioned, and we expect high-single-digit consolidated topline growth for FY24. The expansion of our global specialty business is expected to continue. As business operations have normalised globally, overall expenses are expected to increase. Our R&D spending is expected to be about 7-8% of sales in FY24 with an increasing share of spending expected on clinical trials for specialty products.

Top priorities for FY24

- Sustainable and profitable business growth
- Supply chain continuity along with focus on inventory optimisation
- Continued focus on cost and operational efficiency
- Increased investments in IT to ensure secure systems, facilitate business operations and digital transformation
- Focus on improving overall return ratios
- Embed sustainability practices in our operations. We have set clear and actionable targets to achieve our sustainability goals

Sun Pharma's dedicated workforce has been instrumental in attaining our organisational goals. We have faced several challenges in the recent years including pandemic-induced disruptions and an IT security incident in March 2023. Our employees have ensured that operations remained on track during these disruptive threats.

We are grateful to our Board of Directors for their guidance and support.

Your support to us as a shareholder is of vital importance, and we hope that you will continue to repose your confidence in us in the future.

Dilip Shanghvi
Managing Director
Sun Pharmaceutical Industries Limited