Sun Pharmaceutical Industries Limited) Annual Report 2022-23

Managing Director's Message



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 \gtrless 433 Billion while EBITDA grew by 12% to \gtrless 116 Billion. Adjusted net profit was up by about 12.8% to \gtrless 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. **Corporate Overview** (Statutory Reports) (Financial Statements

Managing Director's Message

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 HaloI 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 UractivTM 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 NCELLTM 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 HCI (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.

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Managing Director's Message

Corporate Overview)

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

Board of Directors



Dilip S. Shanghvi Managing Director



Dr. Pawan Goenka Lead Independent Director

Sailesh T. Desai Whole-time Director



Gautam Doshi Independent Director

Rama Bijapurkar Independent Director





Corporate Overview

Board of Directors

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Aalok D. Shanghvi Whole-time Director (appointed with effect from June 01, 2023)

Sudhir V. Valia Non-Executive and Non-Independent Director



Sanjay Asher Independent Director (appointed with effect from November 01, 2022)

Rolf Hoffmann Independent Director (appointed with effect from June 15, 2023)

Leadership Team



Abhay Gandhi CEO – North America



Dr. Sapna Purohit Senior Vice-President, Head of Human Resources



Aalok D. Shanghvi Whole-time Director Executive Vice-President, Emerging Markets, Global generic R&D, Global BD (Generics Segment) & API



C. S. Muralidharan Chief Financial Officer



Jila Breeze Executive Vice-President, Global Head – Quality



Anil Rao Senior Vice-President, Chief Information Officer

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Kirti Ganorkar CEO - India Business



Corporate Overview

Leadership Team

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Hellen de Kloet Business Head – Western Europe, Australia and New Zealand



Dr. Azadar H. Khan Senior Vice-President, Corporate Relations and CSR



Uday Baldota CEO – Taro Pharmaceutical Industries Ltd.



Sreenivas Rao Senior Vice-President, Head – Global Supply Chain



S. Damodharan CEO – API Business

Management Discussion and Analysis

Global Pharmaceutical Industry¹

The global pharmaceutical industry has risen to the challenge of the COVID-19 pandemic by developing effective vaccines and therapeutics and overcoming unprecedented supply chain disruptions. This is a true testament to the industry's adaptability and resilience in the face of a global health crisis. While the industry is expected to return to pre-pandemic growth rates by 2024, uncertainties related to viral variants, vaccine distribution, economic and geopolitical factors may impact future growth.

Following a rebound in global medicine use in 2021 after the pandemic, growth slowed in 2022 and spending inched up from US\$ 1.42 Trillion to US\$ 1.48 Trillion. The global pharmaceutical spending is projected to grow by a CAGR of 3-6% between 2023 and 2027, to reach a total market size of approximately US\$ 1.9 Trillion. The growth is expected to be primarily driven by the COVID-19 vaccination and introduction of novel medicines. This will be offset by the loss of exclusivity and the lower costs of generics and biosimilars.

Regional spending and volume growth trends will continue to diverge with developed markets growing at a slower rate than Pharmerging markets**. US pharmaceutical spending is expected to grow at 2.5%-5.5% CAGR through 2027 helped by increased spend on existing medicines as well as introduction of new medicines. However, on a net price basis, the US market is forecast to grow at lower rate reflecting the impact of newly introduced Inflation Reduction Act. The Asia-Pacific region is projected to experience steady growth after the pandemic, while China is expected to see a slowdown in growth due to pricing pressures. It is expected that spending on pharmaceuticals in India will continue to increase at a CAGR of 7.5-10.5% to reach US\$35-39 Billion annually by 2027. Among other Pharmerging markets, Latin America and Eastern Europe are among the fastest-growing regions in terms of medicine spending globally.

Graph 1



** Includes Argentina, Bangladesh, Brazil, Chile, China, Colombia, Egypt, Hungary, India, Indonesia, Mexico, Pakistan, Philippines, Poland, Romania, Russia, Saudi Arabia, South Africa, Taiwan, Turkey, Ukraine, and Vietnam.



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Table 1

Table 2

Management Discussion and Analysis

Global Pharmaceutical Market¹

			Table 1
			(US\$ Billion)
2022	2018-2022 CAGR	2027	2023-2027 CAGR
1,088	5.7%	1,370-1,400	2.5-5.5%
371	7.2%	487-518	5-8%
23	6.0%	29-33	4.5-7.5%
1,482	6.1%	1,900-1,930	3-6%
	1,088 371 23	1,088 5.7% 371 7.2% 23 6.0%	1,088 5.7% 1,370-1,400 371 7.2% 487-518 23 6.0% 29-33

Corporate Overview

Global Pharmaceutical Market - Share by Product Type¹

										(% of Total)
Region	Original (%		Non-or Brand	0	Unbra Generi		OTC, Vac Other			Total \$ Billion)
Year	2022	2027	2022	2027	2022	2027	2022	2027	2022	2027
Developed Markets	73	71-75	10	11-12	9	7-8	8	7-8	1,088	1,370-1400
Pharmerging Markets	28	26-31	34	30-36	13	12-13	25	22-27	371	487-518
Other Markets	33	27-37	47	36-55	6	6-10	14	8-19	23	29-33
Global Markets	61	60-62	16	17-19	10	8-10	13	11-13	1,482	1,900-1,930

Specialty Medicines: Specialty medicines that treat chronic, complex, and rare diseases have been increasing as a share of spending in higher-income countries. They are expected to be 43% of global spending by 2027. Pharmerging countries have lagged behind in usage of Specialty medicines mainly due to higher prices. Specialty medicines comprised 16% of Pharmerging countries drug spending in 2022, and it is expected to be unchanged as a share of spending in 2027.

Key Therapy Areas: The therapy areas with the highest spending forecast in 2027 are Oncology, Immunology, and Diabetes, followed by Cardiovascular System. Oncology is expected to grow 13–16% CAGR through to 2027 as novel treatments will continue to be launched in this category. Immunology is expected to grow relatively slower in the range of 3-6% due to the price erosion driven by launch of biosimilars. With nearly US\$ 168 Billion in revenues by 2027, Diabetes is expected to be the thirdlargest therapy area globally, with growth estimated to be 3–6% over the next five years. Most other therapy areas are expected to grow at lower growth rates through 2027 with the exception of Obesity. Availability of new highly effective treatments and wider global usage is expected to enable Obesity spending to grow at 35-38%.

Per Capita Consumption: Per capita use of medicines is directly correlated with GDP. Countries such as Japan and those in Western Europe have more than double the per capita medicine use of Pharmerging markets.

COVID-19 Impact: The COVID-19 pandemic has had a significant impact on the pharmaceutical industry, with global spending on medicines expected to exceed pre-pandemic projections by US\$ 497 Billion by 2027 due to new spending on COVID-19 vaccines and therapeutics.

Key Trends

One of the key growth drivers for the pharmaceutical industry is the increasing life expectancy. With declining fertility rates and improved healthcare, the proportion of elderly in the population is increasing. This demographic shift is driving demand for healthcare solutions that can address age-related health issues and chronic ailments.

Longer Life Expectancy

Improved Purchasing Power

The middle-class population and per capita income are expanding, particularly in emerging markets. As purchasing power and awareness increases, patients can afford newer and more expensive treatments. This phenomenon has led to increasing spend on healthcare solutions, including pharmaceutical products. Another significant factor driving increased pharmaceutical spending involves people's lifestyle. Sedentary lifestyles, unhealthy dietary habits, hectic and stressful work habits, decreasing sleep quality and exposure to environmental factors are leading to a higher incidence of chronic and lifestyle related diseases. This shift is driving demand for relevant medical and pharmaceutical solutions.

Changing Lifestyle

Health Insurance and Infrastructure

The penetration of health insurance is expected to increase with government-sponsored initiatives and programmes, making healthcare more affordable and accessible to the population. This will drive demand for healthcare solutions. Additionally, improvements in healthcare infrastructure, including hospitals and clinics, will also drive demand for pharmaceutical products.

Innovation and Digital Adoption

Major technological shifts have encouraged the rapid adoption of advanced analytics in the pharmaceutical industry. Advanced analytics provide insights into customer behaviour, help in clinical trial design, and optimise the supply chain, driving growth and productivity across the pharma value chain. The use of digital technologies such as telemedicine and artificial intelligence (AI) enables remote diagnosis, personalised medicine, and drug discovery. These digital technologies and advanced analytics are expected to play a significant role in increasing the adoption of modern medicine.



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Table 3

Developed Markets

Growth in the pharmaceutical industry in developed markets is expected to be led by the introduction of new drugs. Specialty medicines are forecast to account for a significant portion, exceeding 55% of total spending in developed markets in 2027. However, pharmaceuticals in developed markets face challenges such as biosimilar competition and increasing number of patent expiries. Despite these challenges, the increasing adoption of specialty medicines is expected to persist, particularly in oncology and immunology.

Developed Markets – Pharmaceutical Spending and Growth¹

				(US\$ Billion)
Region/Country	2022	2018-2022 CAGR	2027	2023-2027 CAGR
Top 10 Developed Markets	968.9	5.7%	1,207-1,237	2.5-5.5%
Other Developed Markets	119.4	6.4%	156-176	4-7%
Total Developed Markets	1088.3	5.7%	1,370-1,400	2.5-5.5%

US¹

The US pharmaceutical industry is expected to witness subdued growth over the next five years due to several factors namely increased discounts and rebates, upcoming patent expiries and heightened competition from new generic and biosimilar drugs. However, spending on medicines is still projected to increase by US\$ 134 Billion annually by 2027, with the main driver being the use of existing branded products.

The key contributors towards the annual increase in US medicine spending by 2027 are expected to include the increasing use of existing protected brand products (154 Billion) and new brands (122 Billion) offset by Loss of Exclusivity on existing products (141 Billion). Therefore, despite the challenges of Loss of Exclusivity, innovation is expected to drive growth with the launch of new oncology drugs and next generation biotherapeutics.

Off-invoice discounts and rebates result in spending that is estimated at 36% lower than the invoice level in 2022 and projected to be 45% lower than the invoice level in 2027. On a net price basis, US market is expected to grow at -1 to 2% through 2027. Introduction of Inflation Reduction Act or IRA is expected to be a key reason of increasing off-invoice discounts and rebates.



Top 5 Western European Markets (WE5)¹

The top five Western European pharmaceutical markets are expected to experience a mix of opportunities and challenges over the next five years. Despite the pandemic's sustained impact on marketing operations early on and budget pressures affecting reimbursement decisions later, the launch of new brands is expected to continue driving growth through to 2027. Additionally, generics and biosimilars are projected to contribute to growth, though this may be offset by price deflation and losses of exclusivity.

The oncology and neurology therapies are among the areas expected to see significant growth, along with next generation biotherapeutics.



Japan¹

The Japan pharmaceutical market is expected to register limited or no growth due to long-term trends affecting long-listed brands. Although there will be a rebound from the pandemic's impact, annual pricing revisions are expected to continue. Protected brands have gained a larger share of spending while long-listed product spending has continued to decline. Generic spending is expected to rise due to effective government policies.



Pharmerging Markets¹

The Pharmerging markets are projected to show 5-8% revenue CAGR between 2023-27, primarily driven by the increasing usage of generic drugs and branded generics. These markets have shown resilience during the pandemic, with many countries being impacted by COVID-19 in later waves and thereby experiencing less of the early wave behaviour changes. Pharmerging and lower-income countries have a lower share of spending from originator products, with a greater focus on either generics or non-original branded products, which are typically priced lower.

Latin America and Eastern Europe are among the fastestgrowing regions in terms of medicine spending globally. Brazil and Mexico are expected to lead the growth in Latin America at 9-12% and 7.5-10.5%, CAGR respectively through 2027. In Eastern Europe, Russia is projected to grow at 6-9% CAGR through 2027. However, the ongoing Ukraine conflict has impacted medicine use and spending in Ukraine, as well as potentially impacting neighbouring countries with the medical needs of displaced persons and economic activity.

Table 4

Pharmerging Markets – Pharmaceutical Spending and Growth¹

				(US\$ Billion)
Region	2022	2018-2022 CAGR	2027	2023-2027 CAGR
Pharmerging Markets	370.8	7.2%	487-518	5-8%

India¹

The Indian pharmaceutical industry has been experiencing steady growth with a focus on generic medicines. It is expected that spending on pharmaceuticals in India will continue to increase, with a CAGR of 7.5–10.5% between 2023-27 to reach US\$ 35-39 Billion annually. The industry's continued focus on generics is a key factor to its growth, as they are typically priced lower than branded medicines. The industry's low-cost structure and its ability to produce large quantities of medicines have also made it a key player in the global pharmaceutical market.





Speciality Medicines¹

Specialty medicines, which treat chronic, complex, and rare diseases, have seen an increase in spending in higher-income countries, including the 10 largest developed countries and other high and upper-middle-income countries.

By 2027, it is projected that specialty medicines will make up 43% of global medicine spending. The share of specialty spending in the top-10 developed economies is expected to be higher at 56%. As Specialty medicines treat rare diseases with smaller patient population, they tend to treat only 2-3% of overall patients. As the spend on Specialty medicines is increasing, it is also notable that the costs of traditional therapies have been declining.



Active Pharmaceutical Ingredients (APIs)²

The global market for Active Pharmaceutical Ingredients (APIs) has been growing steadily and is expected to continue growing from US\$ 210 Billion to reach US\$ 292 Billion by 2027, at a CAGR of 5.64% during 2021-27.

Growth Drivers for API



Consumer Healthcare (CHC) Market³

The consumer health industry has demonstrated impressive resilience throughout the past three years of the COVID-19 pandemic. Despite the challenges posed by the outbreak, the industry has maintained steady growth, with categories such as Vitamins, Minerals, and Supplements (VMS) stepping up to compensate for the shortfalls in Cold/flu and Pain categories during periods of lockdown and social distancing. The global consumer healthcare (CHC) market is currently valued at US\$ 175 Billion (MAT Q2 2022) and is expected to continue growing at a rate of approximately 6% annually over the next five years.

Sun Pharma: A Leading Global Pharmaceutical Company

Sun Pharmaceutical Industries Limited, its subsidiaries, and associates (together, "Sun Pharma") is a leading global pharmaceutical company and the largest pharmaceutical company in India. Sun Pharma delivers high-quality medicines that are trusted by customers and patients in more than 100 countries. The Company boasts of a multicultural workforce comprising over 50 nationalities.

Sun Pharma's marketed portfolio comprises innovative specialty medicines, branded generics, pure generics and APIs. The Company's R&D skills, strong manufacturing capabilities and a global commercial presence enable it to meet the evolving needs of patients and customers worldwide.

Sun Pharma has a large and diverse manufacturing footprint spread across multiple countries, approved by major regulatory agencies. The Company's manufacturing capabilities include a broad range of dosage forms, namely pills, capsules, injectables, sprays, ointments, creams, liquids, drug delivery systems, APIs and intermediates.

Management Discussion and Analysis

Strong Global Positioning 4, 5

Largest Pharmaceutical company in India	Leading Global specialty generic company	Among the Largest Indian pharmaceutical companies in emerging markets	10th Largest generic pharmaceutical company in the US
100+ Countries market reach	43 Global manufacturing sites across six continents	41,000+ Global employee base	50+ Employee nationalities

Major Milestones

Year	Deals	Country	Rationale
2023	Launched Sezaby	US	Addition to portfolio of specialty branded products. Treatment of neonatal seizures
2022	Acquired Concert Pharma in the US	US	Adding a late-stage product to dermatology franchise
2022	Acquired Uractiv™ Portfolio from Fiterman Pharma	Romania	Expand non-prescription product basket in Romania and neighbouring markets
2022	In-licensing agreement to expand Winlevi®	Japan, Australia, New Zealand, Brazil, Mexico and Russia	Increasing access to new markets for Winlevi®
2022	Taro (Sun's subsidiary company) acquired Alchemee Business from Galderma	US, Japan and Canada	Acquired the 'Proactiv', 'Restorative Elements' and 'In Defense of Skin' brands. Strengthens Taro's OTC portfolio
2021	In-licensed agreement for Winlevi®	US and Canada	Topical treatment of acne vulgaris
2020	Exclusive out-licensing agreement with Hikma for Ilumya	Middle East and North Africa	Registration and commercialisation of the product in all Middle East & North Africa (MENA) markets
2020	In-licensing agreement with SPARC for SCD-044	Global	Potential indication in psoriasis, atopic dermatitis and other auto-immune disorders
2019	Out-licensing agreement with AstraZeneca UK for ready-to-use infusion oncology products	Mainland China	Access to oncology market in Mainland China
2019	Licensing agreement with CMS for Tildrakizumab, Cequa and 8 generic products	Greater China	Access to Greater China market
2018	Acquired Pola Pharma in Japan	Japan	Access to Japanese dermatology market
2016	Acquired global rights for Cequa and Odomzo	Global	Enhances specialty pipeline
2016	Acquired Biosintez	Russia	Local manufacturing capability to enhance presence in Russian market
2016	Out-licensing agreement with Almirall for Tildrakizumab	Europe	Access to European market for Tildrakizumab
2016	Acquired 14 brands from Novartis	Japan	Entry into Japan
2015	Acquired InSite Vision Inc.	US	Strengthens branded ophthalmic portfolio in the US
2015	Sun Pharma-Ranbaxy merger	Global Markets	Strengthen position in the global generic pharma industry. #1 Pharma Company in India and strong positioning in emerging markets
2014	In-licensing agreement with Merck for Tildrakizumab	Global Markets	Strengthening the specialty product pipeline
2014	Acquired Pharmalucence	US	Access to sterile injectable capacity in the US
2012	Acquired DUSA Pharma, Inc.	US	Access to specialty drug-device combination in dermatology segment
2010	Acquired Taro Pharmaceutical Industries Ltd.	Israel and Canada	Access to dermatology generics portfolio manufacturing facilities at Israel & Canada
1997	Acquired Caraco	US	Entry into the US market

Our Global Specialty Business*

Specialty medicines are the latest generation of products that are specifically developed for treating chronic, complex, and rare diseases. In 2022, they accounted for around 43% of the global pharmaceutical spending, up from 32% in 2017. They account for 49% of pharmaceutical spending in top-10 developed markets in 2022, expected to grow to 56% in respective markets by 2027. This highlights the sustained growth of specialty medicines in addressing the unmet medical needs of patients worldwide.

are of Speciality Medicines in Overall Pharmaceutical Spending – By Market ¹					
				(%)	
Year	2012	2017	2022	2027	
Top 10 Developed Market	28	40	49	56	
Other Developed Market	27	36	39	47	
Pharmerging Market	10	12	16	16	
Global Market	24	32	43	43	

Beginning with acquisition of DUSA in 2012, Sun Pharma has continued to expand its global specialty offering. Within specialty, the Company is mainly focused on addressing patient needs in areas of dermatology, ophthalmology and onco-dermatology. Sun's investments in specialty have continued in three core areas

- Attain product access through in-licensing/acquisitions and in-house R&D
- Clinical development of pipeline specialty assets
- Build front-end commercial infrastructure

*Global Specialty revenues are separately reported but also as a part of geographical businesses, including US and others.

FY23 Highlights

During the year, Sun acquired Concert Pharma Inc. The lead asset of Concert, deuruxolitinib, has successfully completed global Phase-3 trials including in the US, for the indication of treatment of Alopecia Areata. The Company also launched SEZABY (phenobarbital sodium injection) for the US market, for the treatment of neonatal seizures. SEZABY is the first and only product approved by the U.S. Food and Drug Administration for the treatment of neonatal seizures in term and preterm infants.

Till date, Sun Pharma has marketed approximately 26 specialty products across different markets, which contributed ~16.2% to the Company's consolidated revenues for FY23.

Currently Marketed Specialty Portfolio

	Table 6
Product	Description
llumya/	For treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
llumetri	• Long term clinical data shows that the significant response rate seen in 52 & 64 weeks were maintained over five years ¹
	Ongoing Phase-3 trials for Psoriatic Arthritis
	Current Markets: US, Australia, Japan, Canada, Europe (by partner Almirall)
	• Out licensed to CMS for Greater China where it received approval in May 2023 & to Hikma for Middle East & North Africa
Winlevi	Topical treatment of acne vulgaris in patients 12 years of age and older
	Results from two pivotal clinical trials showed favourable safety and efficacy data for WINLEVI in patients with acne aged 12 years and older ²
	Current Markets: US
Levulan Kerastick +	For photodynamic therapy (treatment) of minimally to moderately thick actinic keratoses of the face or scalp, or actinic keratoses of the upper extremities
BLU-U	• First and only PDT approved to treat the face and scalp as well as the upper arms, forearms, and hands ³
	Current Markets: US

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Management Discussion and Analysis

Table 6

Product	Description
Absorica LD	Treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater
	 After one 20-week course of ABSORICA therapy, 95% of patients didn't require additional isotretinoin treatment up to two years posttreatment⁴
	Current Markets: US
Odomzo	Treatment of adult patients with locally advanced Basal Cell Carcinoma (BCC) that has recurred following surgery or radiation therapy or those who are not candidates for surgery or radiation therapy.
	 ODOMZO was shown to shrink laBCC in almost 6 out of 10 patients (56%) in a clinical study. laBCC Patients were treated with ODOMZO[®] and followed for at least 18 months⁵
	Currently marketed in US, Canada, Germany, France, Denmark, Switzerland, Spain, Italy, Australia and Israel
Cequa	To increase tear production in patients with keratoconjunctivitis sicca (dry eye)
	• Phase 3 confirmatory study observed clinically and statistically significant improvements in tear production and ocular surface integrity in patients ⁶
	Current Markets: US, Canada
	Out-licensed to CMS for Greater China in June 2019
Bromsite	Treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery
	• More than 2x as many patients treated with Bromsite [®] were inflammation-free at day 15 than those treated with vehicle and nearly 80% of patients treated with Bromsite [®] were pain-free at day 1 post surgery ⁷
	Current Markets: US
Xelpros	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.
	 In clinical trials, XELPROS demonstrated reductions from baseline in intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension⁸
	Current Markets: US
Yonsa	In combination with methylprednisolone for the treatment of patients with metastatic castration resistant prostate cancer (CRPC).
	 Yonsa[®] was shown in clinical studies to be an effective form of abiraterone acetate, and can be taken with or without food, in combination with methylprednisolone⁹
	Current Markets: US
Sezaby	First and only product approved in the US for treating seizures in neonatal patients
	 NEOLEV2 study compared phenobarbital to levetiracetam in the first-line treatment of neonatal seizures. 24 hours following the administration, 73% vs. 25% were seizure-free in the respective groups¹⁰
	Current Markets: US
Sprinkle	For therapeutic solutions for long-term care (LTC) patients
portfolio	Products using sprinkle technology for patients who have difficulty swallowing
	Sprinkle versions of metoprolol (cardiology), rosuvastatin (cardiology) & duloxetine (neuro-psychiatry)
	Current Markets: US

(Corporate Overview)

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Source: (1, 2, 4, 6, 9 & 10 - Sun press release), (3 - Levulan website), (5 - product label), (7 & 8 - product label)

Specialty R&D Pipeline

Sun Pharma has a pipeline of five specialty molecules undergoing clinical trials:

Molecule/Asset	Indication	Route of Administration	Mechanism of Action	Pre-clinical	Phase-1	Phase-2	Phase-3	Registration
CTP-543 (deuruxolitinib)	Alopecia Areata	Oral	JAK Inhibitor					
llumya (tildrakizumab)	Psoriatic Arthritis	Injection	IL-23 Antagonist					
MM-II	Pain in osteoarthritis	Injection	Liposomal intra -articular lubrication					
SCD-044	Psoriasis, Atopic Dermatitis	Oral	Selective SIPR1 Agonist					
GL0034	Type 2 Diabetes	Injection	GLP-1R Agonist					

Table 7

Business Model

At Sun Pharma, we are committed to our Vision of "Reaching People and Touching Lives Globally as a Leading Provider of Valued Medicines." We strive to achieve this vision through a well-defined strategy that focuses on sustainable growth, cost leadership, business development, balanced investments, and future profitability.



* Global Specialty revenues are separately reported but also as a part of geographical businesses, including US and others. ** Global Consumer Healthcare revenues are reported as part of geographical businesses, included India and others.



Focus Areas -

- Enhance share of specialty products in overall business
- Develop and commercialise differentiated and difficultto-manufacture products
- Focus on improving return ratios

- Maintain market leadership and high brand equity in India – leverage strengths for in-licensing latest generation innovative products for the domestic market
- Gain critical mass across key international markets

Management Discussion and Analysis



^{##} RoW includes Western Europe, Canada, Israel, Japan, Australia, New Zealand and other markets.

Financial Ratios

Consolidated

Ratios	FY23	FY22	Variance (%)	Reasons if variance is more than 25%
Return on Net Worth (%)	15.1	6.8	122.1	Return on Net Worth is higher for the year ended 31 March 2023, due to reduced exceptional expenses
Debtors Turnover (times)	3.8	3.7	2.7	-
Inventory Turnover (times)	1.0	1.2	(16.7)	-
Interest Coverage	56.7	72.0	(21.3)	-
Current Ratio (times)	2.0	2.0	0.0	-
Debt Equity Ratio (times)	0.12	0.03	300.0	Increase in borrowings
Operating Profit Margin (%)	25.5	26.5	(3.8)	-
Net Profit Margin (%)	19.6	8.5	130.6	Increase in profit on account of reduced exceptional expenses

Standalone

Ratios	FY23	FY22	Variance (%)	Reasons if variance is more than 25%
Return on Net Worth (%)	7.1	(0.4)	(1,850.7)	Return on Net Worth is higher for the year ended 31 March 2023, due to increase in profit on account of higher sales during the year
Debtors Turnover (times)	2.9	3.7	(21.7)	-
Inventory Turnover (times)	1.5	1.7	(8.6)	-
Interest Coverage	10.9	6.5	68.3	Interest coverage ratio is higher due to increase in profit before interest and tax, on account of higher sales during the year
Current Ratio (times)	1.97	0.96	104.7	Increase in current assets on account of classification of loans given as current loans during the year
Debt Equity Ratio (times)	0.33	0.21	59.0	Increase in borrowings
Operating Profit Margin (%)	29.7	18.3	62.2	Increase in profit on account of higher sales and product mix
Net Profit Margin (%)	8.3	(0.6)	(1.386.6)	Increase in profit on account of higher sales and product mix

FY23 Business Highlights

Sun Pharma demonstrated a strong performance across its global operations with a consolidated topline growth of 12.6% compared to FY22. Business-wise, the topline growth was primarily led by the US market with 19% Y-o-Y growth, followed by emerging markets with 17.1% Y-o-Y growth. India business also demonstrated 6.6% growth in revenue over the past year and Rest of the World revenue witnessed a steady growth compared to previous year.

The Company's EBITDA for FY23 witnessed a growth of 12% compared to last year, with an EBITDA margin of 26.5%. Adjusted net profit for the year grew by 12.8% Y-o-Y, demonstrating profitable growth for FY23.

Overall, these results reflect Sun Pharma's continued focus on growth and profitability across its global operations. The Company's strong performance across its key markets demonstrates its ability to navigate through challenging times and continue to deliver value to its stakeholders.

Business-wise Review

US Business

31%	₹ 135,352 Million	616	519
Revenue share	Revenue in FY23	Cumulative ANDAs filed as on March 31, 2023	Cumulative ANDAs approved as on March 31, 2023
67	54	97	13
Cumulative NDAs filed as on March 31, 2023	Cumulative NDAs approved as on March 31, 2023	ANDAs pending USFDA approval as on March 31, 2023	NDAs pending USFDA approval as on March 31, 2023

Table 9



Management Discussion and Analysis

Table 10

Sun's US business comprises of sales of Specialty and Generic medicines. Over the years, Sun Pharma has solidified its position as a major player in the US generics market. The Company has emerged as the 10th largest generics pharmaceutical company in the US and is ranked 2nd by prescriptions in the US dermatology market. In addition, the Company has been continuously expanding its footprint in the specialty segment, focusing on dermatology, ophthalmology, and oncology. In FY23, the US business contributed 31% to the Company's consolidated revenues.

Sun Pharma has established valuable relationships with leading wholesalers, distributors, chain drugstores, healthcare providers, and payors in the US. Moreover, Sun Pharma possesses vertically integrated manufacturing capabilities that enables it to serve its customers efficiently in the US.

Milestones in the US Business

Years **Major Initiatives** FY23 • Acquired Concert Pharma giving access to deuruxolitinib for Alopecia Areata Launched SEZABY in the US FY22 Launched Winlevi® in the US Presented long-term clinical data for Ilumya and other clinical insights for Odomzo and Levulan at the American Academy of FY21 **Dermatology Conference** FY20 Launched Cequa and Absorica LD in the US FY19 Launched Ilumya, Yonsa & Xelpros in the US Received USFDA approval for Cequa Released Ready-to-Infuse INFUGEMTM FY18 • Launched Odomzo in the US Received USFDA approval for llumya FY17 Acquired Ocular Technologies to receive access to Cequa for dry eye Acquired Odomzo, a branded oncology product from Novartis FY13 Acquired DUSA for entry into branded specialty FY10 Acquired Taro Pharma for entry into US dermatology • FY98 • Entry into the US through Caraco acquisition

FY23 Highlights

Revenues from the US grew by 19% Y-o-Y to ₹ 135,353 Million in FY23. The growth was mainly driven by the ramp-up in specialty.

Sun Pharma Acquires Concert Pharmaceuticals, Inc.

Sun Pharma acquired Concert Pharmaceuticals, a clinical-stage biopharmaceutical company that has been developing a novel oral JAK1/2 inhibitor called 'deuruxolitinib' for treating moderate to severe alopecia areata in adult patients. The acquisition will expand Sun Pharma's global dermatology portfolio and presence in the Boston biotech hub. The combined expertise of Concert's talented team and Sun Pharma's commercial capabilities will help bring 'deuruxolitinib' to the global market, benefitting alopecia areata patients worldwide.

Approvals and Launches in the US

- Sun Pharma launched SEZABY[™] (phenobarbital sodium) in the U.S. for the treatment of neonatal seizures. SEZABY is the first and only product approved by the U.S. Food and Drug Administration (US FDA) for the treatment of neonatal seizures in term and preterm infants. Earlier during the year, Sun Pharma and SPARC entered into a licensing agreement for commercialisation of the product in the United States.
- A wholly owned subsidiary of Sun Pharma received final approval from US FDA for its Abbreviated New Drug Application (ANDA) for generic lenalidomide Capsules, 5mg, 10mg, 15mg, 25mg, 2.5mg, 20mg. The respective product approval is based on Revlimid[®] Capsules, 5mg, 10mg, 15mg, 25mg and 2.5mg, 20mg as a reference product.
- Sun Pharma received final approval from US FDA for its Abbreviated New Drug Application (ANDA) for generic Mesalamine Extended Release Capsules, 500 mg. The generic product approval is based on Pentasa[®] Extended-Release Capsules, 500mg as a reference product.

[Source: Press Releases]





Road Ahead

- Enhance share of specialty/branded business.
- Continue to focus on complex generics and high entry barrier segments.
- Ensure broad product offering to customers across multiple dosage forms.
- Focus on compliance, product robustness and supply chain efficiencies.

India Branded Formulations Business: Largest Pharma Company in India 4, 5

32% Revenue share	₹ 136,031 Million Revenue in FY23	#1 Rank with 8.3% market share
#1	32	12,600+
Rank by prescription with 12 different classes of doctors	Brands among India's top 300 brands	Strong field force

Sun Pharma is India's largest pharmaceutical company, with 8.3% market share and a strong position in the chronic and acute segment in India. The Company offers a comprehensive product portfolio across various therapeutic segments, including neuropsychiatry, cardiology, diabetes, gastroenterology, pain/analgesics, gynaecology, ophthalmology, urology, dermatology, respiratory, anti-infectives and other segments. Sun Pharma has one of the largest sales force in the country, coupled with a strong distribution and geographical reach. It enjoys strong brand equity among the medical fraternity.

While the Company continues to launch a slew of new products in India, developed through its in-house R&D efforts, it is also leveraging its strengths in India to position

itself as a partner of choice for in-licensing of latest generation innovative products for patients in India.





Management Discussion and Analysis

	Gr	aph 21
India Business Therap	eutic Revenue Break-Up	4 (%)
	Therapy	(%)
(Cardiology	18
(Neuropsychiatry	16
(Gastroenterology	12
	Anti-infectives	11
	Pain/Analgesics	7
	Diabetology	7
	Dermatology	6
	Respiratory	5
	 Vitamins/Minerals/ Nutrients 	5
	Urology	4
	Gynaecology	3
	Ophthalmology	2
(Others	4

India Prescription Ranking - Leadership in Key Therapeutic Areas⁵

		Table II
Specialist	February 2023	February 2022
Psychiatrists	1	1
Neurologists	1	1
Cardiologists	1	1
Orthopaedic specialists	1	2
Diabetologists	1	1
Gastroenterologists	1	1
Nephrologists	1	2
Consultant Physicians	1	1
Urologists	1	1
Dermatology	1	1
ENT Specialists	1	1
Chest Physicians	1	1
Ophthalmologists	2	2
General Surgeons	2	1
Gynaecologists	2	2

Best-in-class Field Force Productivity

Sun Pharma has among the highest sales per Medical Representative (MR) ratio in India's pharma sector. The Company's MRs are well trained and scientifically oriented, with a strong performance record.



Table 11

Corporate Overview

FY23 Highlights

Revenue from the India business* grew by 6.6% to ₹ 136,031 Million, driven by growth across most of the Company's therapies.

*India business comprises India Branded Formulations business, described here, and part of Global Consumer Healthcare business, described in a later section.

New Product Approvals, Launches and **Acquisitions in India**

- Sun Pharma acquired three brands viz. Disperzyme[®] (Trypsin BP 96 mg, Bromelain 180 mg & Rutoside Trihydrate 200 mg), Disperzyme-CD[®] (Trypsin BP 48 mg, Bromelain 90 mg & Rutoside Trihydrate 100 mg) and Phlogam[®] (Trypsin BP 48 mg, Bromelain 90 mg & Rutoside Trihydrate 100 mg) from Aksigen Hospital Care. All the brands are approved by the Drugs Controller General of India (DCGI) for post-operative inflammation in patients undergoing minor surgery and dental procedures. The addition of Disperzyme[®] and Phlogam[®] strengthens Sun's anti-inflammatory portfolio.
- Sun Pharma launched a novel anti-cancer drug, Palbociclib in India for patients who have advanced breast cancer, the most common cancer among women in the country. The Company has made the drug available under the brand name, PALENO[™] (Palbociclib) 75 mg, 100 mg, 125 mg. Palbociclib is already approved by the USFDA, EMA and CDSCO in combination with hormonal therapies for patients with hormone receptor positive, human Epidermal Growth Factor Receptor-2 negative locally advanced or metastatic breast cancer.

[Source: Press Releases]

Road Ahead

- Continue to focus on productivity improvement
- Strive to maintain leadership position in a fiercely competitive market
- Continuously innovate to ensure high brand equity with prescribers
- Continue to evaluate in-licensing opportunities for latest generation innovative products

Sun Pharmaceutical Industries Limited Annual Report 2022-23

18%
Revenue share₹ 78,977 Million
Revenue in FY23Leading
Indian company in Emerging Markets~80
Markets sales reach7
Markets with local
manufacturing footprint2,300+
Sales representative

Emerging Markets: Among the Leading Indian Companies in Emerging Markets

Sun Pharma is one of the largest Indian pharmaceutical companies operating in the Emerging Markets with presence in ~80 countries. The Company has local manufacturing facilities in Bangladesh, South Africa, Malaysia, Romania, Egypt, Nigeria, and Russia, giving it flexibility to serve these markets. Emerging markets accounted for 18% of the consolidated revenues for FY23.

FY23 Highlights

• Revenues from Emerging Markets grew by 17.1% Y-o-Y to ₹78,977 Million driven by growth across multiple markets.

Road Ahead

- Gain critical mass in key markets
- Enhance specialty product basket in Emerging Markets
- Focus on profitable growth

Rest of the World (RoW): Western Europe, Canada, Israel, Japan, Australia & New Zealand (ANZ) and Other markets

14%
Revenue share₹ 60,426 Million
Revenue in FY23Leading
Indian company in RoW5
Markets with local manufacturing footprint

Sun Pharma is one of the leading Indian pharmaceutical companies in Western Europe, Canada, Japan, Australia and New Zealand (ANZ). These markets have high penetration of modern medicines, mainly driven by government-administered healthcare or by significant private insurance coverage for pharmaceutical products. Most of these markets have similar characteristics, such as an ageing population, rising rates of chronic illnesses and lifestyle diseases, and government efforts to reduce healthcare spending. Sun Pharma has an expanding product portfolio in RoW markets, including injectables, hospital products, and retail products. It has local manufacturing in Canada, Japan, Australia, Israel, and Hungary, and has a distribution-led business model that focuses on the development and commercialisation of complex generics to achieve long-term profitability.

Over the past few years, Sun Pharma has initiated the process of commercialising its specialty products in some of these markets.

Corporate Overview Statutory Reports Financial Statements Management Discussion and Analysis

FY23 Highlights

- Revenue from RoW markets increased by 10.8% to ₹ 60,426 Million
- Sun Pharma and Cassiopea agreed to expand the License and Supply Agreements for WINLEVI cream 1% to include more countries such as Japan, Australia, New Zealand, Brazil, Mexico, and Russia. In 2021, they had already signed agreements for the US and Canada markets, and Sun Pharma launched WINLEVI in the US market in November 2021. Sun Pharma will has exclusive rights to develop and sell WINLEVI in the newly added countries, while Cosmo is the only supplier of the product.

Road Ahead

- Enhance contribution of specialty products to revenues
- Focus on complex generic launches
- Gain critical mass in key markets

Global Consumer Healthcare Business⁶

Among Top 5 Consumer healthcare companies in India with a science-based portfolio	25 Countries footprint	Among Top 10 Consumer healthcare companies in Romania, Nigeria and Myanmar
~500,000		
Pharmacy and Retail outlets in India where Sun Pharma's products are available		

Sun Pharma's Consumer Health Care business is India's 5th largest business with a portfolio based on scientific formulations, having operations in about 25 emerging markets. It is one of the leading consumer health franchisees in India with bellwether brands such as Revital, Volini and Abzorb in its portfolio. In India, Sun Pharma's consumer healthcare products have strong distribution reach across pharmacies, retail stores and online e-commerce platforms.

FY23 Highlights

- In FY23, Sun Pharma's key brands Volini and Revital continued to maintain strong market position in their respective categories on the back of higher consumer preference and brand recall
- Given the heightened consumer interest in the health supplement space, new campaigns to strengthen the position of the Revital H franchisee in the nutraceutical category were undertaken

Road Ahead

- Sustained focus and investments in anchor brands with a view of category development
- Maintain leadership in existing markets through focus on innovative solutions
- Enhance presence in high growth markets
- Augmenting consumer reach through opening of new markets and distribution channels
- Activating digital for wider consumer outreach

Active Pharmaceutical Ingredient (API) Business



Sun Pharmaceutical Industries Limited Annual Report 2022-23

Sun Pharma prioritises the API business as it enables strong backward integration and reduces its dependence on thirdparty suppliers. Over the years, the Company has developed many APIs that cater to captive requirements and also helps it supply to large generics manufacturers and innovator companies. The Company has 14 API facilities which support its formulation business.

FY23 Highlights

• Revenue from the API business increased by 7.5% to ₹ 19,724 Million mainly due to higher sales recorded in India

Road Ahead

- Continue to focus on supporting the formulations business through the development of strategic APIs
- Ensure consistent supplies and high service standards for customers

Research and Development (R&D)

5.5%	₹ 238+ Billion	2,800+
R&D spend as percentage of sales in FY23	Cumulative R&D expenditure till date	Strong R&D team

Sun Pharma's dedicated R&D team endeavours to offer patients with innovative and affordable medicines and treatments to alleviate their ailments. The Company has been continuously investing in building a strong portfolio of generics, branded generics, and specialty products for the global market.

Our R&D capabilities extend across various dosage forms, including injectables, orals, liquids, ointments, gels, sprays, hormones and oral products. Additionally, our robust intellectual property capability provides support to its R&D team.





** Excludes Expired/Abandoned Patents (All data as of March 31, 2023)

Road Ahead

- Focus on developing complex products across multiple dosage forms
- Invest to further build the specialty pipeline
- Addition and progress on Specialty R&D Pipeline

• Developed and filed ~200 formulation dossiers globally

Overall R&D investments for the year was

₹ 23,676 million (5.5% of sales)

FY23 Highlights

Statutory Reports)

Management Discussion and Analysis

Global Manufacturing Base: World-Class Manufacturing Infrastructure

With 43 state-of-the-art manufacturing facilities spanning across 6 continents, Sun Pharma has established a leading position in the global pharmaceutical industry. Our vertically integrated network enables us to produce a wide range of pharmaceuticals, including oncology, hormones, peptides, and steroidal drugs, while adhering to the highest quality standards. We offer a variety of dosage forms, including orals, creams, ointments, injectables, sprays, and liquids. At Sun Pharma, we are committed to providing high-quality pharmaceutical products that make a positive impact on people's lives. Our extensive global footprint and world-class manufacturing infrastructure allow us to deliver on this promise to our customers and patients around the world.

Sun Pharma's manufacturing facilities are certified by global regulatory agencies such as the USFDA, European Medicines Evaluation Agency (EMEA); UK Medicines and Healthcare Products Regulatory Agency (MHRA); Australia's Therapeutic Goods Administration (TGA); South Africa's Medicines Control Council (MCC); Germany's Federal Institute for Drugs and Medical Devices (BfArM); Brazilian Health Regulatory Agency (ANVISA); the World Health Organization (WHO), and South Korea's Ministry of Food and Drug Safety and Japan's Pharmaceuticals and Medical **Devices Agency.**

Finished dosage API facilities manufacturing facilities

Finishing Dosage Manufacturing Facilities

Country	Number of Finished Dosage Facilities
India	15
US	3
Japan	1
Canada	1
Hungary	1
Israel	1
Bangladesh	1
South Africa	1
Malaysia	1
Romania	1
Egypt	1
Nigeria	1
Russia	1
Total	29

API Manufacturing Facilities

Corporate Overview

Country	Number of API Facilities
India	9
Australia	2
Israel	1
US	1
Hungary	1
Total	14

People: Nurturing a Diverse and Inclusive Global Workforce

With a global workforce of over 41,000 people from more than 50 nationalities, Sun Pharma is committed to providing a work environment that is conducive to employee growth and development. The Company recognises and values the diverse perspectives and experiences that its employees bring to the table and strives to promote a culture of inclusivity and equal opportunities. Sun Pharma encourages its employees to continuously learn and share their knowledge and invests in various learning and development initiatives to help them stay future-ready. This dedication to employee well-being and development has helped Sun Pharma earn the Great Place To Work[®] in 2022.

Great Place to Work[®] Certified

Sun Pharma has been certified as a 'Great Place To Work[®]' in India which is a testament to the positive and fulfilling experience of our employees. We are proud of this achievement and will continue to prioritise our employees' well-being and satisfaction.

A great team makes a workplace great. This recognition truly belongs to each member of the Sun team. At Sun, we are always guided by our ideologies - humility, integrity, passion and innovation. This is our DNA and it inspires us to grow, innovate and improve access to high-quality medicines that help patients with unmet medical needs.

Dilip Shanghvi

Table 12

Commitment to Quality

Sun Pharma's robust quality management system ensures the highest quality standards are maintained across its research centres, manufacturing divisions, testing labs, and distribution centres. Our Quality Management Team oversees regulatory compliance for all products and manufacturing plants, and we hold Current Good Manufacturing Practice (cGMP) certifications from various international regulatory bodies such as USFDA, EMA, WHO, and TGA. Our Corporate Quality Unit ensures the execution of the latest GMP upgrades and guidelines.

Table 13

(Financial Statements

The May 2022 US FDA inspection of Halol facility was classified as Official Action Indicated (OAI). The Halol facility was put under import alert in December 2022 with certain products exempted from import alert. Company is in continuous communication with the USFDA to resolve the outstanding issues to resolve the OAI status and import alert.

The August 2022 US FDA inspection of Mohali facility was classified as Official Action Indicated (OAI). In April 2023, US FDA has directed the Company to take certain corrective

actions at the Mohali facility before releasing further final product batches into the US. These actions include, among others, retaining an independent CGMP expert to conduct batch certifications of drugs manufactured at the Mohali facility. The Company is taking required corrective steps.

Road Ahead

- Ensure 24x7 compliance to cGMP
- Continuously enhance systems, processes and human capabilities to ensure compliance with global regulatory standards

SWOT Analysis 1,3,4,5

Strengths

- Strong global prominence
 - Leading global specialty generics company
 - 10th largest generics Company in the US
 - 2nd largest by prescriptions in the US dermatology segment
 - Largest pharma company in India by market share
 - No. 1 ranking across 12 different classes of doctors in India
 - Among the largest Indian pharmaceutical companies in the Emerging Markets
 - Largest Indian pharmaceutical company in Japan
- Robust R&D infrastructure and capabilities to develop technologically complex products in the generics and specialty segments
- Focus on driving growth and profitability through a pragmatic mix of organic and inorganic initiatives
- Strong balance sheet imparts ability to undertake inorganic initiatives without any significant leverage, allowing future growth headroom
- Ability to supply high-quality products at affordable prices across the world

Opportunities

- The pandemic has resulted in increased healthcare awareness globally. This augurs well for companies like Sun Pharma, which can supply high-quality pharmaceutical products at affordable prices
- Favourable macro-economic parameters for India and emerging markets are likely to ensure reasonable volume growth for pharmaceutical products across these markets in the long term
- Developed markets have witnessed a consistent increase in contribution of specialty products in their overall pharmaceutical spending and this trend is expected to continue in the future. Sun Pharma has already commercialised many of its specialty products in developed markets, and hence will be able to reap the benefits of this expanding opportunity
- Growing penetration of generics in Japan and opening of the China market present good long-term opportunities for Indian companies, including Sun Pharma

Threats and Weaknesses

- The current geopolitical issues give rise to uncertainties related to supply chains, inflation and overall economic growth
- Potential fresh outbreaks of the pandemic across the world and subsequent disruption in economic activities may impact economic growth across countries and could indirectly impact pharmaceutical consumption
- Challenging US generics pricing environment, driven by customer consolidation and higher competitive intensity on account of the faster pace of generic drug approvals by the USFDA
- Significant volatility in the forex market, especially for emerging market currencies, may adversely impact reported growth of these markets, even though they may be recording growth in local currency terms
- Given the additional spending on battling the pandemic, governments across the world may try to control pricing of certain products, which may lead to governmentmandated price controls on pharmaceutical products
- Developing a specialty pipeline entails high upfront investments for long-term benefits, and may impact short-term profitability

Internal Controls (IC) and Internal Financial Controls (IFC)

The management believes that internal controls are the prerequisite of governance and that action emanating out of agreed business plans should be exercised within a framework of checks and balances. The management is committed to ensuring an effective internal controls environment, commensurate with the size and complexity of the business, which assures compliance with internal policies, applicable laws and regulations, ensures reliability and accuracy of records, promotes operational efficiency, protects resources and assets, helps to prevent and detect fraud, errors and irregularities and overall minimises the risks.

The Company has a well-established internal controls framework comprising a set of policies, procedures and systems, instrumental in enhancing the efficiency and effectiveness of business operations, reducing risks and costs, and improving decision-making and accountability.

Internal financial controls framework, sub-set of internal controls framework assures the reliability and accuracy of financial reporting and the preparation of financial statements for external purposes following generally accepted accounting principles.

Disclaimer

Statements in this 'Management Discussion and Analysis' describing the Company's objectives, projections, estimates, expectations, plans or industry conditions or events are 'forward-looking statements' within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied. Important factors that could make a difference to the Company's operations include global and Indian demand-supply conditions, finished goods prices, feedstock availability and prices, competitors' pricing in the Company's principal markets, changes in government regulations, tax regimes, economic conditions within India and the countries within which the Company conducts business and other factors, such as litigation and labour unrest or other difficulties. The Company assumes no responsibility to publicly update, amend, modify or revise any forward-looking statements, based on any subsequent development, new information or future events or otherwise except as required by applicable law. Unless the context otherwise requires, references in this document to 'we', 'us' or 'our' refers to Sun Pharmaceutical Industries Limited and consolidated subsidiaries.

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