

2 0 1 6 - 2 0 1 7 SUN PHARMACEUTICAL INDUSTRIES LTD.



Reaching People. Touching Lives.



approach to illustrating multifaceted connections that come together to drive growth, which is representative of multiple growth engines.

**Management Discussion** and Analysis

**Consolidated Financial Statements** 



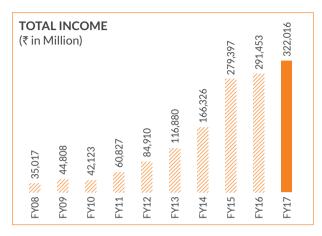
At Sun Pharma, we have consistently focused on augmenting the long-term growth drivers for the Company. As a part of this approach, we have added another growth engine to our business - the specialty business - which is gradually evolving for us. This is besides our existing growth engines of the generics and branded generics businesses.

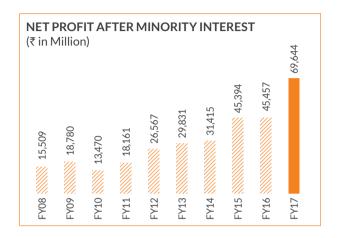
We are undergoing a gradual transformation as we continue to invest in enhancing our global specialty and complex generics pipeline. These investments will enable us to augment long-term growth avenues for future.

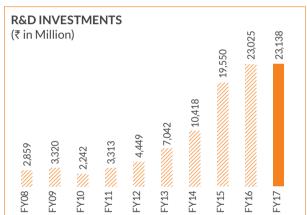
WE ARE NOT JUST COMMITTED TO AUGMENTING OUR GROWTH AVENUES, PATIENT CARE REMAINS AT THE CORE OF OUR STRATEGY.

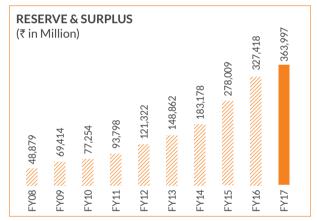


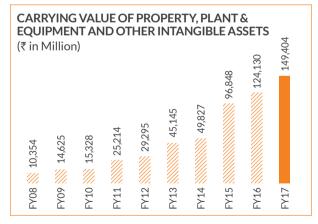
# KEY PERFORMANCE INDICATORS (CONSOLIDATED)

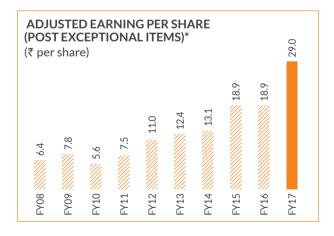












<sup>\*</sup> During FY11, each equity share of ₹ 5/- was split into five equity shares of ₹ 1/- each.

The Company has adopted Ind-AS accounting standards with effect from 1st April, 2015. Hence, FY16 onwards, the financials are reported as per Ind-AS and are not strictly comparable with previous years. For FY15, balance sheet items are as per Ind-AS.

<sup>\*</sup> During FY14, the Company issued bonus shares in the ratio of one equity share of ₹ 1/- for every share held.

<sup>\*</sup> During FY15, the Company's equity shares have increased to 2,406 Million due to the merger of erstwhile Ranbaxy Laboratories Ltd. (RLL) with the Company, wherein 0.80 equity share of ₹ 1 each of the Company have been allotted to the shareholders of RLL for every 1.00 share of ₹ 5 each held by them.

# TEN YEAR FINANCIAL HIGHLIGHTS

## **CONSOLIDATED**

₹ in Million

Particular	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17
Operating Performance										
Revenue from Operations	34,606	43,751	38,086	57,279	80,195	112,999	160,804	273,920	284,870	315,784
Total Income	35,017	44,808	42,123	60,827	84,910	116,880	166,326	279,397	291,453	322,016
Profit for the year (after minority interest)	15,509	18,780	13,470	18,161	26,567	29,831	31,415	45,394	45,457	69,644
R&D Expenditure	2,859	3,320	2,242	3,313	4,449	7,042	10,418	19,550	23,025	23,138
a) Capital	134	222	159	236	362	427	556	1,178	783	1,679
b) Revenue (Excluding Depreciation)	2,725	3,098	2,083	3,077	4,088	6,616	9,862	18,373	22,242	21,459
c) % of Turnover	9%	8%	6%	6%	6%	6%	7%	7%	8%	8%
Financial Position										
Equity Share Capital	1,036	1,036	1,036	1,036	1,036	1,036	2,071	2,071	2,407	2,399
Reserve and Surplus	48,879	69,414	77,254	93,798	121,322	148,862	183,178	278,009	327,418	363,997
Property, Plant & Equipment and other Intangible assets (at cost/ deemed cost)	15,960	21,476	23,340	45,473	54,269	75,763	86,505	143,616	187,212	217,315
Carrying value of Property, Plant & Equipment and other Intangible assets	10,354	14,625	15,328	25,214	29,295	45,145	49,827	96,848	124,130	149,404
Investments	6,565	18,595	31,664	26,557	22,129	24,116	27,860	35,028	18,299	11,919
Net Current Assets	33,995	35,485	28,542	58,622	76,749	86,618	126,969	135,488	167,973	150,666
Stock Information										
Number of Shares (Million)	207	207	207	1,036	1,036	1,036	2,071	2,071	2,407	2,399
Adjusted Earing per Share (post exceptional items) (In ₹)*	6.4	7.8	5.6	7.5	11.0	12.4	13.1	18.9	18.9	29.0
Earnings per Share-Basic (In ₹)*	74.7	87.8	65.2	17.5	25.7	28.8	15.2	18.9	18.9	29.0
Earning per Share-Diluted (In ₹)*	71.8	87.8	65.2	17.5	25.7	28.8	15.2	18.9	18.9	29.0

<sup>\*</sup> During FY11, each equity share of ₹ 5/- was split into five equity shares of ₹ 1/- each.

The Company has adopted Ind-AS accounting standards with effect from 1st April, 2015. Hence, FY16 onwards, the financials are reported as per Ind-AS and are not strictly comparable with previous years. For FY15, balance sheet items are as per Ind-AS.

<sup>\*</sup> During FY14, the Company issued bonus shares in the ratio of one equity share of ₹ 1/- for every share held.

\* During FY15, the Company's equity shares have increased to 2,406 Million due to the merger of erstwhile Ranbaxy Laboratories Ltd. (RLL) with the Company, wherein 0.80 equity share of ₹ 1 each of the Company have been allotted to the shareholders of RLL for every 1.00 share of ₹ 5 each held by them.



# MANAGING DIRECTOR'S LETTER



THE GLOBAL PHARMACEUTICAL LANDSCAPE IS RAPIDLY CHANGING. HENCE. BUSINESSES OF FUTURE WILL NEED TO DEVELOP AN ABILITY TO CONSTANTLY MOVE UP IN THE PHARMACEUTICAL VALUE CHAIN. THIS WILL MANDATE IDENTIFYING NEW AND PROFITABLE GROWTH DRIVERS IN ORDER TO GENERATE CONSISTENT SHAREHOLDER VALUE.

#### Dear Shareholders,

The global pharmaceutical landscape is rapidly changing. There are both, opportunities and challenges. Opportunities include an ageing population, leading to growing needs of modern medicines at affordable cost and evolution of new chemical and biological approaches towards targeted drug delivery. At the same time, rising healthcare costs (which force governments to intervene on pricing), increasing competitive intensity, customer consolidation and increased focus on value delivered; imply that businesses of future will need to develop an ability to constantly move up in the pharmaceutical value chain. This will mandate identifying new and profitable growth drivers in order to generate consistent shareholder value.

#### **HIGHLIGHTS OF FY17**

Our FY17 topline grew by 9% to ₹ 302 Billion which, was in line with our annual guidance. In the US, which is a large contributor to our revenues, we faced increased pricing pressure driven mainly by

customer consolidation and higher competitive intensity. We also faced anticipated delays in product approvals at the Halol facility, driven by the cGMP compliance remediation efforts at the facility. However, the US performance was partly boosted by the 180-day exclusivity on generic Imatinib, which expired in July 2016. Overall, we recorded 2% growth in the US for the year.

Our subsidiary Taro recorded 8% decline in overall revenues for the year. This decline was mainly driven by a difficult pricing environment in the US, resulting from increased competitive intensity and buying consortium pressures.

We recorded a steady 8% growth in our India formulations business, while our performance in emerging markets improved, resulting in 26% growth in revenues. This growth was broad-based across emerging markets and was driven by improvement in underlying business supported by stable currencies.

Our R&D investments for the year were ₹ 23 Billion, targeted mainly at developing complex generics and specialty products. R&D is the engine, which will drive our journey of moving up the pharmaceutical value chain. We are also investing in enhancing our product pipeline for emerging markets and other non-US developed markets. We continued to build our specialty pipeline during the year and simultaneously investing in developing the requisite front-end for this business in the US. We expect this trend to continue in future as well.

#### **BUILDING THE SPECIALTY BUSINESS**

Over the past few years, we have allocated significant resources in building the specialty business. Since this business is in an evolutionary stage, it currently does not generate revenues commensurate to our investments. Our current profitability is after taking into account these investments.

Our specialty initiatives target the global market with the US being one of the important markets. Our strategy entails building a pipeline of patented products for global markets with a focus on improving patient outcomes either by targeting unmet medical needs or by enhancing patient convenience through differentiated dosage forms.

Specialty projects have long-gestation timelines and we have to cover a long distance in this journey. Our initiatives in this segment cover the entire value chain, from in-licensing early-to-late stage clinical candidates, as well as getting access to on-market patented products. Dermatology, Ophthalmic, Oncology and CNS are the key segments targeted through these initiatives.

Over the past two years, we have also focused on establishing the requisite front-end capabilities for our specialty business. This involves setting up relevant sales force (for promoting these products to doctors), establishing the required regulatory and reimbursement teams along with support staff.

#### SIGNIFICANT RAMP-UP IN SPECIALTY PIPELINE

During the year, we significantly ramped-up our specialty portfolio. We enhanced both, our specialty pipeline as well as our on-market portfolio. Some of the key highlights are:

- 1. We received approval from USFDA for the New Drug Application (NDA) related to BromSite™ (bromfenac ophthalmic solution) 0.075%. This product was subsequently commercialised in November 2016.
- 2 We also continued our investment in the development and commercialisation of tildrakizumab, which we had in-licensed from Merck in 2014. In May 2016, we announced positive results from the Phase-3 trials of tildrakizumab to treat chronic plaque psoriasis. Subsequently, in July 2016, we announced a licensing agreement with Almirall S.A. (Spain) for the development and commercialisation of tildrakizumab for psoriasis in Europe. In March 2017, Sun Pharma

WE CONTINUE TO ALLOCATE SIGNIFICANT RESOURCES IN BUILDING OUR GLOBAL SPECIALTY BUSINESS, CURRENTLY. THIS BUSINESS IS IN AN INVESTMENT PHASE AND DOES NOT GENERATE REVENUES COMMENSURATE TO OUR INVESTMENTS. OUR SPECIALTY STRATEGY FNTAILS BUILDING A PIPELINE OF PATENTED PRODUCTS FOR GLOBAL MARKETS WITH A FOCUS ON IMPROVING PATIENT OUTCOMES.

and Almirall announced the validation of the regulatory filing of tildrakizumab with the European Medicines Agency (EMA). Post the close of the year, we announced the acceptance of the regulatory filing of tildrakizumab by the USFDA. Hence, tildrakizumab is now awaiting regulatory approval from both the US and Europe.

- 3. During the year, Sun Pharma announced the launch of Gemcitabine InfuSMART in Europe. InfuSMART is a technology in which oncology products are developed in a ready-to-administer (RTA) bag. With the roll-out of Gemcitabine InfuSMART, Sun Pharma becomes world's first pharmaceutical company to manufacture and launch a licensed RTA oncology product.
- 4. We also in-licensed ELEPSIA XR<sup>TM</sup> (Levetiracetam Extended Release tablets) from Sun Pharma Advanced Research Company Ltd. (SPARC). ELEPSIA XR™ was approved by the USFDA in March 2015. However, in September 2015, SPARC received a complete response letter (CRL) from the USFDA rescinding its earlier approval, citing that the compliance status of the manufacturing facility of the Company at Halol was not acceptable on the date of approval. We are currently in the process of de-risking these filings by transferring them to alternate facilities.
- 5. In October 2016, Sun Pharma announced the acquisition of Ocular Technologies (Ocular), which gives us exclusive worldwide rights to Seciera<sup>™</sup> (cyclosporine A, 0.09% ophthalmic solution) targeted at Dry Eye Disease. Subsequently, we announced successful Phase-3 confirmatory clinical trial results for Seciera™. Coupled with Sun Pharma's existing ophthalmic portfolio consisting of BromSite™,



Xelpros™ and DexaSite™ this acquisition will enable Sun Pharma to significantly expand its ophthalmic presence and reach to millions of patients - globally. We expect to file this product with the USFDA by Q3FY18.

- 6. During the year, we also enhanced our specialty oncology portfolio through the acquisition of a branded oncology product, Odomzo®, from Novartis. Odomzo® (Sonidegib) was approved by the USFDA in July 2015. It is a hedgehog pathway inhibitor indicated for the treatment of adult patients with locally advanced basal cell carcinoma (IaBCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy. Odomzo® gives Sun Pharma an opportunity to meaningfully expand its already established branded dermatology business and support its expansion into branded oncology with a launched brand. This acquisition has the potential to leverage and expand the relationships that the Dusa sales team has with dermatologists that treat common pre-cancerous skin conditions.
- 7. During the year, we also entered into an exclusive worldwide licensing deal to further develop MM-II, a novel pharmaceutical candidate for the treatment of pain in osteoarthritis. MM-II is a novel non-opioid product that leverages the physical properties of proprietary liposomes to lubricate arthritic knee joints, thereby reducing friction and wear, consequently leading to joint pain reduction. The product is based on patent-protected technology licensed by Moebius Medical from the Hebrew University of Jerusalem, Technion Israel Institute of Technology and Hadassah Medical Centre.

#### **RANBAXY INTEGRATION**

We are entering the third and the most important year of integration of Ranbaxy into Sun Pharma. The synergy benefits from this integration are reflected in our financials in FY17 and we expect to build further on these synergy benefits in FY18. We continue to target US\$ 300 Million in synergy benefits from this acquisition by FY18 and are on track to achieve this significant milestone. The synergy benefits will arise from both revenue and cost synergies and will be driven by the combined technology capabilities, combined R&D pipeline and the global product portfolio.

### **GLOBAL cGMP COMPLIANCE**

Given the stringent cGMP requirements of global regulators, pharmaceutical companies need to focus on 24x7 compliance status. Ability to successfully adhere to these cGMP standards has become a key determinant of future for the pharmaceutical industry.

During the year, Sun Pharma made significant progress towards  $24x7\,cGMP$  compliance. Many of our facilities underwent successful audits by multiple regulatory agencies, including the USFDA. At the same time, remediation work continued at some of the facilities, which have been impacted by cGMP deviations.

WE ARE ENTERING THE THIRD AND THE MOST IMPORTANT YEAR OF INTEGRATION OF RANBAXY INTO SUN PHARMA. THE SYNERGY BENEFITS FROM THIS INTEGRATION ARE REFLECTED IN OUR FINANCIALS IN FY17 AND WE EXPECT TO BUILD FURTHER ON THESE SYNERGY BENEFITS IN FY18. WF CONTINUE TO TARGET US\$ 300 MILLION IN SYNERGY BENEFITS FROM THIS ACQUISITION BY FY18.

Our Halol facility, which was impacted by cGMP deviations in FY15, underwent a re-inspection by the USFDA in November 2016. On completion of the re-inspection, the USFDA issued nine observations for the facility. While none of these are repeat observations, compared to those issued for the September 2014 inspection, we will need to remediate these nine observations also. We are currently in the process of implementing the requisite remediation steps. New approvals from this facility will continue to be on hold till we have a successful re-inspection.

During the year, we also had a re-inspection of the Mohali facility by the USFDA. Post the completion of the re-inspection, the USFDA informed Sun Pharma that it will be lifting the import alert imposed on Sun Pharma's Mohali manufacturing facility and remove the facility from the Official Action Initiated (OAI) status. This has cleared the path for Sun Pharma to supply approved products from the Mohali facility to the US market, as well as make this facility available for future filings. The Mohali facility was inherited by Sun Pharma as part of its acquisition of Ranbaxy Laboratories Ltd. in 2015. The USFDA had acted against the Mohali facility in 2013, when it ordered the facility to be fully subject to Ranbaxy's Consent Decree of permanent injunction. Certain conditions of the Consent Decree will continue to be applicable to the Mohali facility even after the lifting of the import alert. This development illustrates Sun Pharma's commitment to work closely with the USFDA and strive for 100% cGMP compliance at its manufacturing facilities.

# **JAPAN FNTRY**

During the year, Sun Pharma initiated the process of transferring marketing authorisations of the 14 brands (acquired from Novartis in March 2016). The transfer of these brands has commenced in a phased manner beginning October 2016 onwards. Simultaneously, Sun Pharma entered into a distribution alliance with Mitsubishi Tanabe Pharma Corporation (MTPC) for these brands. Under this alliance, following the transfer of manufacturing and marketing rights to Sun Pharma, MTPC will market and distribute all 14 brands as well as provide information on their proper use to healthcare professionals in Japan. Through this alliance, Sun Pharma can leverage MTPC's specialised expertise to create a strong business foundation in Japan.

## **ENHANCING PRESENCE IN RUSSIA**

During the year, we also enhanced our presence in Russia through the acquisition of JSC Biosintez, a Russian pharmaceutical company engaged in manufacture and marketing of pharmaceutical products in Russia and CIS region for US\$ 24 Million. Sun Pharma also assumed a debt of approximately US\$ 36 Million as part of this transaction. Biosintez focuses on the hospital segment and had annual revenue of approximately US\$ 52 Million for 2015. It has a manufacturing facility in Penza region with capabilities to manufacture a wide variety of dosage forms, including pharmaceuticals for injections, blood substitutes, blood preservatives, ampoules, tablets, ointment, creams, gels, suppositories, APIs, and so on. This acquisition is consistent with Sun Pharma's philosophy to invest in strategic emerging markets. It provides the Company access to local manufacturing capability across multiple dosage forms in Russia, enabling it to serve the Russian pharmaceutical market effectively.

#### OVFRALL OUTLOOK

As we target moving up the pharmaceutical value chain, Sun Pharma is undergoing a gradual transformation. We need to cross many milestones in this transformation. Our capable and committed employees will be key drivers of this transformation.

The short-term outlook continues to be challenging. The US generics industry is facing rapidly changing market dynamics. Increased competitive intensity and customer consolidation is leading to pressure on pricing; while continued delay in approvals from the Halol facility is also impacting us. Also, we had the benefit of Imatinib exclusivity in the US in FY17, which has ended in July 2016. In the Indian market, there is uncertainty amongst the trade channels due to the GST implementation, although it may be temporary. Given these factors, growth could be a challenge in FY18 and we expect a single-digit decline in consolidated revenues for FY18 over FY17. Our consolidated R&D investments for FY18 will be about 9-10% of revenues.

Despite these challenges, we continue to invest in enhancing our global specialty and complex generics pipeline. Investments will also continue for setting up the requisite front-end capabilities for our specialty business in the US. These investments may not have commensurate revenues in FY18, but in the long term, the revenue from specialty products will justify these investments.

As a shareholder, you have continuously supported our endeavours over the past many years. As always, we are grateful to you for this confidence.

Warm regards,

# Dilip Shanghvi

Managing Director Sun Pharmaceutical Industries Ltd.



# MANAGEMENT DISCUSSION AND ANALYSIS



THE TWO MAIN
DRIVERS OF OVERALL
GROWTH FOR THE
PHARMACEUTICAL
INDUSTRY WILL BE
INTRODUCTION OF NEW
INNOVATIVE PRODUCTS
IN THE DEVELOPED
MARKETS AND
INCREASED VOLUMES OF
BRANDED GENERICS IN
THE FMERGING MARKETS

## GLOBAL PHARMACEUTICAL INDUSTRY<sup>1</sup>

The global spending on medicines is expected to reach nearly US\$ 1.5 Trillion by 2021. This is an increase of nearly US\$ 370 Billion from the 2016 estimated spending level, representing a CAGR of 4-7%. The two main drivers of this growth will be introduction of new innovative products in the developed markets and increased volumes of branded generics in the emerging markets.

The growth of a country's pharmaceutical industry closely mirrors its general economic progress. As economies of the world demonstrate widely divergent growth patterns, industry growth is also different. However, taking a macro perspective, global pharmaceutical growth depends on worldwide economic momentum, government healthcare programmes and spending patterns. While R&D efforts will drive the introduction of new products in the market, challenges remain. For countries grappling with sluggish economies and limited resources, funding access to these medicines remains an uphill task.

Each country in the world is facing these challenges and addressing them in its own way. Overall, generic products will continue to be an integral part of these efforts, targeted at striking a balance between access to healthcare and ability to fund it.

