

<u>Text of the speech delivered by Mr. Israel Makov, Chairman & Mr. Dilip Shanghvi,</u> <u>Managing Director at the 25th Annual General Meeting of Sun Pharmaceutical</u> <u>Industries Ltd., held on September 26, 2017 at Vadodara</u>

Mr. Israel Makov

Dear Fellow Shareholders,

On behalf of the Board of Directors, I welcome all of you to the 25th AGM of your company. Let me begin with some key highlights:

- 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 an additional growth engine to our business - the specialty business – which is gradually evolving for us. We are undergoing a gradual transformation as we continue to move up the pharmaceutical value chain driven by our investments in enhancing our global specialty and complex generics pipeline. These investments will enable us to augment long-term growth avenues for future. More details on the specialty initiative will be discussed by Mr. Shanghvi shortly.
- Let me update you on the Ranbaxy acquisition. We commenced the integration of Ranbaxy with effect from end of March-2015. Most of the integration steps are now complete. I am happy to share with you that we are on-track to achieve the targeted synergies of US\$ 300 million in the current financial year. These synergy benefits will help us fund our evolving specialty business.

I'll now list some of the key trends in the global pharmaceutical industry:

As per IMS, the global pharmaceutical market is estimated to reach US\$ 1.5 trillion by 2021, growing at a compounded growth of approximately 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 emerging markets are expected to grow slightly faster than other markets over the next five years. The global demand for pharmaceuticals will be driven by: demographic trends, increased incidence of chronic diseases, ageing and growing population, improving access to healthcare and increasing per capita income. They are all connected to each other.
- Innovation in specialty medicines will drive the share of global specialty spending from 30% in 2016 to 35% in 2021. This increase will be driven by the acceptance of new breakthrough medicines. Most of this spending on specialty medicines will be driven by developed markets.
- Globally, almost all governments are facing the constraint of increasing healthcare costs for their populations. Generics are an integral part of the solution to reduce healthcare costs. The global demand for generic medicines will continue to grow as governments, payors and consumers pursue avenues to reduce healthcare costs. Overall, we expect this trend to continue to favor generic use which increases the potential of our business. As per Deloitte's Global Lifescience Report, the global generics market is expected to reach US\$ 283 billion by 2018 registering a CAGR of about 6-7% between 2016-2018.

Let me briefly talk about some of the key markets:

- As per IMS, the US was the largest pharmaceutical market globally in 2016, and it is estimated to grow at a CAGR of 6-9% to reach US\$ 645-675 billion by 2021. Sun Pharma is the largest Indian supplier of pharmaceutical products to this large market. While innovative specialty products will be the key driver for this growth, generics will continue to remain an important contributor to reducing the overall healthcare cost in the country.
- The Indian pharmaceutical market is estimated to reach US\$ 26 billion by 2021 recording a low double-digit growth. Key demand drivers for increased medicine consumption in India include: rising healthcare awareness leading to an increase in spending on medicines, changing life-styles leading to growing incidence of chronic ailments, improving health insurance coverage and increased access to modern medicines driven



by rapid urbanization. Key challenges include government-mandated price controls on certain medicines, changes in the regulatory environment and competitive intensity.

- As per AIOCD-AWACS Report, Sun Pharma is the market leader in India with about 8.6% market share enjoying a significant lead over competition. As per SMSRC report, it enjoys the No. 1 ranking by prescriptions with 11 different doctor categories. Hence, Sun Pharma is strongly positioned to capitalize on the market opportunities in India.
- IMS expects the overall pharmaceutical spending in pharmerging markets, including India, to grow at 6-9% CAGR to US\$ 315-345 billion between 2016 and 2021. Sun Pharma is amongst one of the leading Indian companies operating in these markets.

I now request Mr. Dilip Shanghvi our Managing Director to discuss and review our business and share a summary of our key challenges, opportunities, and steps ahead.

<u>Mr. Dilip Shanghvi</u> – Thank you Mr. Israel.

Let me begin with an overview:

- The global pharmaceutical landscape is rapidly changing. There are opportunities as well as 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, 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.
- We have identified the specialty segment as one such driver which can help us transition up the value chain. I will discuss our specialty initiatives in detail in the later part of my speech.
- But let me first discuss some of the key highlights of FY17:



- Our FY17 topline grew by 9% to Rs. 302 Billion which was in line with our annual guidance. Net profit after minority interest grew by 53% to Rs. 69 billion. This growth was mainly driven by the contribution from the Imatinib exclusivity in the US and the exceptional charges of Rs. 6.85 billion for the previous year which were related to the Ranbaxy integration leading to a lower base.
- Our business continues to generate healthy cash flows. For FY17, net cash-flow from operations grew by 6% to Rs. 71 billion.
- 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, reported a 8% decline in topline to US\$ 879 million, while its net profit declined by 15% to US\$ 456 million. This decline was mainly driven by a difficult pricing environment in the US, resulting from increased competitive intensity and buying consortium pressures.
- Our India formulations revenues recorded 8% growth to Rs. 77 billion and accounted for about 26% of consolidated sales.
- Our revenues in emerging markets grew by 26% to Rs. 45 billion and accounted for about 15% of our consolidated revenues. This growth was broad-based among multiple markets.
- Our Rest of World sales grew by 19% for the year to Rs. 26 billion mainly driven by the consolidation of the Japanese business and accounted for about 9% of consolidated revenues.
- Our API revenues grew by 14% to Rs. 16 billion and accounted for about 5% of sales, partly driven by the full year consolidation of the Australian Opiates business.



 We spent over Rs. 23 billion on R&D accounting for about 7.6% of sales. As of 31-March-2017, we had a comprehensive portfolio of 427 approved ANDAs and 157 ANDAs pending approval, 5 New Drug Applications and 1 BLA pending approval with the US FDA. During the year, we filed 27 ANDAs and received 18 approvals from the US FDA.

Let me talk briefly about the Ranbaxy integration:

- The integration of Ranbaxy into Sun Pharma is on track.
- Approximately 2/3rd of the targeted synergy benefits have been achieved in FY17 and we are confident of achieving US\$ 300 million mark in FY18. These synergy benefits have helped us fund our specialty initiatives.

Let me also talk about our efforts towards enhancing our presence in the specialty segment:

- Some years back we commenced investing in the specialty business as a part of our efforts to build an additional engine of long-term sustainable growth.
- 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.
- The year under review was eventful for Sun Pharma's specialty initiatives. We significantly enhanced our global specialty pipeline through acquisitions and partnerships as well as made substantial progress in successfully completing clinical trials for key products. Key events in chronological order include:



- We received US FDA approval for BromSite in April-2016 and subsequently commercialized this product in the US in November 2016.
- In May 2016, we announced positive results from the Phase-3 trials for Tildrakizumab in patients with moderate-to-severe plaque psoriasis.
- In July 2016, Sun Pharma announced a licensing agreement with Almirall a Spanish company – for the development and commercialization of Tildrakizumab for psoriasis in Europe. Sun Pharma is eligible for milestone payments and royalty on sales from Almirall.
- During the year, we strengthened our specialty pipeline by in-licensing Elepsia from Sun Pharma Advanced Research Company. This product was filed from the Halol facility and we are now in the process of transferring it to an alternate site as a derisking measure.
- In October 2016, Sun Pharma announced the acquisition of Ocular Technologies giving it access to Seciera, an ophthalmology product. At the time of the acquisition, Seciera was undergoing Phase-3 trials for the treatment of dry eye disease. These trials were successfully completed in January 2017. We have had a pre-NDA meeting with the US FDA post the completion of the trials and the NDA filing for this product with the US FDA is targeted in the next few months.
- During the year, we also announced the acquisition of Odomzo a branded oncology product – from Novartis for US\$ 175 million. Odomzo is already approved in 30 different markets including the US. It is indicated for treatment of adult patients with locally advanced basal cell carcinoma – a type of skin cancer. Some months back, we have commercialized Odomzo in the US.
- Very recently, we announced USFDA approval for a new label for Odomzo incorporating long-term data from the 30-month analysis of the clinical trial. This will help us strengthen the positioning of the product in the market.
- Overall, we now have four commercialized specialty products in the US market, i.e., Absorica, Kerastick, Odomzo and BromSite. We have already filed Tildrakizumab with USFDA and the European Medicines Agency. The product is now awaiting regulatory



approvals both in the US and Europe. The product will be commercialized in Europe, post approval, through our partner Almirall. As indicated before, we plan to file the NDA for Seciera with the US FDA over the next few months. The approval for two other specialty products – Xelpros and Elepsia – has been delayed due to the cGMP issues at Halol facility. We are in the process of shifting these two products to alternate sites.

 We have started investing in building the specialty teams in the US and towards establishing the requisite front-end infrastructure. While these investments currently do not generate commensurate revenues streams, they will augur well for the company in the long term as more specialty products get commercialized.

Let me now update you on our efforts towards global cGMP compliance:

- During the year, Sun Pharma made significant progress towards 24x7 cGMP compliance. Many of its 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. Key highlights were:
- In November 2016, the Halol facility underwent a re-inspection by the US FDA resulting in nine new Form-483 observations. The company has filed its response to these observations within the stipulated time and has also implemented the remedial steps required to address these observations. We have completed these remedial activities and now, we are awaiting a re-inspection by the US FDA. This remediation process has temporarily impacted our supplies and product approvals from this facility, which we expect to improve, once the facility gets recertified.
- The remediation process at the erstwhile Ranbaxy facilities, which were found to be non-compliant in the past, also continues as per plan. In March 2017, the US FDA informed Sun Pharma that it will be lifting the import alert imposed on the Mohali facility. This action has cleared the path for supply of approved products from this facility to the US as well as makes this facility available for future filings.



- We remain committed to 24x7 cGMP compliance. Over the past few years, we have also significantly strengthened our capabilities by recruiting global talent with strong expertise in quality and compliance. We have also made improvements to our systems and processes as well as focused on training and automation to ensure cGMP compliance.
- Let me now update you on the Japan business. As you are all aware, we entered the Japanese market towards the end of last year, through the acquisition of 14 longlisted prescription brands from Novartis. I am happy to inform you that these brands have been transferred in Sun Pharma's name starting October 2016 onwards. We are promoting and distributing these brands through Mitsubishi Tanabe Pharma, a leading Japanese company.
- In emerging markets, we continued with our market expansion initiatives. Key highlight amongst these initiatives includes the acquisition of Biosintez, a Russian pharmaceutical company. 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.

Let me now give you an overall outlook for the Company:

- We are targeting a transformation into a more innovative company over the next few years. This will help us drive a stable and consistent growth in cash flows, which is a key objective of our corporate philosophy. We are targeting to increase the share of complex generics and specialty products to our overall business in the coming years.
- This evolution will entail taking multiple initiatives, both organic and inorganic as well as assuming measured risks.



Let me discuss the outlook for the current year.

- The US generics industry is facing rapidly changing market dynamics. Increased competitive intensity and strong customer consolidation is leading to pressure on pricing. Continued delay in approvals from the Halol facility is also impacting Sun Pharma. Also, the Company had the benefit of Imatinib exclusivity in US in FY17 which has ended last year. In the Indian market also, there was uncertainty amongst the trade channels due to GST implementation, although it may considered as 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 experienced Board of Directors brings in significant integrity and accountability and acts as a key guiding force as well as an important factor for checks and balances. We also have a pool of highly skilled and motivated employees which helps us in achieving our objectives year after year. I would like to thank both, our Board and our employees for this.
- I am also grateful to our other stakeholders including our customers, the local community and various regulators for their constant support.

All this would not have been possible without your long-standing support. We are grateful to all of you for this trust and faith. Thank you.

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