Sun Pharmaceutical Industries Ltd.
SUN HOUSE, CTS No. 201 B/1,
Western Express Highway, Goregaon (E),
Mumbai 400063, India
Tel.: (91-22) 4324 4324 Fax.: (91-22) 4324 4343
CIN: L24230GJ1993PLC019050
www.sunpharma.com

Text of the speech delivered by Mr. Israel Makov, Chairman at the 26th Annual General Meeting of Sun Pharmaceutical Industries Ltd., held on September 26, 2018 at Vadodara

Mr. Israel Makov

Dear Fellow Shareholders,

On behalf of the Board of Directors, I welcome all of you to the 26th AGM of your company. Let me begin with some key highlights of the global pharmaceutical industry:

- The global pharmaceutical market is estimated to reach US$ 1.4 trillion by 2022, growing at a compounded growth of approximately 3-6%. Demographic changes in population, advances in medical treatments and improving access are expected to translate into a rise in pharmaceutical spending.
- In terms of geographical spending, the emerging markets are expected to grow faster than developed markets over the next five years. While developed markets are expected to record 2-5% compounded growth, the emerging markets are like to grow at 6-9%.
- The share of specialty medicines in the overall pharmaceutical spending has increased significantly over the past decade from 19% in 2007 to 32% in 2017, and is expected to increase further in coming years. This increase will be driven by the acceptance of new breakthrough medicines. Most of this increase in spending on specialty medicines will be driven by developed markets.
- Every nation globally is experiencing increasing healthcare costs and each nation is trying to reduce this cost by different means. Generics are an integral and important part of the solution to reduce healthcare costs. Therefore, 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 Evaluate Pharma World Preview 2018, the generics market in the developed world is expected to reach US$ 104 billion by 2022

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registering a CAGR of about 5% between 2017-2022. If we include the pharmaceutical spending in pharmerging markets to this, the overall global combined spending on generics and branded generics is likely to cross US$ 400 billion by 2022, thus offering long-term growth opportunity for our company.

Let me briefly talk about some of the key markets:

- The US was the largest pharmaceutical market globally in 2017, and it is estimated to grow at a CAGR of 4-7% to cross US$ 600 billion by 2022. While innovative specialty products will be the key driver of growth for the overall US market, generics will continue to remain an important contributor in reducing the overall healthcare cost in the country. While Sun Pharma has been a large supplier of generic pharmaceutical products to the US for many years, going forward, it will also be able to participate gradually in certain key specialty segments as well thus expanding the overall addressable market for our company.
- The Indian pharmaceutical market is estimated to reach US$ 26-30 billion by 2022 recording a low double-digit compounded 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 and government's efforts towards universal healthcare. 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 8.5% market share enjoying a significant lead over competition. As per SMSRC report, it enjoys the No. 1 ranking by prescriptions with 13 different doctor categories. Hence, Sun Pharma is strongly positioned to capitalize on the market opportunities in India.
- The overall pharmaceutical spending in pharmerging markets, including India, is estimated to grow at 6-9% CAGR to US$ 345-375 billion between 2017 and 2022. Sun Pharma is amongst one of the leading Indian companies operating in these markets and is well positioned to exploit this opportunity.

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Let me now discuss and review our business and share a summary of our key challenges, opportunities, and steps ahead.

- The global pharmaceutical industry offers significant opportunities to service the healthcare needs of a growing and ageing global population. The industry has witnessed major investments in developing innovative specialty medicines like monoclonal anti-bodies, immunotherapy drugs and gene therapies. Many of these medicines have seen significant success as they are serving the unmet medical needs of patients, resulting in improved medical outcomes and thus changing the lives of patients. However, pricing in key markets like the US has come under severe pressure in the last two years. The industry will have to adapt to this changed scenario, although it also offers significant learning opportunities.
- Focus on developing and commercializing innovative specialty products coupled with cost control measures in the generics business will be the key priorities for us. I will discuss these initiatives in detail in the later part of my talk.
- But let me first discuss some of the key highlights of fiscal 2017-18:
- Our topline de-grew by 14% to Rs. 261 Billion mainly due to the decline in our US revenues. We have recorded steady growth in all other markets except the US.
- 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 driven by faster pace of ANDA approvals by the USFDA. We also had a high base of last year boosted by the Imatinib 180-day exclusivity which expired in July-2016. Our US sales were also impacted, as we continued to face anticipated delays in product approvals at the Halol facility, driven by the cGMP compliance remediation efforts at the facility.
- Overall, we recorded 34% decline in our US revenues for the year.
- Our subsidiary Taro, reported a 25% decline in topline to US$ 662 million, while its net profit declined by 54% to US$ 211 million. This decline was mainly driven by a

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challenging pricing environment in the US, resulting from increased competitive intensity and buying consortium pressures.

- We recorded a 4% growth in our India formulations business. Overall growth for the domestic market was impacted by the temporary disruption in the trade channel due to the implementation of the Goods & Services Tax during the year. Post GST, India sales are now reported net of GST compared to the previous practice of including excise duty in sales. Adjusted for the impact of these two factors, our India revenues have grown by about 9% for the year.
- We grew by 11% in emerging markets for the year. This growth was broad-based across various markets.
- Our sales in the Rest of World markets grew by 20% for the year.
- We spent over Rs. 22 billion on R&D accounting for about 8.6% of sales. As of 31-March-2018, we had a comprehensive portfolio of 422 approved ANDAs. Our pipeline pending USFDA approval includes 139 ANDAs and 3 New Drug Applications.
- R&D is the backbone of our business and a key determinant of our future growth and profitability. Our efforts to move up the pharmaceutical value chain mandate that we keep investing in R&D. Our R&D investments are targeted mainly at developing complex generics and specialty products. We continue to be disciplined in identifying future R&D projects for the generics market while simultaneously investing in developing a global specialty portfolio. We are also investing in enhancing our product pipeline for emerging markets and other non-US developed markets.

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

- Our journey of building a global specialty business commenced a few years ago, and over the years, we have nurtured this evolving business through increased focus and investments. We have allocated significant resources in building the specialty business.
- Our specialty initiatives are directed at achieving two main objectives – to build an additional engine of future growth and secondly to move up the pharmaceutical value chain through development and commercialization of branded patented products. While

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we intend to target the global markets with our specialty products, developed markets are likely to be key contributors to this strategy.

- Our specialty portfolio targets Dermatology, Ophthalmic, Oncology and CNS segments.
- We have also invested in establishing the requisite front-end capabilities for our specialty business. This involves setting up a relevant sales force, establishing the required regulatory and market access teams, along with support staff.
- 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, which are recorded as costs in our P&L.
- The year under review was an eventful for Sun Pharma's specialty initiatives. Let me first discuss the highlights of our dermatology segment.
- The USFDA approved our Biologics License Application for Ilumya in March 2018. Launch preparations are on-going in the US, with the launch expected shortly.
- As you all are aware, we had out-licensed Ilumetri to Almirall for EU markets for the psoriasis indication. Almirall filed the product with European Medicines Agency in March 2017 and just a few days back, it received approval for the product. Roll-out of Ilumetri in EU will commence over the next few weeks.
- We also recently announced Ilumya's approval in Australia by the Australian TGA.
- We have also recently initiated investments in the development of two new indications for Ilumya, viz., psoriatic arthritis and ankylosing spondylitis. Although the clinical trials for these new indications will require large front-ended investments, a successful outcome of the trials will significantly expand the addressable market for Ilumya globally.
- Hence, Ilumya is now approved in many important markets for the psoriasis indication. This coupled with the evaluation of two new indications will help in the global positioning of Ilumya.
- In the ophthalmology segment, our New Drug Application for Cequa was accepted by USFDA in December 2017. This is an important product for Sun Pharma's specialty ophthalmology portfolio. Post the close of the year, we received USFDA approval for

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this product in August-2018 and a launch in US is scheduled in the later part of this fiscal.

- Just a few days back, we announced the USFDA approval for Xelpros, post the clearance of the Halol facility by the USFDA.
- In the oncology segment, we announced USFDA approval for Yonsa, a novel formulation of abiraterone acetate in combination with methylprednisolone, for the treatment of patients with metastatic castration-resistant prostate cancer. We received this approval in May-2018. We had acquired this product from Churchill Pharmaceuticals and we have commercialized this product in the US in the first quarter of current fiscal.
- During the year, we also received approval from the USFDA for a new label for Odomzo, an oral hedgehog inhibitor to treat patients with locally advanced basal cell carcinoma. The new label incorporates long-term data from the 30-month analysis of the clinical trial, in which Odomzo continued to show sustained durable tumour response of 26 months with no new safety concerns.
- Overall, we now have five commercialized specialty products in the US market, i.e., Absorica, Kerastick, Yonsa, Odomzo and BromSite. We expect to commercialize Ilumya in US, EU and Australia in the coming months and Cequa in the US towards the later part of the year.
- Hence, by the close of the current fiscal, we are likely to have commercialized a significant portion of our specialty pipeline in the US and we will now be entering the scale-up stage for these products. However, this scale-up will happen gradually over the next few years.

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 had been impacted by cGMP deviations. Key highlights were:

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- In February 2018, the Halol facility underwent a re-inspection by the US FDA resulting in three Form-483 observations. The company filed its response to these observations within the stipulated timeline and has also implemented the remedial steps required to address these observations. The USFDA issued the EIR for Halol in June-2018 thus clearing the facility and it has started approving new products filed from this facility.
- The remediation process at the erstwhile Ranbaxy facilities, which were found to be non-compliant in the past, also continues as per plan.
- 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 briefly talk about our cost control initiatives:

- As you are all aware, the dynamics of the US generics market has undergone significant changes in the last two years and the economics of this market has deteriorated in this period.
- Given this backdrop, we continue to make efforts towards optimizing our costs. It mandates an unwavering focus on cost control across the organization. We are trying to achieve better results with lower resources as we try to make the organization more efficient.
- Our efforts in this direction will cover multiple operational aspects. The focus will be on optimizing our manufacturing footprint as well as generic R&D investments, to ensure a reasonable return on investment as well as overall cost management.

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

- While our specialty business will become an additional engine of growth for us, we will continue our relentless focus on the generics business and our attempt will be to find ways to grow the generics business faster than respective markets. This should help us

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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 strategy will entail taking multiple initiatives, both organic and inorganic as well as assuming measured risks. The specialty initiative will entail incurring up-front cost and investments for long-term benefits.

Let me discuss the outlook for the current year.

- Some of our key specialty products are likely to be commercialized in the US in fiscal 2018-19 and hence we expect to incur significant pre-launch and branding costs along with increasing sales force costs. The short-term outlook for the US generics market continues to be challenging given the pricing pressures. We expect normalization of the India business in the current year post the disruption last year due to GST implementation.
- We are also expecting reasonable growth in our emerging markets business, however, as always, currency fluctuations continue to be a risk.
- Given these factors, we expect a low double-digit topline growth in our consolidated revenues for fiscal 2018-19 over last year. Our consolidated R&D investments for the year will be about 8-9% of revenues.
- Our talented team of employees and our committed outstanding management team have been the key driver of all the above initiatives and will remain so in future as well. We are grateful to our Board of Directors for their guidance and support. I would like to thank our Board, our management team 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.
- We are thankful for your support as a shareholder. You have continuously supported our endeavors over the past many years and we hope that you will continue to repose your confidence in us in future. Thank you very much.

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