



**Text of the speech delivered by Mr. Israel Makov, Chairman & Mr. Dilip Shanghvi, Managing Director at the 21st AGM of Sun Pharmaceutical Industries Ltd., held on Sept 30, 2013 at Vadodara**

Dear Fellow Shareholders,

On behalf of the Board of Directors, I welcome all of you to the 21<sup>st</sup> AGM of your company. Last year has been a good one on several counts. Let me mention some of the key highlights:

- We crossed an important milestone by recording revenues of over US\$ 2 bn for FY12-13. It is important to note that while it took us 27 years to cross the US\$ 1 bn mark, the next billion was added in just 3 years.
- The approval for the generic version of Doxil<sup>®</sup> (Doxorubicin Liposomal Injection, an anti-cancer product) by the USFDA in February 2013 was a milestone in Sun Pharma's journey towards developing differentiated and complex products. The successful approval and commercialization of this product is a culmination of painstaking effort, spanning several years and scaling up the right technology for achieving the above objective.
- We acquired DUSA Pharmaceuticals in the US, with all cash deal of approximately US\$230 million. DUSA provides access to Levulan<sup>®</sup> photodynamic therapy for the treatment of non-hyperkeratotic actinic keratoses or AKs of the face or scalp. Additionally, DUSA's BLU-U<sup>®</sup> treatment has been approved by USFDA for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions. This acquisition denotes Sun Pharma's first major initiative in establishing its presence in the US specialty pharma market. Caraco has also acquired URL Pharma's non-colcrys business in the US. This acquisition expands Sun Pharma's product basket in the US generics market.
- The USFDA gave clearance to Caraco for manufacturing three products, post inspection and confirmed that its facility is now in compliance with USFDA cGMP requirements.
- The US courts ruled in favor of Caraco in its patent litigation against Novo Nordisk over Caraco's generic version of Prandin<sup>®</sup>, Repaglinide Tablets. The final US FDA approval for



this product was received in Jun-2013. Being the First-to-File Para-IV filer, Caraco is entitled to 180 days of marketing exclusivity for this product in the US market.

- In FY 2012-13, we increased our commitment towards specialty products and launch of complex technology products. We sharpened our specialty intent, building strengths with new people, new skills and new technologies. Our focus on specialty and differentiation are the core drivers of our business.
- We received a total of 20 ANDA approvals from the US FDA during the year, including that for Doxorubicin Liposomal Injection.
- Post the closure of the financial year, in June-2013; we settled our on-going litigation for generic Protonix with Wyeth & Altana in the US. This settlement will entail a one-time payment of US\$ 550 mn by Sun Pharma in FY13-14. We have already made this payment.
- The Company had proposed spinning off its domestic formulations business to a wholly-owned subsidiary with effect from 31-Mar-2012. This move was initiated to enhance business focus and facilitate faster response to competitive market conditions. Post the closure of the financial year FY12-13, the Company has received the requisite regulatory approvals for this scheme.
- During the year, Sun Pharma and Taro mutually agreed to terminate their merger agreement in the best interest of respective companies and shareholders.

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

**Global Pharma Markets** - As per IMS, the global pharmaceutical market was valued at US\$ 956 billion in 2011, with an estimated annual incremental spending of US\$ 30 billion in 2012. IMS expects that the global pharmaceutical market is likely to witness a CAGR of 3-6% over 2012-16, to reach a market value of US\$1.2 trillion. The key growth drivers for future include an increasing shift to the use of generics medicines, accompanied by patent expires in the US and volume-driven growth in pharmerging markets.



**Global Generic Markets** – As per IMS, the global generic spending on medicines is projected to increase from US\$ 242 billion in 2011 to US\$ 400-US\$ 430 billion by 2016. Of the total increase in generics spending, around US\$ 224-US\$ 244 billion of increase is expected to arise from low-cost generics in pharmerging markets. Moreover, increased generics spending in the developed markets over the next five years will be fuelled by patent expiries, with some additional increases due to expanded generic use for off-patent molecules.

Across developed markets, governments continue to be concerned about escalating healthcare costs thus often making generics a preferred choice. Overall, we expect this trend to continue to favor generic use.

**US Market** – As per IMS, the US pharmaceutical market was valued at US\$ 322 billion in 2011. It is projected to grow at a CAGR of around 1-4% during 2012-16 to reach \$350-380 billion by 2016. However, US's share of global pharmaceutical spending is expected to decline from 41% in 2006 to 31% in 2016. The reason for decline is attributed to patent expiries and slow growth for the branded products.

The US generic market will continue to be driven by patent expiries and healthcare reforms. The relatively low share of Indian companies in the US generics market implies good long-term potential.

**India Market** - As per IMS, India's pharmaceutical market size is expected to rise from about US\$14 billion in 2011 to US\$24-34 billion by 2016. A previous study by Mckinsey had forecasted that India will be amongst the top 10 market globally by 2020.

- Demographics, rise in disposable incomes, increasing reach of corporate hospitals and other medical infrastructure, health insurance, are among the key drivers of this growth.



- While mass medicines are expected to account for half the market in 2020, the mix would favor specialty and super specialty.
- Metro and tier-1 markets are estimated to contribute significantly to growth, driven by rapid urbanization and greater economic development.
- Competitive intensity will continue to remain high.
- Over the past few years, multinational companies have begun to rebuild their businesses to participate in this growth. They have restructured, entered into long term manufacturing agreements, or bought out Indian companies so as to benefit from the advantages of low cost development and manufacturing that other Indian companies enjoy. As India powers into one of the fastest growing markets in the world, we expect this trend to continue.

**Regulatory Changes** - Pharmaceutical regulation is evolving rapidly around the world, both in the developed and developing countries. Regulatory agencies like the US FDA continue to raise quality standards, implying that companies will have to continuously improve quality systems and processes to remain compliant. Regulatory agencies from other countries are raising the standards bar. These tightened requirements makes quality and system adherence the topmost priority.

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

**Mr. Dilip Shanghvi** - I will now begin with a review of our business and share a summary of our key challenges, opportunities, and steps ahead.

Let me begin with the overall performance highlights of 2012-13:

- Net sales were Rs 11,239 crore up by 40% YoY.
- EBITDA was up by 51% to Rs 4,906 crore.
- PBT before exceptional items was up 47% to Rs 4,943 crore.



- Net profit after minority interest grew by 13% to Rs 3,008 crore. This is post the provision of Rs 583 crore for generic Protonix litigation.
- US was the largest contributor to our revenues, accounting for 54% of consolidated sales. US revenues recorded 77% growth to Rs 6,154 crores.
- Taro's performance has been quite strong in FY12-13. Taro's topline grew by 24% to US\$ 671 million, while the net profit surged by 30% to US\$ 266 million. Most of the increase is catalyzed by better pricing environment, while volumes declined marginally. Taro enjoyed the benefits from favorable sale prices throughout the year.
- Growth for India formulations was almost flat due to higher one-time sales recorded in the previous year. However, adjusted growth in this business for the year was about 19%. India accounted for about 26% of consolidated sales.
- Our Rest of World sales grew by 37% for the year and accounted for about 13% of consolidated revenues.
- API revenues grew by 23% and accounted for about 7% of sales.
- We spent about Rs 700 crores on R&D accounting for 6% of sales.

## **Performance**

India and the US, our highest priority markets, together accounted for 80% of our turnover. We continue to build on our presence in these two markets, even as we strengthen our approach for emerging markets to the next level.

## **US generics business**

We continued to put in place an interesting product offering for the US generic space. We offer a wide product basket in the US, including a prudent mix of normal generics, Para-IV filings and limited competition products.

Over the years, Sun Pharma has launched technically complex and differentiated products at regular intervals, such as Sumatriptan auto injector, Diltiazem CD, Azelastine nasal spray. The recently launched generic Doxil<sup>®</sup> is also a step in this direction.



Sun Pharma, along with its subsidiaries, currently has 12 US FDA, approved formulation facilities – 6 in the US, 3 in India and one facility each in Canada, Israel and Hungary. This is one of the largest US FDA approved manufacturing infrastructure amongst Indian companies.

This year, across the company, we filed 25 ANDAs, taking the total ANDAs pending approval to 138 as of 31-Mar-2013. We received 20 ANDA approvals during the year.

### **India formulations**

According to AWACS March-2013 data, Sun Pharma was ranked 3<sup>rd</sup> with overall market share of 4.9% in the Indian market. Subsequently, the ranking has improved to No. 2.

We continue to build market leadership across specialties. We are ranked No.1 by prescriptions with 7 classes of specialists. The company continues to be a market leader in chronic segments in India. About 25 new products were introduced in the Indian market in FY12-13.

The Indian pharmaceutical industry is currently witnessing the implementation of the New Pharma Pricing Policy as mandated by the government. As per the current provisions of the policy, we expect an adverse impact of approximately Rs 50 crore on annualized basis for our India formulations business.

### **International generics (ex-US)**

We continue to be excited about growth opportunities in our rest of the world branded business, which currently accounts for 13% of turnover. As you know, we have a presence with branded prescription products in 45 countries across SE Asia, Russia, CIS, and Latin America. Taro brings a footprint in Canada, Israel and some other parts of Europe. A rich product offering, country-relevant strategies, and a focus on execution sets us apart.



Going ahead, our joint venture with Merck for innovative branded generics in ex- India emerging markets is expected to fortify this part of our business. The JV will facilitate to utilize partner's infrastructure for development, manufacturing, regulatory and commercialization. The joint venture will also provide an opportunity to use SPARC Proprietary Delivery Technologies. The joint venture progress is on schedule with on-going product evaluation and development.

### **Specialty API**

Our API business continues to be largely used for vertical integration on key products. External sales of API, account for a fraction of our total API production. Our API business accounted for about 7% of turnover last year.

### **R&D**

This year, we spent about Rs 700 crores or 6% of net sales on generic R&D. We scaled up 25 APIs, developed and filed 25 ANDAs, and launched 25 products in India. As of 31-Mar-2013, on a consolidated level, we had filed over 800 patents of which, about 450 have been approved.

### **Environment and challenges**

As we grow our international business, add technically complex products to our business profile, and move to the next growth orbit, regulatory, quality standards and people remain critical to our sustained performance.

We have released our Business Responsibility Report (BRR) for FY12-13. Sun Pharma is complaint with all the 9 policies of National Voluntary Guidelines. In the past, our sustainability initiatives were working in isolation and there was merit in weaving them together in a cohesive framework. The National Voluntary Guidelines became a perfect tool for us to streamline our sustainability processes. The BRR reflects our efforts towards sustainable development and covers three main aspects – Economic, Social and Environmental. The report is available on our website for your reference.



### **And finally a brief on future outlook**

We expect our consolidated revenues to record about 18-20% growth for FY13-14. We target to file 25 ANDAs in the US during the year. We will continue to work towards building a strong company, positioned for success in the world's generic and specialty markets.

Thank you.

### **Disclaimer**

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