



**Text of the speech delivered by Mr. Dilip Shanghvi, Chairman and Managing Director of the Sun Pharmaceutical Industries Ltd., at the 17<sup>th</sup> Annual general meeting of the company held on Sept 11, 2009 in Vadodara**

Dear Fellow Shareholders

On behalf of the Board of Directors, I take pleasure in welcoming all of you to the 17<sup>th</sup> AGM of your company.

2008-09 has been an unusual year. Large parts of the business have performed well, though it is the US business at Caraco that hasn't done as well as expected.

Over the next few minutes, I will attempt to provide a roundup of the key challenges and opportunities that our business faces, and also, how we are preparing to face these issues on our path to growth.

To begin with, I would like to first share with you performance highlights of 2008-09.

- Net sales increased by 27% over that achieved in 2007-08 crossing Rs. 4,272 crores
- Net profit grew by 22% to Rs. 1,818 crores. Resulting net margin of 42% is one of the highest for your company in its (listed) history.
- International operations this year accounted for 53% of sales.
- Formulations were 89% of sales, which is in line with our objective of remaining a formulations driven company

Of course, as we have reminded our shareholders several times in the past, these financials include significant non-recurring revenues and profits from the US as well as India businesses. To that extent, this performance is not strictly comparable to the preceding year, and not something that will get repeated in its entirety

### **Environment and challenges**

Events that have occurred in the past year have served to highlight how important people, quality and processes are to our business. As Sun Pharma continues to expand its international presence, these will remain as basic factors that need to be addressed to create and run a company that is truly world class. Even as we continue to build a business that grows from strength to strength, we have refocused attention on these fundamental issues.

## India

The key trends we see:

- The Rs.36,000 crore pharmaceutical market in India continues to be one of the faster growing markets of this size in the world, and yet offers most reasonably priced medicines for patients. Competition has been intense and will continue to remain so in the foreseeable future.
- Multinational companies continue to either set up operations or enter into contract manufacturing agreements with companies in India with the purpose of creating a low cost sourcing base for their global operations. Others have bought out companies, or entered into marketing deals with Indian companies with the idea of creating a presence in the fast growing Indian pharma market.
- Over and above this, competition from Chinese companies is on the increase as they make a strong effort at enhancing their presence in the regulated markets globally.
- The new patent regime, which was introduced in 2005, is likely to have an impact in the years to come. We expect the pipeline of new drugs available for launch to gradually shrink. The recent acceptance of the revised Mashelkar Report which recommends patenting of incremental changes, currently not allowed under the law, may be an indicator of things to come. Of course, these are not the country's best interests in the long run. This will open up a floodgate of patent applications for rudimentary changes and may result in patent life being extended far beyond what it is worth.

## International

On the international side, again we observe a few key trends.

- Above all, regulatory agencies like the US FDA seemed to have stepped up their attention to the quality of medicines reaching their citizens. A significant tightening in implementation of regulatory requirements has caught several companies off guard, making quality and system adherence the topmost priority.
- In several countries, particularly in the developed world, which also happen to be the largest pharmaceutical markets, citizens, politicians and governments remain concerned about high cost of healthcare and are working hard to lower or contain this cost. Healthcare reforms designed to ensure access to medical care for all, are at the discussion stage. A preference for generics, and the cost savings this results into, is one of the primary means of extending the reach of healthcare across classes.

- In an attempt to reduce business uncertainty, generic companies and innovator companies continued with settlement of infringement cases. This still works as pro-consumer because several of these cases have generics coming to the market before patent expiry.
- While the concern on affordability can be partly addressed by stimulating competition through global sourcing, there are a set of countries which believe that long term strategy of affordable medicines for its citizens requires a stronger local industry. This preference is often evident through explicit and implied protectionist measures favouring local manufacturers.

In such a scenario, companies that can offer a basket of products, including technically complex yet affordable products, of consistent high quality have a clear advantage.

The USD 30+ billion US generic market, the largest generic market in the world, is of great interest to all pharmaceutical companies across the world with global aspirations. In 2008, generics accounted for 71% of the US pharma market by prescription, a number that has been steadily rising. A sustained price erosion continues to be witnessed across several existing products, even as new generic products witness a price fall of over 90% compared to the brand price, soon after launch. Crowding of the US generic market is also obvious from the number of companies that file complicated patent challenges. All of this is likely to keep the generic product prices under pressure in the US market.

## **Performance**

International markets accounted for 53% of our turnover, helped by couple of large products in the US.

India and the US, 2 of our largest markets, together accounted for 80% of our turnover. Our capability in product selection, speedy development of technically complex speciality products, cost and manufacturing efficiencies with backward integration into API have helped us compete across these and several other markets.

### India formulations

Our domestic branded prescription products business, at 45% of our consolidated sales offers a solid, dependable base reflecting the intrinsic repeat prescription nature of the business, has grown at a compounded annual growth rate of 27% over the last five years. We remain confident about growing at a rate higher than industry growth rate. We posted sales of Rs 1,960 crores, up 33% from the previous year. As we have shared earlier, this included a significant element of one time

sale which needs to be adjusted for while making any comparisons across years. Market share as per IMS ORG is at 3.5% for 12 months to July 2009.

We are ranked at the top with key classes of customers: Psychiatrists, Neurologists, Cardiologists, Ophthalmologists, and Orthopedicians. We continue to enhance the treatment alternatives we offer by bringing the latest products, several of which are technically complex dosages and products that fill a therapy gap. Products like Octrice, Tamlet, Tyrogef and Cernos Depot were brought to the market this year. Such products help us enable us to offer a complete product basket in India, including some products introduced for the first time in the country. This also enables us to offer a rich pipeline of products under registration in international markets.

A subsidiary has commissioned a plant in Sikkim during the first quarter of 2009-10 to meet the growing demands of the market.

#### US generics

As you are aware, US FDA issued a warning letter to Caraco for its Michigan facilities in October 2008. This was essentially for non-compliance with cGMP requirements of the FDA. Despite Caracos' efforts at resolving these issues, FDA in its inspection during March to May 2009 made some observations on the continued non-compliance. Subsequently, in June 2009, US marshals seized material worth USD 23 million at the Michigan facilities of Caraco. This has brought the manufacturing activity at Caraco to a standstill. Caraco is working with the US FDA to resolve all the problems at the earliest possible and will give a regular update on the progress. In face of this issue with the USFDA and the recalls it instituted, Caraco reported revenues of USD 337 million for the year ending March 31, 2009, which is a marginal decline over last year. On this it had a profit of USD 20 million. We continue to selectively sell generic Pantoprazole that we have launched at risk, and this causes fluctuations in the distributed product sales at Caraco.

Factories in Sun Pharma remained fully compliant with USFDA cGMP requirements. We continue to spend for product development and file new products from these sites in India and the US. Between Sun and Caraco, 111 products are pending approval with the USFDA as at the end of June 2009.

#### International branded generics

Our international branded generics presence, currently 9% of our business, continues to build strength as we build brands across markets. We are now present in over 30 markets across SE Asia, China, CIS, some countries in Latin America such as Brazil and Mexico. With the addition of requisitely sized manufacturing facilities in Mexico and Brazil, we have created the base required to



take our business to the next stage. Our presence with a strong offering of brands, an expert sales force, and country-relevant strategies has set us in a different slot from the competition.

Across these markets, we have 2,600 products filed, of which 1,600 are approved.

#### Speciality API

Our API offering continues to grow with complex products added to the list. We now have 133 filings received or awaiting approval for US/ Europe.

Currently our API business is 11% of turnover, which largely reflects the sales of API to large companies, including those in Europe and US.

#### R&D

Our 600 scientists strong R&D team works on product development and ensures a rich pipeline of filings across the markets we operate in. This year, we spend Rs. 3.3 bill or 8% of net sales on R&D.

This year, we scaled up 30 APIs, developed and filed 37 ANDAs in addition to filings for non US markets, and brought 42 formulations to the Indian market. The current number of patents is at 233 patents filed of which 76 have been received.

#### Taro

2008-09 witnessed hectic activity on Taro. Just to recap, earlier in the year Taro illegally purported to terminate the merger agreement, which is something we are vigorously contesting in the NY Supreme Court. In order to block Sun Pharma and its subsidiaries from taking a majority control in Taro via the option agreement, that entitled us to buy the shares of the current promoters of Taro, outside directors of Taro commenced litigation in Israel. The lower court ruled unequivocally in favour of Sun Pharma. The other side quickly appealed to the Supreme Court of Israel and we are awaiting a judgement from the Supreme Court. Earlier, the Supreme Court recommended to all parties to look for a settlement. Towards this, Sun Pharma made extremely attractive proposals but ultimately all efforts at settling the dispute were unsuccessful. In the meanwhile, a tender offer for Taro shares launched in June 2008 in compliance with our obligations under the option agreement, remains open.



## Growth and Team Sun Pharma

As we increase our international business, our team, too, is becoming more international, assimilating people across different cultures and countries.

For the current year, we have decided not issue a guidance until there is more clarity with the situation at Caraco. This year too, we intend to file 30 ANDAs in the US across the two companies.

Our eight thousand-plus strong team works to lead the company to new challenges across markets. We will continue to create a rewarding and achievement oriented work environment.

Thank you.