Ind-Swift

annual report 2013-14

Ind-Swift Laboratories Limited

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Ind-Swift Labs Ltd. seeks to establish global leadership through innovative pharmaceutical solutions.

Focusing on the development of active pharmaceutical ingredients, involving complex chemistry for high-growth therapeutic segments, coupled with an excellence in execution.













VICE-CHAIRMAN CUM MANAGING DIRECTOR'S OVERVIEW

Dear Stakeholders

It gives me an immense pleasure to interact with you and apprise you on the performance of your company during the financial year ended 31st March 2014.

It is a matter of satisfaction for all of us that your company is gradually coming out of turbulence which it got into during past few years.

It is noteworthy that despite severe financial and business pressures, your company has been able to sail through and achieve Revenues and EBIDTA of Rs. 954 Crores and Rs.72 Crores respectively during the financial year 2013-14. But for few abnormal, one time loss item, these figures are close to the targets set out by us for this financial year.

I have also to inform you that your company has set out higher targets for the next financial year 2014-15, which it is very likely to achieve. The operations and business strategy of the company are being continuously monitored to improve efficiencies and performances. The ongoing Internal debottlenecking and capacity optimisation exercise is surely going to bear fruits in days to come. These measures will definitely strengthen your company and enable it to come back on the same place on which it was before onset of trouble.

Your company has been producing and marketing APIs for the last 18 years and its marketing reach spans over 50 countries worldwide besides its strong presence in the domestic market. It has an excellent manufacturing infrastructure and processes in place, which have been regularly audited by various international health authorities including USFDA, PMDA Japan, MHRA, KFDA Korea and several others agencies. As part of our already ongoing Your company is expecting audits from USFDA, ANVISA Brazil & Cofepris Mexico in 2014 and we are hopeful that with these approvals in place it would open up new vistas for the company and further strengthen its place in international markets.

efforts, Japan remains a focus market for ISLL where it has already filed 6 DMFs and is expected to file 3 more within this year. Our early entry in this market has given us a strong foothold which we have been able to leverage in the last few years and we are looking forward to consolidate on the same.

Our presence in US and Europe has strengthened during the last few years and these markets are expected to generate good business volumes in future. In domestic markets too we are a well known player and our products are being sourced by almost all the top pharmaceuticals companies in India. Your company now focuses more on value added products and export markets to achieve better revenue and EBIDTA.

On an optimistic note, I would like to share with you that your company is expecting audits from USFDA, ANVISA Brazil & Cofepris Mexico in 2014 and we are hopeful that with these approvals in place it would open up new vistas for the company and further strengthen its place in international markets.

I am confident that, with these efforts, in coming years, your company will present much better and healthier state of affairs and will be able to suitably reward its stakeholders.

Your company appreciates the support provided by its customers, bankers, creditors, fixed deposit holders, shareholders and above all its employees. With their support we are confident that we will pass through this phase and emerge as a much better company in coming years.

N. R. Munjal Vice Chairman Cum Managing Director

MANAGEMENT DISCUSSION AND ANALYSIS REPORT

INDUSTRY STRUCTURE AND DEVELOPMENT

The Pharmaceutical Sector

The Indian pharmaceutical industry ranks 3rd by drug volumes (10% global market) and 14 by sales at ~US\$25 billion (3% global market). The size of the Indian pharmaceutical industry was estimated at US\$12 billion in 2013 (estimated), compared to US\$10.9 billion in 2012 (US\$1=INR 60). The sector experienced a slowdown from 16.6% in 2012 to 9.8%; the sector grew at a CAGR of 15% between 2010 and 2012. Chronic therapies (cardio, gastro, CNS and anti-diabetic) outperformed the market for 4 years, growing at 14%, faster than acute therapies (anti-infectives, respiratory, pain and gynaecology) which grew at 9.6%. India now figures in the 5 leading emerging pharmaceutical markets, expected to grow to a size of US\$20 billion by 2015.

Generics: The global spending on medicines is expected to shift towards generics in 5 years, rising from 27% of the total spending to 36% by 2017, even as brands account for more than two thirds of all spending in developed markets. Absolute spending on brands in developed markets is expected to decline by US\$113 billion in the next 5 years due to exclusivity losses, slower uptake of new medicines and restrictive access approaches. This is expected to be offset by projected US\$40 billion generic spending, resulting in a US\$73 billion patent 'dividend' in 2017. In the U.S., US\$83 billion (34%) of 2012 brand spending will shift to generics at lower prices. In other developed markets, the average brand spending exposed to generic competition will be 22%, except in Canada where 30% of spending will be exposed. Generics consumption will be highest in pharmerging markets (63% of all spending).



Patients in pharmerging markets will enjoy an increasing access to affordable generics for primary care treatment. Total spending on traditional pharmaceuticals in these markets is expected to rise from US\$199 billion in 2012 to US\$336 billion in 2017.

Outlook on Threats, Risks and Concerns

The pharmaceutical industry is highly competitive and the challenges are from both the Indian manufacturers who have similar production facilities as well as those abroad. Human resources with similar skills, talents and experiences in the industry are mobile between competing companies. Price pressures are intense and are expected to remain so. Going forward, there is a risk of inability to maintain current margins on its products. Price sensitivities get tested in a crowded market where price tends to sag while volume business gets done.

Competing pharmaceutical companies have several similar bio-equivalent products in the same market manufactured at facilities that have been approved by the highest regulatory authorities. All of them stay focused on the same markets resulting in price elasticity being tested and margins eroding.

The scientists and professionals of Ind-Swift have been trained to create opportunities, replicate the successes and drive business growth. The Company has unmatched strengths to cope with the challenges of the market such as experienced staff with ability to anticipate market needs, plan for product launches with supportive documentation, create products that meet regulatory norms and execute plans within tight cost and time budgets.





REVIEW OF KEY MARKETS

We continued to perform well during the year on marketing front. We achieved export sales of Rs. 6104.08 millions from our Active Pharmaceutical Manufacturing Business. We continued to cater our customers spread across the World through our strong and efficient marketing team. The performance across various regions and countries during the financial year is as under:

The **US** generics market is the biggest in the World, comprising more than half of the share of the global generics market. The huge potential of this market can be interpreted from its vast pharmaceutical market, which is again the largest in the world. Generics had an estimated share of around 78% in the US pharmaceuticals market and growth of generics has outpaced the growth of overall pharmaceutical market. This generic drugs market is anticipated to grow at a CAGR of around 9% in next two years.

The Company is proud to be associated with first generic launch of Acamprosate and actively continuing commercial sales of more than 7 APIs in North America viz. Clarithromycin, Naratriptan, Letrozole, Acamprosate, Donepezil, Ropinorole & Quetiapine. Company will be launching three more products in US through its US subsidiary, ISLL Inc. immediately upon the expiry of the product patent of these products in coming year. Also the Company has supplied bio-batch quantity of two new products this year. The Company is continuously building alliances with top North American Pharmaceutical companies. The Company's manufacturing facilities are already USFDA certified and three additional products are being actively reviewed by regulatory authorities of the US . Ind-Swift's efforts put in **Japan** for last several years have yielded good results. The company has been able to establish commercial tie ups with leading generic companies in Japan. The company registered impressive sales of around \$ 10 mn in this market.

The experts predict Japanese pharmaceutical market to experience a slight CAGR contraction in dollar terms between 2012 and 2017. Japan is poised to be the second largest pharmaceutical market in the Asia Pacific region, expecting to be overtaken by China in 2016.

China is the fifth largest pharmaceutical market in the world. We have already commenced commercial supplies of one API where we have obtained IDL to this market.Other products including the oncology range and CNS drugs etc. are the some of the other products that are currently being developed with customers in China.

South Korea is perceived as one of the growing markets in Asia in the pharmaceutical industry and the only developed country so far to have been included in the group of Next Eleven countries. Apart from the macrolide range, we have started supplies of other cardiovascular products for development as well as on a commercial scale. Several new products such as Rosuvastatin, Risedronate etc. are under development with the various customers which will ensure growing business in the future.

During the year, the company submitted Drug Master Files to Drug Control Authority in Taiwan, based on new interests for products such as Ezetimibe, Quetiapine, Rosuvastatin etc. More products were added during the year for Thailand and Malaysia . We continued catering to companies in Vietnam.

Pakistan and Bangladesh remain strong markets for the company despite the cut-throat competition on pricing. Our proactive and efficient strategies help maintain our strong position in these countries.

Latin American pharmaceutical market is becoming the fastest growing regions across the world. Although individual markets are growing at different rates, the total market is expected to grow at a compound annual growth rate of more than 12% over the next five years.





The company recorded sales of around USD17 million during the year recording a growth of around 30%. The major share of revenues came from Mexico, Brazil, Colombia and Peru whereas increasing potential is also being seen across other countries such as Paraguay, Uruguay and El Salvador.

The price war in **Argentina** did force us to lower our prices, however the volumes covered up the sales in this region. The market for our range of Macrolides and Cardiovascular products remains strong in Argentina.

The on-going consolidation through mergers and acquisitions of Brazilian companies by global companies has come as a boon to us for additional business opportunities. Our facilities are expected to be audited by ANVISA during the next year, which will boost our business during the coming years.

Mexico is moving towards stricter controls on medicines and regulatory approvals COFEPRIS, the regulatory authority in Mexico is expected to Audit our facilities within financial year 2014-15. Our business of Macrolides recorded positive sales growth in Mexico during the year. Peru has come up as one of the best emerging markets during the FY 2013-14. The company won several government tenders through its Peruvian customers. This trend will help us bag further business in 2014-2015 as well. On the lines of Peru, Government tenders in El Salvador increased our sales in the region.

Middle East & North African Markets

(MENA) In spite of the ongoing political unrest, economic, social and demographic changes are making the pharmaceutical markets in the Middle East & North Africa (MENA) region more attractive. Major advances for the pharmaceutical market in the Middle Eastern region include the establishment of a number of healthcare and biotech parks and the initiation of strategic partnerships between foreign and regional institutions for pharmaceutical R&D. Further adding to this is the general increase in the incidence rates of lifestyle diseases such as cancer. This has led to the mushrooming of numerous hospitals across many Middle East countries thus fulfilling the demand for specialized care and targeted therapies. The announcement of recent policies to liberalise the economy and the introduction of robust regional health insurance systems are likely to play a key role in contributing to the growth of this market in the next five to ten years. Analyst estimates show a steady increase in the market size to as much as \$15 billion by 2015.

Despite the progress, the pharmaceutical sector in the Gulf is still in an emerging phase, and drug manufacturing is at a relatively nascent stage due to a number of obstacles. ISLL has achieved good growth rate i.e. around7-8% in terms of revenue over the previous year.

Jordan is a key market for the company where we have achieved consistent growth and new opportunities are being developed each. We continuously introduce new products besides the existing business with leading companies in this market. Due to the political unrest in neighbouring countries, exports from local companies has suffered which has led to a slight decrease in overall revenues from the market.

The **Egyptian** pharmaceutical industry enjoyed a period of considerable development over the last decade, however the last 2 years saw a political turmoil and



instability which led to slow down in production of local manufacturing companies. The ever changing political scenario and new policies from new regimes also affected the situation. The company has a wide customer profile and many new customers have been developed recently.

The financial sanctions have caused a major impact on pharmaceutical trade with Iran, although our company is reaping benefits due to its joint venture with HFC through our subsidiary. This year again we have seen good growth over the last year.

The company has a strong customer base in Syria, Oman, Yemen, Algeria, Tunisia, Morocco and Saudi Arabia. Political unrest in region is affecting the growth rate. Largely almost all states in North Africa and the Persian Gulf have seen an uprising for political reform. Some countries are gradually becoming stable, however there are still many which are struggling.

Europe today is emerging from the long drawn financial crisis which affected the whole of EU region in general and several countries specifically. The European Federation of Pharmaceutical Industries and Associations have outlined new landmark proposals. They have realized the need to take concrete steps to improve the overall prospects of the health industry, which includes greater collaboration within the EU member states and an agreement for a comprehensive strategy on supporting and improving sustainable healthcare systems to speed access to medicines and most importantly promote European competitiveness.

The company has taken several steps ahead towards its goal of reaching out to the market leaders in Europe. New launches have ensured our growing presence with key players in the market.

Since the expiry of the world's largest selling product 'Atorvastatin' an year earlier, the company has successfully taken a major share of the European market for this product with effective alliances. Our API is now being used by more than 50 well-known companies across the whole of Europe. New companies in markets such as Germany, Spain, France, Slovak, Czech Republic, Greece etc. have initiated development / source change activity with our API, and the company expects a surge in revenues from this activity. Atorvastatin is set to return the largest share of revenues from this region in the coming years.