

INDOCO REMEDIES LIMITED
MANAGEMENT DISCUSSION & ANALYSIS
FOR THE 4TH QUARTER MARCH 2010

➤ **Revenue figures:**

The table below gives the break-up of revenues (Net of excise duty):

(Rs. in Lacs)

	4 th Quarter					Full Year				
	Jan 10 – Mar 10	% to Net Sales	Jan 09 – Mar 09	% to Net Sales	% Gwth	Apr 09 – Mar 10	% to Net Sales	Apr 08 – Mar 09	% to Net Sales	% Gwth
Net Sales :										
Domestic – Formulation	7175	65.90	5765	67.83	24.46	27067	67.95	23949	68.30	13.02
- API	280	2.57	321	3.78	(12.77)	883	2.22	1090	3.11	(18.99)
Total Domestic ... (A)	7455	68.48	6086	71.61	22.49	27950	70.17	25039	71.41	11.63
Formulation Exports :										
- Regulatory	2410	22.14	1739	20.46	38.59	9001	22.60	7576	21.61	18.81
- Semi-Regulatory	712	6.54	587	6.91	21.29	1908	4.79	1905	5.43	0.16
Formul. Exports Total:	3122	28.68	2326	27.37	34.22	10909	27.39	9481	27.04	15.06
API's Export :	310	2.85	87	1.02	256.32	975	2.45	544	1.55	79.23
Total Export ... (B)	3432	31.52	2413	28.39	42.23	11884	29.83	10025	28.59	18.54
Total Net Sales (A+B)	10887	100	8499	100	28.10	39834	100	35064	100	13.60
Other Operating Income	158		142		11.27	483		338		42.90
Total Income	11045		8641		27.82	40317		35402		13.88
EBIDTA	1560	14.33	1053	12.39	48.15	6835	17.16	5912	16.86	15.61
Operating Profit	1148	10.54	617	7.26	86.06	5325	13.37	4182	11.93	27.33
Profit After Tax	823	7.56	392	4.61	109.95	4209	10.57	3144	8.97	33.87

➤ ***Financial Highlights :***

During the 4th quarter ended March 31, 2010, the company's net sales have grown by 28.10% i.e. Rs. 108.87 Crores from Rs. 84.99 Crores, over same quarter previous year. The overall increase in turnover was due to increase in domestic formulation business by 24.46% and export business by 42.23% over the same quarter previous year.

The profit after tax for the quarter is Rs. 8.23 crores compared to Rs. 3.92 crores during the same quarter previous year. The increase in the profit is mainly on account of increase in the sales.

The interest cost has shown downward trend consistently from Rs. 1.29 crores during the previous quarter to Rs. 0.72 crores during the current quarter. The reduction is mainly due to lesser borrowing & borrowings in foreign currencies at very competitive rates. However, the manpower cost has increased by Rs. 1.89 crores over previous quarter. This is due to normal annual increase in salary and new recruitment across the organisation.

During the quarter the electricity cost has gone up due to increase in fuel prices globally. Company has already initiated steps to switchover to Goa Electricity Board. This will be functional during current quarter April 2010 to June 2010.

➤ **ORG Ranking :**

The Company has been ranked by ORG Marg as under:

	Feb. 2010	Feb. 2009
Secondary Sales Audit (S.S.A.)		
Monthly	30	31
MAT	31	32
	Feb. 2010	Feb. 2009
Prescription Audit		
Monthly	23	24
MAT	22	25

➤ **Therapeutic Segment Revenues & Their Performance :**

(Rs. in Lacs)

Particulars	Jan. 2010 – Mar. 2010	Jan. 2009 – Mar. 2009	% Growth
Anti-infective	1653.49	1129.84	46.35
Respiratory & Anti-Allergy	1252.42	941.17	33.07
Dental	1072.65	1012.27	5.96
Alimentary Systems	902.97	618.40	46.02
Ophthalmic / ENT	450.09	259.23	73.63
Nutrition	391.35	447.54	(12.56)
Dermatology	380.14	262.09	45.04
Anti-Diabetic	350.72	352.26	(0.44)
Cardiovascular System	237.05	268.66	(11.77)
Urinary	229.89	218.92	5.01
Analgesics & Antipyretics	185.27	142.85	29.70
Anti-Hemorrhages	109.84	138.34	(20.60)
Musculo-Skeletal Disorders	52.67	30.61	72.07

➤ **Formulation Business**

- Domestic Business:

The domestic formulations business showed a growth of 24.46% during the 4th quarter ended March 2010 over corresponding period last year. Products like Cyclopam, Vepan, Oxipod, Clamchek, Tuspel Plus, Tuspel PX, Losamax, Methycal, Aloha-XT, Fevorit, Cital, Spera-69, Sensodent-KF, Irivisc, Mofloren have shown a positive trend in this quarter. Even some small products like Kidodent, Ofoloren-OZ, Rexidin Mouthwash, Alerchek have shown improvement in sales. During the quarter, Apispur, Cyclochek, Oxipod-CV were launched in the domestic market.

➤ **International business (Formulations):**

The International Business has done exceedingly well in the last quarter of the financial year 2009-2010 by registering a growth of 34.22%. The formulation business during the same quarter last year was Rs. 23.26 Crores as compared to Rs. 31.22 Crores in the 4th quarter of the financial year 2009-2010.

Regulated Markets:

The exports to regulated markets at the end of the 4th quarter was Rs. 24.10 Crores registering a growth of 38.59% over the same quarter last year, when the sales from Regulated market were Rs. 17.39 Crores.

The last quarter has been exceptionally good because we could sign 2 major contracts, which will give a boost to Indoco's growth plans in Regulated Markets. The 1st deal was signed with a 3rd largest generic company in USA, viz., **Watson** Pharmaceuticals, Inc., to develop and manufacture six sterile products on a cost/profit sharing basis. Under the terms of the agreement, Indoco will develop, manufacture and supply six products to Watson for the US market. The current market size of these products is US\$ 679 million.

The 2nd contract was signed with South Africa's largest pharmaceutical company, **ASPEN** (Pharmacare Limited). The deal encompasses seven ophthalmic products, extending to 30 countries from emerging markets. These include major geographies such as Brazil, Venezuela, Mexico, Russia, South Africa & Australia. INDOCO will offer these products for registration and supply the same from their USFDA and EU approved manufacturing facilities. ASPEN will market and distribute these products immediately on obtaining regulatory approval.

During this quarter, we also received a pleasant surprise from IDMA that our Indian Patent IN 225501 issued on 14/11/2008 for A Gastric Retentive Floating Dosage Form For Controlled Delivery Of Vitamins had been selected for the 'IDMA INDIAN PATENT APPRECIATION AWARD 2008-2009'. The Award was presented at IDMA's 48th Annual Day Celebrations on 16th January 2010.

Emerging Markets:

The Emerging markets have gathered momentum and have registered a decent growth of 21.29% in the 4th quarter. The sales from Emerging markets for our branded formulations during the same quarter last year was Rs. 5.87 Crores as compared to Rs. 7.12 Crores in the 4th quarter of the financial year 2009-2010.

We could commence shipment against KEMSA tender (KENYA) and expect to accelerate the number of shipments to KEMSA in the coming quarters. This business comes out of manufacturing from a third party location, which allows our current facility to be utilized for the usual trade business for the other countries.

We successfully completed a number of inspections of our manufacturing facilities from Regulatory authorities of Uganda, Yemen and Botswana. The quarter has been good for the product registrations, as we received 10 new registrations in Phillipines, Bolivia, Uganda, Kenya and Malaysia.

We also bagged a tender in Costa Rica for supply of Ibuprofen tablets valued at Rs. 150 Lacs and the required quantities will be supplied before the end of May'10 with initial shipments commenced in the 4th quarter.

➤ ***API Business :***

The company's API business recorded revenues of Rs. 5.90 Crores during the 4th quarter ended March 31, 2010 as compared to Rs. 4.08 Crores for the same period previous year.

All three facilities **Kilo Plant-Rabale** (As per cGMP, EDQM, USFDA standards) **Multi-Ton Plant-Patalganga** (As per cGMP, EDQM, USFDA Standards) and **API & Intermediate Plant – Rabale** (As per Local GMP Standards) are regularly manufacturing various API's to optimum capacity. New manufacturing block at Patalganga was commissioned and started production for manufacturing **Mid-Volume** Ophthalmic API's. This plant started production of Dorzolamide HCL & Betaxolol HCL.

Kilo Plant, Multi-Ton plant & Mid-Volume plant are expected to face regulatory inspections like WHO:GMP. This will enable us to export products in semi-regulated countries like Mexico, Iran etc.

The APIs manufactured by the company are also used for captive consumption in the various formulations thus adding to the cost efficiency in the formulation business.

➤ **Research & Development :**

Indoco's ultra modern R & D centre is spread over an area of 70,000 sq. feet. The present strength is 130 Scientists including 12 Doctorates. The new R&D set up houses state-of-the-art equipments, analytical instruments and latest databases.

R & D (API)

1. Synthetic Chemistry:

➤ ***Generics:***

- Filing of in-house DMF, COS, for Regulated markets.
- Development of non-infringing process for patent filing and creation of intellectual wealth.
- Scale up and process optimization for new and existing processes.

➤ ***Custom Synthesis/ Contract Research***

- Developing processes for Intermediates/ finished products as per the customers requirement.

➤ ***Development of New Polymorphs***

➤ ***Synthesis And Development Of Impurities And Their Standards***

2. Analytical Chemistry:

- a. Analytical method development
- b. Validation,
- c. Impurity Characterization and Impurity isolation,
- d. Polymorphic studies

3. IPR Studies:

- Literature update, ROS selection.
- Filing and maintaining of Patents
- Evaluation of Patent infringement/ Non-infringement analysis.

The project status of various R &D (API) projects is summarized below:

Project Status	No of Projects Oct-Dec 09 Qtr.
Under development	14
Lab Validation completed and ready for Scale Up, Plant Validation	4
Under Scale Up and Plant Validation	2
Plant Validation Completed	3
Contract Research Projects	1
Total No. Of Projects	24

IPR Status

Patents filed	No of Patents Oct-Dec.09 Qtr.
India	11
PCT application	4

Analytical Status :

Project Status	No of Projects
Development Concluded	4
Under Development	6
Analytical method validation	2
Stability Sample	7 (ongoing)
Cleaning method validation	3
DMF and COS filing related studies	2
Isolation and characterization of impurity standards	6
Working standards of impurities, intermediates and finished products	6
Analytical Method Transfer	3
Novel Polymorphism Study	-

DMF / COS filing status :

Project Status	No of Projects
Total US DMF filed	6
Total COS filed	5
Canada	1
Cyprus (EU DMF)	1
US DMF under progress	2
COS/EU DMF under progress	3
Other DMFs Filed (open part)	16 (in last three months)
Other DMFs under progress (open part)	4

R & D (Formulation)

The formulation R & D is capable of handling formulations in various dosage forms, Novel drug delivery systems and Technology platforms. The above efforts are supplemented by the company's regulatory department which has tie-ups with external CROs to conduct Bio-Equivalence Studies and Clinical trials. The department is in the development of various dosage forms which include solid orals, topicals, injections and ophthalmic preparations.

Indoco is also working on new drug delivery system projects including mix miceller solutions, sustained release dosage forms and micro emulsions.

The aim of the research centre is to develop and scale up the various type formulations to commercial batch sizes.

The centre has capabilities to develop any type of dosage form, work on non-infringing routes and file Para IV applications.

Apart from the in-house development work, Indoco is involved in contract research where Indoco's research centre develops the products for other organizations for both domestic and international business markets and prepare the dossiers for submissions to the various regulatory agencies all over the world (USA, Europe, South Africa, Australia, Brazil and other semi regulated countries).

The project status of various R & D (Formulation) projects is summarized below:

Project Status	No of Projects
Under development	12
Scaled up and under validation	5
Ready for scale up with Lab validation completed	5
Contract Research Projects	9
Under Scale up and plant validation	4
Novel Polymorphism Study	2
Scaled up and Plant Validated	4

Project under pipeline : 5

IPR Status :

Patents filed	No of Patents
India	8
PCT application	3 under process for PCT filing
USA	1 under process for filing

Analytical Status :

Project Status	No of Projects
Analytical method development	More than 50 methods of RM and final products
Analytical method validation	6 completed
Novel Polymorphism Study	2

DMF/COS Filing Status :

Project Status	No of Projects
ANDA Filing	1
EU Dossier Filing	5
Emerging Market Dossier Filing	31
Semi-Emerging Dossier Filing	5

Regulatory Affairs :

Following are the status of regulatory submission / approval received in the quarter of Jan. 2010 to March 2010.

Bulk Drug :

1. Reply to EDQM Glimipride query
2. Open part DMF for ROW market = 9 products.

Formulation :

South Africa – Dossier submitted to South Africa = 4

1. Phenytoin Sodium Tablets 100 mg to Dezzo Trading (South Africa)
2. Clonazepam Tablet 0.5 mg and 2 mg to Pharmadyne (South Africa)
3. Brimonidine 0.20% ophthalmic solution to Aspen Pharmacare (South Africa)
4. Brimonidine 0.2% + Timolol 0.5% ophthalmic solution to Aspen Pharmacare (South Africa)

EU CTD Dossier = 1

1. Cetrizine dihydrochloride Tablet 10 mg to Galpharma (UK)

ROW Market Dossiers = 15 dossiers

➤ ***Peep into the Future:***

Formulations

The signing of contract with the 2 major generic players has established Indoco's credentials further as a reliable service provider for development & manufacturing of Finished Dosage Forms. These deals cover Ophthalmic products, where Indoco has been investing the major portion of its R&D efforts. Indoco will further add on to its expertise and the infrastructure in Ophthalmic arena and build on it in the near future.

Our success in churning out over a dozen generic molecules in a recent span of less than 2 years, gives us the confidence to foray into the new technology platforms.

We are currently working on a dual strategy of going with partners in USA and also filing a basket of ANDAs on our own. During the next couple of years, we will have over a dozen ANDAs filed in Indoco's name. We are also contemplating implementation of our plans to register our own dossiers in Europe through DCP (Decentralised Procedure) and MRP (Mutual Recognition Procedure) routes. This will enhance our margins and give us a sustainable business, since the marketing authorization will be controlled and owned by Indoco.

To increase production capacity & accommodate more products, the company has successfully expanded its formulation plant at Baddi and has commenced construction on a war footing of the new tablet manufacturing plant in Goa. Baddi Plant has started despatches of various products to UK and Germany.

API

We are doing Research & development on products due to go off-patent from 2014 to 2016. These products will be registered with DCGI & marketed in India & non regulated markets. This will enable company to ready for products much earlier for regulated markets to qualify for first to file cases.

To expand our reach we have initiated registration activities of our API in emerging markets such as Mexico, Brazil, Iran, China, Ukraine etc. We are also appointing exclusive Product & Customer wise exclusive agents to serve customer, better in semi-regulated markets.

Our cGMP plants are prepared to face regulatory inspections from USFDA & EDQM in near future.

➤ ***Credit Rating :***

Company's Commercial Paper Programme is rated as A1+ by ICRA. Similarly the working capital facilities are rated as A1+ and company's long term borrowings are rated as LA+. A1+ rating indicates highest credit quality rating & LA+ rating indicates adequate credit quality rating.
