

INDOCO REMEDIES LIMITED
MANAGEMENT DISCUSSION & ANALYSIS
FOR THE 3RD QUARTER DECEMBER 2009

➤ **Revenue figures:**

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

(Rs. in Lacs)

	3 rd Quarter					Nine Monthly				
	Oct 09 – Dec 09	% to Net Sales	Oct 08 – Dec 08	% to Net Sales	% Gwth	Apr 09 – Dec 09	% to Net Sales	Apr 08 – Dec 08	% to Net Sales	% Gwth
Net Sales :										
Domestic – Formulation	6663	69.62	4854	62.29	37.26	19891	68.71	18218	68.48	9.18
- API	173	1.80	261	3.34	(33.71)	603	2.08	773	2.90	(21.99)
Total Domestic ... (A)	6836	71.43	5115	65.64	33.64	20494	70.79	18991	71.38	7.91
Formulation Exports :										
- Regulatory	2079	21.72	2037	26.14	2.06	6591	22.76	5838	21.94	12.89
- Semi-Regulatory	409	4.27	446	5.72	(8.29)	1197	4.13	1317	4.95	(9.11)
Formul. Exports Total:	2488	25.99	2483	31.86	0.20	7788	26.90	7155	26.89	8.84
API's Export :	246	2.57	194	2.48	26.80	665	2.29	457	1.71	45.51
Total Export ... (B)	2734	28.56	2677	34.35	2.12	8453	29.20	7612	28.61	11.04
Total Net Sales (A+B)	9570	100	7792	100	22.81	28947	100	26603	100	8.81
Other Operating Income	26		60		(56.66)	325		196		65.81
Total Income	9596		7852		22.21	29272		26799		9.22
EBIDTA	1397	14.60	848	10.88	64.74	5275	18.22	4843	18.20	8.92
Operating Profit	1031	10.77	387	4.97	166.40	4177	14.43	3548	13.34	17.72
Profit After Tax	773	8.08	63	0.81	1126.98	3386	11.70	2740	10.30	23.60

➤ ***Financial Highlights :***

During the 3rd quarter ended Dec. 31, 2009, the company's net sale has grown by 22.81% i.e. Rs. 95.70 Crores from Rs. 77.92 Crores, over same quarter previous year. The increase in turnover was mainly due to increase in domestic formulation business by 37.26% over the same quarter previous year. The company's export business also registered growth of 2.12%.

The profit after tax for the quarter is Rs. 7.73 crores compared to Rs. 0.63 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 substantially reduced from Rs. 1.74 crores during the previous quarter to Rs. 0.60 crores during the current quarter. The reduction is mainly due to lesser borrowing & borrowings in foreign currencies. The drop in borrowings is a favorable effect of continued strict credit control measures. However, the manpower cost has increased by Rs. 2.29 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. However, the company is actively pursuing the switch over in the power service provider from the current private company to the Goa Electricity Board. This will reduce the cost of power at its Goa Plants by approx, 25%, thus reducing the overall power cost considerably.

➤ **ORG Ranking :**

The Company has been ranked by ORG Marg as under:

	Dec. 2009	Dec. 2008
Secondary Sales Audit (S.S.A.)		
Monthly	30	32
MAT	30	32
	Nov. 2009	Nov. 2008
Prescription Audit		
Monthly	23	24
MAT	22	25

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

(Rs. in Lacs)

Particulars	Oct. 2009 – Dec. 2009	Oct. 2008 – Dec. 2008	% Growth
Respiratory & Anti-Allergy	1593.59	1015.10	56.98
Anti-infective	1431.17	836.53	71.08
Dental	1067.84	847.45	26.00
Alimentary Systems	763.26	585.99	30.25
Ophthalmic / ENT	391.85	252.64	55.10
Anti-Diabetic	316.60	270.94	16.85
Dermatology	292.52	238.41	22.69
Nutrition	236.77	289.50	(18.21)
Urinary	228.36	126.56	80.43
Analgesics & Antipyretics	193.70	156.80	23.53
Cardiovascular System	144.69	198.83	(27.22)
Anti-Hemorrhages	66.04	71.81	(8.03)
Musculo-Skeletal Disorders	33.58	25.57	31.32

➤ **Formulation Business**

- Domestic Business:

The domestic formulations business showed a growth of 37.26% during the 3rd quarter ended Dec. 2009 over corresponding period last year. Products like Cyclopam, Oxipod, Clamchek, Karvol Plus, Tuspel Plus, Tuspel PX, ATM, Methycal, Aloha-XT, Cital, Carmicide, Amclaid, Sensodent-KF, Irivisc, Mofloren have shown a positive trend in this quarter. Even some small products like Kidodent, Ofoloren-OZ, Rexidin Mouthwash, Sensodent-R, Flamar-DP, Otorex, Alerchek, Dexoren-S have shown improvement in sales.

➤ **International business (Formulations):**

During the quarter, the company participated in CPhI exhibitions held in Madrid, Spain in the month of October 2009. This is the 7th consecutive year that the company has been participating in CPhI worldwide, which has helped us in spreading our capabilities globally.

Regulated Markets:

The exports to regulated markets at the end of the 3rd quarter stand at 20.79 cr. indicating a growth of 2.06% over last quarter. The division registered a marginal growth in the 3rd quarter with sales of Rs. 20.79 cr. v/s. sales of Rs. 20.37 cr. over last quarter.

The company's order book for International Business is full for the next two to three quarters. However, the revenues have been flat on account of restricted supplies due to capacity constraints.

To overcome this problem, we have commenced construction of a new tablet plant in Verna, Goa with a capacity of 3 billion tablets per annum. This plant will be commissioned in Dec-2010 & is expected to receive the UK-MHRA approval by Mar-2011

Our partner in South Africa was successful in winning a national tender for Metformin tablets worth US\$ 6 million with supplies spreading over a period of 2 years. We have committed to supply 50% of the tender quantity, which will bring revenue of US\$ 3 million over the next couple of years.

Emerging Markets:

The exports to emerging markets during the 3rd quarter December 2009 stands at Rs. 4.09 cr. as compared to Rs. 4.46 cr. for the same period previous year. We are still cautious on the payment position from distributors in a number of countries and are not being aggressive in terms of sales, which explains the reasons for de-growth even during this quarter. We hope to reverse this situation, once the economic slowdown is arrested and financials of the affected countries start looking up.

We have in the meantime, bagged a large tender from Kenya for a couple of products which will generate revenues of Rs. 18 cr. over a period of next 2 years. The first supply will be effected in the month of February 2010.

The Goa II plant was inspected by Sudan authorities in November 2009 as a sequel to our successful bidding of the tender for Lidocaine Injections. Now that the inspection has been completed successfully, we can commence dispatches to Sudan and expect a sales turnover of Rs. 3 cr. over period of 2 years from this single product.

Our Waluj plant was also inspected by authorities from Namibia and we would be in a position to open this market for trade business in a short time and also bid for tenders.

➤ **API Business :**

The company's API business recorded revenues of Rs. 4.19 Crores during the 3rd quarter ended Dec. 31, 2009 as compared to Rs. 4.55 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) stabilized production to optimum capacity. New manufacturing block at Patalganga was commissioned and started production for manufacturing **Mid-Volume** Ophthalmic API's.

Kilo Plant & Multi-Ton plant & Mid-Volume plant are being prepared for regulatory inspections like USFDA & EDQM so that products could be exported to US & European markets. Presently Allopurinol manufactured at our Patalganga Plant is being exported to Germany.

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.

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	11
Scaled up and under validation	4
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

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

ANDA/Dossiers 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 Oct 2009 to Dec. 2009.

Bulk Drug :

COS Certificate received from European Directorate for the Quality of Medicine for Ciprofloxacin.

Formulation :

South Africa – Dossier submitted to South Africa Diclofenac Ophthalmic solution 0.1%.

EU CTD Dossier :

Furosemide 500 mg – EUCTD submitted to German customer.

Paracetamol + Tramadol Tablet EUCTD submitted Spain Customer.

➤ ***Peep into the Future:***

Formulations

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 developing a strong pipeline in the slow release technology and shall provide value added products including Liposomal & Depo Preparations to the Generic Companies, worldwide.

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.

With COS in hand we are consolidating our position in Europe to increase market share. For US market arrangements are to tap big generic customers & initiate FDA inspection of our API facilities in near future. Similar arrangements are under negotiation to enter into Japan market by registering our facilities & filing JDMF.

Indoco is now fully integrated right from API Process Development to Formulation Manufacturing.

➤ ***Credit Rating :***

ICRA has re-affirmed credit rating for company's Commercial Paper Programme as A1+. ICRA had also re-affirmed A1+ rating to the working capital facilities of the company and the long term borrowing is rated as LA+. A1+ rating indicates highest credit quality rating & LA+ rating indicates adequate credit quality rating.
