

INDOCO REMEDIES LIMITED
MANAGEMENT DISCUSSION & ANALYSIS
FOR THE 1ST QUARTER JUNE 2009

➤ **Revenue figures:**

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

(Rs. in Lacs)

	1 st Quarter				
	April 09 – June 09	% to Net Sales	April 08 – June 08	% to Net Sales	Growth %
Net Sales :					
Domestic – Formulation	6781	68.95	8216	75.03	(17.46)
- API	238	2.42	309	2.82	(22.97)
Total Domestic ... (A)	7019	71.37	8525	77.86	(17.66)
Formulation Exports :					
- Regulated	2247	22.84	1954	17.84	14.99
- Semi-Regulated	448	4.55	361	3.29	24.09
Formul. Exports Total:	2695	27.40	2315	21.14	16.41
API's Export :	120	1.22	109	0.99	10.09
Total Export ... (B)	2815	28.62	2424	22.13	16.13
Total Net Sales (A+B)	9834	100	10949	100	(10.18)
Other Operating Income	229		64		257.81
Total Income	10063		11013		(8.62)
EBIDTA	2342		3104		(4.53)
Operating Profit	1968		2675		(4.42)
PAT	1688		2460		(5.31)

➤ ***Financial Highlights :***

During the 1st quarter ended June 30, 2009, the company's net sales have declined to Rs. 98 Crores from Rs. 109 Crores, i.e a decline of 10.18% over same quarter previous year. The reduction in turnover was mainly due to decrease in domestic business. The company's export business however registered growth of 16.13%. Company had introduced certain credit control measures during last few quarters and the same are continued during this quarters which had impacted the domestic sales. However, the de-growth in domestic sale was much lower as compared to earlier quarters. The company's ranking in S.S.A. has improved from 33 in June 2008 to 31 in June 2009 as per ORG Data. The Company is, therefore, confident that the positive impact of the measures taken will be seen in the future quarters.

The credit control measures enforced by the company have substantially improved the liquidity situation. The working capital borrowing has reduced to Rs. 32 crores from Rs. 40 crores in March 2009.

The profit after tax for the quarter is Rs. 16.88 crores compared to Rs. 24.60 crores during the same quarter previous year. The decline in the profit is mainly on account of reduction in the sales, which has impacted the profit by approximately Rs. 5.50 crores. The manpower cost has increased by Rs. 1.71 crores over previous quarter. This is due to normal annual increase in salary and new recruitment across the organisation. During the quarter, the export freight has gone up by around Rs. 1.50 crores. During the quarter, the forex gain was higher by Rs. 1.10 crores and interest earned was higher by Rs. 0.44 crores.

➤ **ORG Ranking :**

The Company has been ranked by ORG Marg as under:

	June 2009	June 2008
Secondary Sales Audit (S.S.A.)		
Monthly	31	33
MAT	32	33

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

(Rs. in Lacs)

Particulars	Apr. 2009 – Jun. 2009	% to Sales	Apr. 2008 – Jun. 2008	% to Sales
Anti-infective	1296.82	18.91	1730.89	20.81
Respiratory & Anti-Allergy	1000.25	14.59	1348.17	16.21
Dental	1057.51	15.42	1223.27	14.70
Alimentary Systems	1143.87	16.68	1162.36	13.97
Nutrition	427.97	6.24	523.74	6.29
Anti-Diabetic	419.51	6.11	438.93	5.27
Dermatology	328.41	4.78	474.98	5.71
Ophthalmic / ENT	360.46	5.25	438.15	5.26
Cardiovascular System	233.49	3.40	292.21	3.51
Urinary	294.45	4.29	251.93	3.02
Analgesics & Antipyretics	165.07	2.40	232.79	2.79
Anti-Haemorrhages	89.35	1.30	128.82	1.54
Musculo-Skeletal Disorders	27.58	0.40	52.97	0.63
Oncology	10.63	0.15	17.22	0.20
TOTAL	6855.38	100.00	8316.42	100.00

➤ **Formulation Business**

- Domestic Business :

The domestic formulations business showed a decline of 17.46% during the 1st quarter ended June 2009 over corresponding period last year. However, the products that show a positive trend are Cyclopam, Tuspel Plus, MCBM-69, Clokit, Febrex Plus Drops, Febrex Plus DS, ATM, Aloha-XT, Speraflox, Speraflox, Sperogest, Amclaid, Kidodent, Dentogel, Amchek, Prichek/M,

Cholechek. Besides these, Oxipod, Clamchek, Megachek, Losamax have done very well in June'09. During the quarter, Prichek GMP a combination of Glimepiride, Metformin & Pioglitazone was launched in the domestic market. The product has a market size of Rs. 125 crores growing @ 40% per annum.

➤ ***International business (Formulations):***

During the 1st quarter ending 30th June 2009, the international business for formulations has grown by 16.41 %.

Regulated Markets :

The exports to regulated markets during the 1st quarter have registered a growth of 15%. The sales for the 1st quarter ending June 2009 is Rs. 22.47 Crores as compared to Rs. 19.54 Crores for the same period previous year.

This quarter saw Indoco's manufacturing facility at Baddi receiving UK-MHRA approval. This is a major achievement for Indoco and adds one more facility to the existing array of approved facilities catering to the Regulated Markets. With addition of capacities and service capabilities from Baddi, the future outlook for Regulated Markets looks positive.

Our efforts in penetrating deeper in the European markets are ongoing and our participation in Europlx was a step in that direction. Europlx holds pharma partnering meetings in Europe and offers a platform to sell/ license the producer dossiers.

This time the event took place in Warsaw, Poland and our participation has helped in cracking a few dossier deals and a few more are under discussion. In Europe, we have licensed our first Ophthalmic dossier to a Spanish company and have entered into the new territory of Turkey with licensing of three dossiers.

The AOK (Germany) tender dispatches are in full swing and we have got our Patalganga API Manufacturing facility approved for supply of Metformin API for the AOK tender. This gives us flexibility in terms of procurement and has an upside on our margins, whenever we use our own Metformin.

Emerging Markets:

The exports to emerging markets during the 1st quarter have registered a growth of 24.09 %. The sales for the 1st quarter June 2009 is Rs. 4.48 Crores as compared to Rs. 3.61 Crores for the same period previous year.

Our manufacturing facility in Waluj was approved by Tanzania Regulatory Authorities and hereafter all the supplies to Tanzania will be manufactured at our Waluj facility. Indoco obtained 19 new registrations across various countries in the emerging market and have opened a new territory in Cameroon.

➤ **API Business :**

The company's API business recorded revenues of Rs. 3.58 Crores during the 1st quarter ended June 30, 2009 as compared to Rs. 4.18 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.

Kilo Plant & Multi-Ton plant are being prepared for regulatory inspections like USFDA & EDQM so that products could be exported to US & European markets. At present our products are exported to more than 25 countries.

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 100 Scientists including 8 Doctorates & Post Doctorates. The new R&D set up houses state-of-the-art equipments, analytical instruments and latest databases.

The type of research activities in the R & D (API) consists of

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
Under development	5
Scaled up and under validation	2
Ready for scale up with Lab validation completed	1
Contract Research Projects	1
Contract Research Manufacturing	-
Under Scale up and plant Validation	1
Novel Polymorphism Study	-
Scaled up and Plant Validated	-
Projects planned for the year 2009-10	a. API : 6 b. Contract : 8

IPR Status

Patents filed	No of Patents
India	8
PCT application	3

Analytical Status :

Project Status	No of Projects
Analytical method development	HPLC 31 completed GC 12 completed Chemical 16 completed
Analytical method validation	3 completed
Stability Sample Analyzed	117 completed
Cleaning method validation	1 completed
DMF and COS filing related studies with mini validation	16 completed
Isolation and characterization of impurity standards	15
Working standards of impurities, intermediates and finished products	22
Novel Polymorphism Study	-

DMF / COS filing status :

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

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, topical, 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	9
Scaled up and under validation	4
Ready for scale up with Lab validation completed	4
Contract Research Projects	9
Contract Research Manufacturing	4
Under Scale up and plant validation	4
Novel Polymorphism Study	2
Scaled up and Plant Validated	4

Projects 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	4 completed
Novel Polymorphism Study	2

ANDA/Dossiers Filing Status :

Project Status	No of Projects
ANDA Filing	-
EU Dossier Filing	5
Emerging Market Dossier Filing	35

➤ ***Peep into the Future:***

Formulations

Our success in churning out 14 generic molecules in a record span of over 2 years, gives us the confidence to embark on new ambitious projects.

On the formulation front, we are developing a strong pipeline in the slow release technology and shall provide value added products to the Generic Companies, worldwide. With a strong position in Solid Dosages and Ophthalmics, Indoco has also developed the technology of deciphering the reference products in the quickest and most scientific manner to pave a way for the successful introduction for submission and clinical trials of Topicals and Liquid Orals. These dosage forms will add substantial value in the future growth, as Indoco will be one of the few companies offering this expertise.

With API, R&D and formulation capabilities of high order, Indoco can take from concept to commercialization any project in a vertically integrated manner, in a limited span of time encompassing the international requirements in a scientific yet speedy and economical way.

To increase production capacity & accommodate more products, the company has successfully expanded its manufacturing facility at Patalganga and Baddi and is on the look out for setting up new plants to augment the rising demands.

API

Currently a team of about 81 scientists are engaged in the activities related to the analyzing, process development and documenting the research work for API research. Drug Master files have been filed for several products. The status of filing with Drug Control Authorities in US & EU is as follows :

1. Metformin HCL-COS: (R0-CEP 2007-188-Rev 01) & USDMF No. 21097.
2. Allopurinol – USDMF No. 21239 & COS: R0-CEP 2008-017-Rev 00.
3. Ciprofloxacin HCL – COS Application No. CEP 2008-176 dated 23/06/2008 & USDMF No. 21909.
4. Brimonidine Tartrate – USDMF No. 22166. EUDMF is ready to file in Europe (Greece).
5. Dicyclomine HCL-COS R0-CEP 2008-281-Rev 00 & USDMF submitted on 18/11/2008.
6. Glimepiride – USDMF No. 22565, Filed No. CEP 2008-067
7. 6 more products (Gliclazide, Dorzolamide HCL, Brinzolamide, Olopatadine Hcl, Bromfenac Sodium, Quetiapine Fumarate) are under various stages of filing.

➤ ***Credit Rating :***

Credit rating assigned by ICRA for company's Commercial Paper Programme as A1+ is valid upto 04.12.2009. ICRA had also assigned A1+ rating to the working capital facilities of the company. Indoco's programme of long term borrowing is rated as LA+ by ICRA. A1+ rating indicates highest credit quality rating & LA+ rating indicates adequate credit quality rating.
