

INDOCO REMEDIES LIMITED
MANAGEMENT DISCUSSION & ANALYSIS
FOR THE 2ND QUARTER 30TH SEPTEMBER 2008

➤ **Revenue figures:**

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

(Rs. in Lacs)

	2 ND Quarter					Half Yearly				
	Jul 08 – Sep 08	% to Net Sales	Jul 07 – Sep 07	% to Net Sales	% Gwth	Apr 08 – Sep 08	% to Net Sales	Apr 07 – Sep 07	% to Net Sales	% Gwth
Net Sales :										
Domestic – Formulation	5149	65.49	6529	77.33	(21.14)	13364	71.04	14092	76.28	(5.17)
- API	202	2.57	214	2.53	(5.61)	512	2.72	384	2.08	33.33
Total Domestic ... (A)	5351	68.06	6743	79.86	(20.64)	13876	73.77	14476	78.35	(4.14)
Formulation Exports :										
- Regulatory	1847	23.49	1209	14.32	52.77	3801	20.21	2621	14.19	45.02
- Semi-Regulatory	510	6.49	420	4.97	21.43	871	4.63	922	4.99	(5.53)
Formul. Exports Total:	2357	29.98	1629	19.29	44.69	4672	24.84	3543	19.18	31.87
API's Export :	154	1.96	71	0.84	116.90	263	1.40	244	1.32	7.79
Total Export ... (B)	2511	31.94	1700	20.14	47.71	4935	26.23	3787	20.50	30.31
Trading /Others ... (C)	-	-	-	-	-	-	-	212	1.15	-
Total Net Sales (A+B+C)	7862	100.00	8443	100.00	(6.88)	18811	100.00	18475	100.00	1.82
Other Operating Income	72		58		24.14	136		133		2.26
Total Income	7934		8501		(6.67)	18947		18608		1.82
EBIDTA	890		1866		(52.30)	3995		4773		(16.30)
Operating Profit	486		1488		(67.41)	3161		3963		(20.26)
PAT	217		1085		(80.00)	2677		3292		(17.80)

➤ ***Financial Highlights :***

During the 2nd quarter ended September 30, 2008, the company's net sales have declined to Rs. 78.62 Crores from Rs. 84.43 Crores, i.e a decline of 6.9% 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 47.7%. Some of the credit control measures introduced by the company had impacted the domestic sales. However, it is interesting to note that the demand for Company's brands at the retail level is growing as indicated by the ORG IMS data. The Company is, therefore, confident that the positive impact of the measures taken will be seen in the future quarters.

The profit after tax for the quarter was Rs.2.17 crores compared to Rs.10.85 crores during the same quarter previous year. The decline in profit is due to factors beyond the control, like increase in cost of power and fuel which is linked to international prices of crude oil, foreign exchange losses and higher raw material costs internationally. Since the Company has taken remedial measures to reduce the impact of these factors, favourable results will be seen in future quarters.

➤ ***ORG Ranking :***

The Company has been ranked by ORG Marg as under:

	September 2008	September 2007
Secondary Sales Audit (SSA)	29	32

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

(Rs. in Lacs)

Particulars	July 2008 – Sept. 2008	% to Sales	July 2007 – Sept. 2007	% to Sales
Anti-infective	1196	22.88	1486	21.80
Respiratory & Anti-Allergy	1055	20.18	1329	19.49
Dental	644	12.32	865	12.69
Alimentary Systems	576	11.02	774	11.36
Nutrition	297	5.68	464	6.81
Ophthalmic / ENT	274	5.24	382	5.60
AntiDiabetic	273	5.22	320	4.70
Dermatology	257	4.91	386	5.66
Analgesics & Antipyretics	244	4.66	272	3.99
Cardiovascular System	192	3.68	202	2.97
Urinary	99	1.90	176	2.58
Anti-Haemorrhagics	65	1.24	125	1.84
Musculo-Skeletal Disorders	29	0.56	36	0.52
Gynaecology	15	0.29	-	-
Oncology	11	0.20	-	-
TOTAL	5227	100.00	6818	100.00

➤ **Formulation Business**

- Domestic Business :

The domestic formulations business showed a decline of 21.1% during the 2nd quarter ended September 2008 over corresponding period of last year. However, the products that did well are Oxipod, Karvol Plus, Tuspel Plus, ATM, Febrex Plus, Methycal, Amchek group, Prichek, Ramichek, Rexidin-M, Speraflox.

The under mentioned new products were launched :

Warren - Sensoform-HK, Kidodent Mouthwash
Cresta - Duocheck, Febrex TM

➤ ***International business :***

During the quarter, the company participated in CPhI exhibitions held in Brazil and Germany in the month of August 2008 & September 2008 respectively. These exhibitions have helped us in spreading our network globally, has given us a platform to reinforce Indoco's Corporate image in the regulated markets. The company could also bag some deals on dossier licensing and supply contracts.

During the 2nd quarter September 2008, the international business for formulation has grown by 44.7%

Regulated Market :

The exports to regulated markets during the 2nd quarter have registered an impressive growth of 52.8%. The sales for the 2nd quarter September 2008 is Rs. 18.47 Crores as compared to Rs. 12.09 Crores for the same period pervious year.

It was an eventfull quarter with Indoco signing it's first contract for co-operation on the New Drug Application (NDA) filed by a US company for a novel product in the category of Ophthalmic solutions. Indoco will manufacture this patented and novel product to be used in Phase II and Phase III clinical trials, followed by a contract for regular supplies when the NDA is approved by USFDA.

We have successfully cracked a deal with Aspen, a well known company internationally, for licensing our own Dossiers for registration and sale in South Africa and neighbouring countries.

We have submitted our bid for "AOK tender in Germany" and expect to bag the award for at least a couple of products which should generate substantial revenue for the next two years.

Semi-Regulated Market :

The exports to semi-regulated markets during the 2nd quarter have registered a growth of 21.4%. The sales for the 2nd quarter September 2008 is Rs. 5.10 Crores as compared to Rs. 4.20 Crores for the same period pervious year.

During the quarter, we introduced 13 products in different markets across the globe and have made a debut in Phillipines and Malaysia. In Malaysia our own metformin dossier got approved and we are expecting approval for Glimipiride dossier.

We have now a range of products in our basket for which we have CTD dossiers with BE studies. This has given an impetus to our marketing efforts and would contribute to improvement in margins. The company has received its first approval from EDQM. We now have a Certificate of Suitability for Metformin API.

➤ **API Business :**

The company's API business recorded revenues of Rs. 3.56 Crores during the 2nd quarter ended September 2008 Lacs as compared to Rs. 2.85 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) stabilised 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. 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	8
Scaled up and under validation	1
Ready for scale up with Lab validation completed	4
Contract Research Projects	3
Contract Research Manufacturing	2
Under Scale up and plant Validation	3
Novel Polymorphism Study	2
Scaled up and Plant Validated	8

Projects under pipeline: 3

IPR Status

Patents filed	No of Patents
India	5 (1 under process)
PCT application	1 (2 under process for PCT filing)

Analytical Status :

Project Status	No of Projects
Analytical method development	More than 200 methods of RM, intermediates and final products
Analytical method validation	47 completed (7 under progress)
Cleaning method validation	42 completed
DMF and COS filing related studies with mini validation	41 completed (10 under progress)
Isolation and characterization of impurity standards	30
Working standards of impurities, intermediates and finished products	85
Novel Polymorphism Study	3

DMF / COS filing status :

Project Status	No of Projects
US DMF filed	3
EU DMF (COS) filed	3
US DMF under progress	3
EU DMF (COS) under progress	3
Other DMFs under progress	2
DMF / COS approval received	1

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 involved 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 microemulsions.

The aims of the research centre are to develop and scale up the formulations to the 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	10
Scaled up and under validation	3
Ready for scale up with Lab validation completed	4
Contract Research Projects	10
Contract Research Manufacturing	4
Under Scale up and plant validation	3
Novel Polymorphism Study	2
Scaled up and Plant Validated	4

Projects under pipeline : 5

Patents filed	No of Patents
India	5
PCT application	3 under process for PCT filing
USA	1 under process for ling

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 / EU filing Status :

Project Status	No of Projects
ANDA Filing (Exhibit / Validation Batches Ready)	2
EU Dossier Ready	5
Semi-Reg. Dossier Filing	30

➤ ***Peep into the Future:***

Company has completed several formulation / Dossier projects for various European companies. The company has received COS certification for Metformin HCL (R0-CEP 2007-188-Rev 00) & filed USD MF for Metformin HCL (DMF No. 21097) and for Allopurional USD MF No. 21239. Three more products were filed for COS & USD MF.

Indoco is also poised to develop some patentable NDDS formulation under Para IV or 505(b)2 applications.

Currently a team of about 40 scientists is engaged in the activities related to the analyzing, formulating and documenting the research work for formulation research.

In conclusion, 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 by intelligent maneuvering.

To increase production capacity & accommodate more products, the company has under taken expansion of facilities at Patalganga plant expected to commission by January 2009.

➤ ***Credit Rating :***

ICRA has re-affirmed an A1+ rating to Indoco's Commercial Paper Program (short term debt) of Rs. 2500 Lacs. The rating A1+ is the highest accorded by ICRA for a Short Term Debt Program. This reflects the sound financial health of INDOCO. The rating is valid till Nov. 30, 2008.
