

INDOCO REMEDIES LIMITED
MANAGEMENT DISCUSSION & ANALYSIS
FOR THE 2ND QUARTER SEPTEMBER 2009

➤ **Revenue figures:**

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

(Rs. in Lacs)

	2 ND Quarter					Half Yearly				
	Jul 09 – Sep 09	% to Net Sales	Jul 08 – Sep 08	% to Net Sales	% Gwth	Apr 09 – Sep 09	% to Net Sales	Apr 08 – Sep 08	% to Net Sales	% Gwth
Net Sales :										
Domestic – Formulation	6448	67.56	5148	65.47	25.25	13229	68.27	13364	71.04	(1.01)
- API	192	2.01	203	2.58	(5.41)	430	2.21	512	2.72	(16.01)
Total Domestic ... (A)	6640	69.57	5351	68.06	24.08	13659	70.49	13876	73.76	(1.56)
Formulation Exports :										
- Regulatory	2265	23.73	1847	23.49	22.63	4511	23.28	3801	20.20	18.67
- Semi-Regulatory	339	3.55	510	6.48	(33.52)	788	4.06	871	4.63	(9.52)
Formul. Exports Total:	2604	27.28	2357	29.97	10.47	5299	27.34	4672	24.83	13.42
API's Export :	299	3.13	154	1.95	94.15	419	2.16	263	1.39	59.31
Total Export ... (B)	2903	30.42	2511	31.93	15.61	5718	29.50	4935	26.23	15.86
Total Net Sales (A+B)	9543	100	7862	100	21.38	19377	100	18811	100	3.00
Other Operating Income	70		72		(2.77)	299		136		119.85
Total Income	9613		7934		21.16	19676		18947		3.84
EBIDTA	1535	16.08	891	11.33	72.28	3877	20.01	3995	21.23	(2.95)
Operating Profit	1178	12.34	486	6.18	142.39	3146	16.23	3161	16.80	(0.47)
Profit After Tax	925	9.69	217	2.76	326.27	2613	13.48	2677	14.23	(2.39)

➤ **Financial Highlights :**

During the 2nd quarter ended Sept. 30, 2009, the company's net sales has grown by 21.4% i.e. Rs. 95.43 Crores from Rs. 78.62 Crores, over same quarter previous year. The increase in turnover was mainly due to increase in domestic formulation business by 25.25% over the same quarter previous year. The company's export business also registered growth of 15.61%. The strategy adopted by company to tighten the credit policy has benefited the company as can be seen from the growth in sales and reduction in debtors.

The credit control measures enforced by the company have substantially improved the liquidity situation. Due to reduced borrowings and better financial management, the interest burden has drastically reduced from Rs. 146 Lacs during the same quarter previous year to Rs. 66 Lacs during the current quarter.

The profit after tax for the quarter is Rs. 9.25 crores compared to Rs. 2.17 crores during the same quarter previous year. The increase in the profit is mainly on account of increase in the sales. The manpower cost has increased by Rs. 2.31 crores over previous quarter. This is due to normal annual increase in salary and new recruitment across the organisation.

➤ **ORG Ranking :**

The Company has been ranked by ORG Marg as under:

	Sept. 2009	Sept. 2008
Secondary Sales Audit (S.S.A.)		
Monthly	30	29
MAT	31	32

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

(Rs. in Lacs)

Particulars	July. 2009 – Sept. 2009	July. 2008 – Sept. 2008	% Growth
Anti-infective	1462.26	1195.63	22.30
Respiratory & Anti-Allergy	1364.67	1054.77	29.38
Dental	1002.14	643.75	55.67
Alimentary Systems	880.04	576.16	52.74
Dermatology	330.00	256.53	28.63
Ophthalmic / ENT	302.22	299.19	1.01
Anti-Diabetic	267.03	273.02	(2.19)
Nutrition	264.83	297.10	(10.86)
Urinary	210.60	99.49	111.67
Analgesics & Antipyretics	189.88	243.66	(22.07)
Cardiovascular System	113.87	192.45	(40.83)
Anti-Haemorrhages	111.65	65.48	70.51
Musculo-Skeletal Disorders	20.80	29.32	(29.05)

➤ **Formulation Business**

- Domestic Business :

The domestic formulations business showed a growth of 25.25% during the 2nd quarter ended Sept. 2009 over corresponding period last year. Products like Febrex Plus Tablets and DS, Cyclopam, Vepan, Oxipod, Clamchek, Cloben-G, Tuspel PX, Methycal, Aloha-XT, Cital, Carmicide, Amclaid, Irivisc, Speraflox, Sperogest have shown a positive trend in this quarter. During this quarter Penchek a combination of Nimesulide + Paracetamol was launched in the domestic market.

➤ **International business (Formulations):**

During the 2nd quarter ending 30th Sept. 2009, the international business for formulations has grown by 10.47%.

Regulated Markets :

The exports to regulated markets during the 2nd quarter 30th Sept. 2009 have registered a growth of 22.63%. The sales for the 2nd quarter ending Sept. 2009 is Rs. 22.65 Crores as compared to Rs. 18.47 Crores for the same period previous year.

Indoco won two awards at the **Pharmexcil Awards** function held at Secunderabad on 25th September 2009. Indoco has bagged these two prestigious award in the area of “Intellectual Property (Patents)” & “**Export Performance**”. The award was received at the hands of Honorable Union Minister for Commerce and Industry, Government of India, Mr. Anand Sharma. Dubbed as a Special Honour in the pharmaceutical Industry, these awards recognise Indoco’s expertise in the coveted areas of Research & Development and International Business.

Indoco received MHRA-UK approval for its solid dosages manufacturing facility at Baddi, Himachal Pradesh. Baddi facility is the second of Indoco’s manufacturing facilities to receive GMP approval from the UK regulatory agency – MHRA. The Baddi facility has already received GMP approval from JAZMP, Agency for Medical Products and Medical Devices of the Republic of Slovenia.

Indoco also received EU approval for its injectable site in Goa. Indoco’s sterile facility in Goa for injectables has been certified as GMP compliant in accordance with EU-GMP principles and guidelines laid down in the Directive 91/412/EC. This plant was inspected in April 2009 and has already been approved by the USFDA for ophthalmic solutions.

Emerging Markets:

The exports to emerging markets during the 2nd quarter Sept. 2009 is Rs. 3.39 Crores as compared to Rs. 5.10 Crores for the same period previous year.

During the quarter, Botswana Regulatory Authorities (DRU) inspected our manufacturing plant in Waluj and have approved the same.

We have signed the contract with Lab Delta, Columbia which now opens the Colombian and Panama markets for Indoco in Latin America.

➤ *API Business :*

The company’s API business recorded revenues of Rs. 4.91 Crores during the 2nd quarter ended Sept. 30, 2009 as compared to Rs. 3.57 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 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 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
Under development	7
Lab Validation completed and ready for Scale Up, Plant Validation	8
Under Scale Up and Plant Validation	2
Plant Validation Completed	2
Contract Research Projects	3
Total No. Of Projects	22

IPR Status

Patents filed	No of Patents
India	9
PCT application	4

Analytical Status :

Project Status	No of Projects
Analytical method development	HPLC 27 completed GC 25 completed Chemical 15 completed
Analytical method validation	7 completed
Stability Sample Analyzed	102 completed
Cleaning method validation	05 completed
DMF and COS filing related studies with mini validation	21 completed
Isolation and characterization of impurity standards	03
Working standards of impurities, intermediates and finished products	27
Analytical Method Transfer	06
Novel Polymorphism Study	03

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	2
EU DMF under progress	3
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.

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	10
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

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	5 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 July 2009 to Sept. 2009.

Bulk Drug :

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

Formulation :

South Africa – Dossier submitted to South Africa in MRF format Furosemide tablets 40 mg & 500 mg.

EU CTD Dossier :

Ketotifen Ophthalmic solution 0.25 mg – ECTD submitted to Spanish customer.

ANDA Submitted to USFDA :

Brimonidine 0.2% Ophthalmic Solution ANDA submitted to USFDA.

➤ ***Peep into the Future:***

Formulations

Indoco has set its eyes on the latest development on a separate fund being created by the 'Government of India' to encourage research and innovation in advanced dosage forms & Novel Drug Delivery System. With the requisite set up in place, we are toying with an idea of venturing into this new area in the future.

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 discovery projects.

On the formulation front, we are developing a strong pipeline in the sustained 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. 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 conceptualisation to commercialization any project in a vertically integrated manner, within 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

Company has filed COS/DMF in Europe & USA, the details of the same are as follows.

1. Metformin HCL-COS: (R0-CEP 2007-188-Rev 01) & USDMF No. 21097.
2. Allopurional – USDMF No. 21239 dated 15/01/2008 & COS (RO-CEP 2008-017-REV00).
3. Ciprofloxacin HCL – COS Application No. CEP 2008-176 & USDMF No. 21909.
4. Brimonidine Tartrate – USDMF No. 22166 dated 29/10/2008.
5. Dicyclomine HCL-COS (RO-CEP 2008-281-REV00) & USDMF submitted on 18/11/2008.
6. Glimepiride COS Application No. CEP 2008-067 COS will be granted soon & USDMF No. 21909.

7. 11 more products are under development & various stages of filing.

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 are engaged in the activities related to the analyzing, formulating and documenting the research work for formulation research.

Currently a team of about 90 scientists are engaged in the activities related to the analyzing, process development and documenting the research work for API research.

➤ ***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.
