

INDOCO REMEDIES LIMITED
MANAGEMENT DISCUSSION & ANALYSIS
FOR THE 4th QUARTER 31ST MARCH 2009

➤ **Revenue figures:**

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

(Rs. in Lacs)

	4 th Quarter					Full Year		Nine Monthly	
	Jan.09 – Mar.09	% to Net Sales	Jan.08 – Mar.08	% to Net Sales	% Gwth	Apr.08 – Mar.09	% to Net Sales	Jul.07 – Mar.08	% to Net Sales
Net Sales :									
Domestic – Formulation	5765	67.83	6107	70.13	(5.58)	23983	68.32	19685	74.93
- API	312	3.67	288	3.30	8.33	1079	3.07	591	2.24
Total Domestic ... (A)	6077	71.50	6395	73.43	(4.95)	25062	71.39	20276	77.18
Formulation Exports :									
- Regulated	1739	20.45	1758	20.18	(1.08)	7576	21.58	4529	17.24
- Semi-Regulated	588	6.91	438	5.02	34.24	1905	5.42	1210	4.60
Formul. Exports Total:	2327	27.37	2196	25.21	5.96	9481	27.00	5739	21.84
API's Export :	87	1.02	117	1.34	(25.64)	544	1.54	255	0.97
Total Export ... (B)	2414	28.40	2313	26.56	4.36	10025	28.55	5994	22.81
Trading /Others ... (C)	8	0.09	-	-	-	15	0.04	(2)	-
Total Net Sales (A+B+C)	8499	100	8708	100	(2.40)	35102	100	26268	100
Other Operating Income	142		70		102.85	338		225	
Total Income	8641		8778		(1.56)	35440		26493	
EBIDTA	1053		1314		(19.86)	5895		5243	
Operating Profit	617		902		(31.59)	4165		4080	
PAT but before MAT Credit & E.O.Items	345		538		(35.87)	2763		2837	

➤ ***Financial Highlights :***

During the 4th quarter ended March 31, 2009, the company's net sales have declined to Rs. 85 Crores from Rs. 87 Crores, i.e a decline of 2.38% 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 4.36%. Company had introduced certain credit control measures during last two 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 32 in March 2008 to 31 in March 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 profit after tax but before MAT entitlement & extra ordinary items for the quarter is Rs. 3.45 crores compared to Rs. 5.38 crores during the same quarter previous year. The decline in the profit is mainly on account of increase in manpower cost by 1.71 crores over previous quarter. This is due to normal annual increase in salary, new recruitment across the organisation etc. The RM consumption ratio was marginally high by 0.48% during the quarter, which has impacted the profit by Rs. 42 Lacs.

➤ **ORG Ranking :**

The Company has been ranked by ORG Marg as under:

	February 2009	February 2008
Monthly	24	26
MAT	25	23

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

(Rs. in Lacs)

Particulars	Jan. 2009 – Mar. 2009	% to Sales	Jan. 2008 – Mar. 2008	% to Sales
Anti-infective	1129.98	19.40	1240.89	19.74
Dental	1012.27	17.38	865.99	13.77
Respiratory & Anti-Allergy	941.17	16.16	1221.62	19.43
Alimentary Systems	618.40	10.62	863.07	13.73
Nutrition	447.54	7.68	370.94	5.90
Anti-Diabetic	352.26	6.05	386.79	6.15
Cardiovascular System	268.66	4.61	185.97	2.95
Dermatology	262.09	4.50	307.99	4.90
Ophthalmic / ENT	248.99	4.27	326.83	5.20
Urinary	218.92	3.76	245.99	3.91
Analgesics & Antipyretics	142.85	2.45	201.16	3.20
Anti-Haemorrhages	138.34	2.37	32.49	0.51
Musculo-Skeletal Disorders	30.61	0.52	33.04	0.52
Oncology	10.24	0.17	1.76	0.02
TOTAL	5822.32	100.00	6284.53	100.00

➤ **Formulation Business**

- Domestic Business :

The domestic formulations business showed a decline of 5.58% during the 4th quarter ended March 2009 over corresponding period last year. However, the products that did well are Sensodent-K, Sensodent-KF, Sensiform, Amclaid, Clamchek, Megachek, Cital, Sperogest. During the quarter, Cef-Vepan 250 mg and 500 mg were launched.

➤ ***International business :***

The 4th quarter ended on a historic note with Indoco clocking export sales of Rs. 100 cr. for the financial year 2008-2009.

Irrespective of the setback to the overall export growth for the country, we registered a growth of 24% for the year ended March 2009 for the formulation exports.

Emerging Market :

The 4th quarter has been exceptionally good for the Emerging markets, which has registered an impressive growth of 34%. The sales for the 4th quarter ending March 2009 are Rs. 5.88 Crores as compared to Rs. 4.38 Crores for the same period previous year.

During the quarter, Tanzania Regulatory Authorities inspected our manufacturing plant in Waluj, which now reduces the burden on our Goa manufacturing facility, as the supplies to Tanzania, until now were manufactured at Goa.

We bagged a tender from CMS Sudan worth US\$ 336000 for Lignox 2% to be supplied over a period of 2 years.

Regulated Markets :

The exports to regulated markets for the year ended 31st March 2009 have registered an impressive growth of 28%. The sales for the 4th quarter ended March 2009 is Rs. 17.39 Crores.

The biggest breakthrough in this quarter came through an award of AOK tender in Germany for Metformin.

The tender award covers all the 3 strengths, viz., 500mg/850mg and 1000mg, and all the 5 territories covering the entire Germany. The supplies will be spread over a period of two years and we expect a business of over US\$ 10 million during this period. The 1st supply against the AOK tender was dispatched by air during this quarter, which will now see Metformin tablets manufactured by Indoco present in every pharmacy in Germany.

Our sterile facility was audited by Slovenian Regulatory Authorities for Carprofen Injection and the Injectable area, now stands approved for supplies in the entire Europe, since Slovenia is a part of EC.

➤ **API Business :**

The company's API business recorded revenues of Rs. 3.99 Crores during the 4th quarter ended March 2009 Lacs as compared to Rs. 4.05 Crores for the same period previous year.

Both **Kilo Plant-Rabale** (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 Multi-Ton plant at Patalganga (As per cGMP, EDQM, USFDA standards) has undergone expansion & modernisation in preparation for regulatory inspections such as USFDA & EDQM. The plant will be fully operational from June 2009.

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	5
Scaled up and under validation	4
Ready for scale up with Lab validation completed	1
Contract Research Projects	3
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	More than 72 methods of RM, intermediates and final products
Analytical method validation	2 completed
Stability Sample Analyzed	81 completed
Cleaning method validation	7 completed
DMF and COS filing related studies with mini validation	22 completed
Isolation and characterization of impurity standards	15
Working standards of impurities, intermediates and finished products	41
Novel Polymorphism Study	-

DMF / COS filing status :

Project Status	No of Projects
US DMF filed	1
EU DMF (COS) filed	1
US DMF under progress	-
EU DMF (COS) under progress	-
Other DMFs Filed	2
Other DMFs under progress	-
DMF / COS approval received	1
DMF/COS Nos. received	5

R & D (Formulation)

The formulation R & D Centre 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 CTOs 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 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

IPR Status :

Patents filed	No of Patents
India	3
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

Indoco has set its eyes on the latest development on a separate fund being created by the 'Government of India' to encourage research in New Chemical Entities. With the requisite set up in place at our new R&D centre, we are toying with an idea of venturing into this new area in the near future.

Our success in churning out 14 generic molecules in a record span of over 2 years, gives us the confidence to embark on this new ambitious discovery 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 Ophthalmic, Indoco has also developed the technology of deciphering the reference products in the quickest and 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.

We have also shifted our strategy of going with partners in USA to filing the ANDAs on our own. During the next couple of years, we will have over a dozen ANDAs filed in Indoco's name.

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 by intelligent maneuvering.

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 dated 30/10/2008) & USDMF No. 21097 dated 12/05/2007
2. Allopurional – USDMF No. 21239 dated 15/01/2008 & COS will be granted soon.
3. Ciprofloxacin HCL – COS Application No. CEP 2008-176 dated 23/06/2008 & USDMF No. 21909 dated 08/11/2008.
4. Brimonidine Tartrate – USDMF No. 22166 dated 29/10/2008
5. Dicyclomine HCL-COS Application No. CEP 2008-281 dated 23/10/2008 & USDMF submitted on 18/11/2008.

6. Glimepiride COS Application No. CEP 2008-067 COS will be granted soon & USDMF submitted in December 2008.
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 81 scientists are engaged in the activities related to the analyzing, process development and documenting the research work for API 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 June 2009.

➤ ***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.
