

**INDOCO REMEDIES LIMITED**  
**MANAGEMENT DISCUSSION & ANALYSIS**  
**FOR THE 3<sup>RD</sup> QUARTER 31<sup>ST</sup> DECEMBER 2008**

➤ **Revenue figures:**

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

(Rs. in Lacs)

	3 <sup>rd</sup> Quarter					Nine Monthly				
	Oct.08 – Dec.08	% to Net Sales	Oct.07 – Dec.07	% to Net Sales	% Gwth	Apr.08 – Dec.08	% to Net Sales	Apr.07 – Dec.07	% to Net Sales	% Gwth
<b>Net Sales :</b>										
Domestic – Formulation	4854	62.29	7047	77.28	(31.11)	18218	68.48	21138	76.60	(13.81)
- API	255	3.27	90	0.98	183.33	767	2.88	474	1.71	61.81
<b>Total Domestic ... ( A )</b>	<b>5109</b>	<b>65.56</b>	<b>7137</b>	<b>78.26</b>	<b>(28.41)</b>	<b>18985</b>	<b>71.36</b>	<b>21612</b>	<b>78.32</b>	<b>(12.16)</b>
Formulation Exports :										
- Regulated	2037	26.14	1570	17.21	29.74	5838	21.94	4191	15.18	39.30
- Semi-Regulated	446	5.72	344	3.77	29.65	1317	4.95	1266	4.58	4.02
Formul. Exports Total:	2483	31.86	1914	20.99	29.72	7155	26.89	5457	19.77	31.11
API's Export :	194	2.48	67	0.73	189.55	457	1.71	312	1.13	46.47
<b>Total Export ... ( B )</b>	<b>2677</b>	<b>34.35</b>	<b>1981</b>	<b>21.72</b>	<b>35.13</b>	<b>7612</b>	<b>28.61</b>	<b>5769</b>	<b>20.90</b>	<b>31.94</b>
<b>Trading /Others ... ( C )</b>	<b>6</b>	<b>0.07</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>6</b>	<b>0.02</b>	<b>212</b>	<b>0.77</b>	<b>(97.16)</b>
<b>Total Net Sales (A+B+C)</b>	<b>7792</b>	<b>100.00</b>	<b>9118</b>	<b>100.00</b>	<b>(14.54)</b>	<b>26603</b>	<b>100.00</b>	<b>27593</b>	<b>100.00</b>	<b>(3.58)</b>
Other Operating Income	60		98		(38.77)	196		231		(15.15)
<b>Total Income</b>	<b>7852</b>		<b>9216</b>		<b>(14.80)</b>	<b>26799</b>		<b>27824</b>		<b>(3.68)</b>
<b>EBIDTA</b>	848		2062		(11.60)	4843		6835		(6.49)
<b>Operating Profit</b>	387		1690		(13.42)	3548		5653		(7.08)
<b>PAT</b>	63		1185		(12.20)	2740		4477		(5.93)

➤ ***Financial Highlights :***

During the 3<sup>d</sup> quarter ended December 31, 2008, the company's net sales have declined to Rs. 77.92 Crores from Rs. 91.18 Crores, i.e a decline of 14.5% 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 35.1%. Company had introduced certain credit control measures during last quarter and the same are continued during this quarters which had impacted the domestic sales. However, it is interesting to note that the demand for Company's brands at the retail level is growing continuously as indicated by the ORG IMS data. The company's ranking in S.S.A. has improved from 33 in December 2007 to 32 in December 2008 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 for the quarter is Rs. 0.63 crores compared to Rs. 11.85 crores during the same quarter previous year. The decline in profit is due to factors beyond our control like loss due to exchange rate fluctuation and increase in marketing costs. In case of foreign exchange fluctuation, the loss is mainly due to appreciation of Re. Vs Pound which was beyond expectations. Under marketing costs, the increase is mainly seen in Overseas freight & Sales promotion expenses. The Company has hedged sufficient GBP at a level above Rs. 84 for the coming quarters and therefore, expects that this impact will reverse in the next quarter.

➤ ***ORG Ranking :***

The Company has been ranked by ORG Marg as under:

	December 2008	December 2007
Secondary Sales Audit (S.S.A.)	32	33

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

(Rs. in Lacs)

<b>Particulars</b>	<b>Oct. 2008 – Dec. 2008</b>	<b>% to Sales</b>	<b>Oct. 2007 – Dec. 2007</b>	<b>% to Sales</b>
Respiratory & Anti-Allergy	1015.10	20.64	1631.25	22.38
Dental	847.45	17.23	957.66	13.13
Anti-infective	836.46	17.01	1586.12	21.76
Alimentary Systems	585.99	11.91	753.02	10.33
Nutrition	289.50	5.88	368.47	5.05
Anti-Diabetic	270.94	5.51	365.96	5.02
Ophthalmic / ENT	242.80	4.93	422.83	5.80
Dermatology	238.41	4.84	374.12	5.13
Cardiovascular System	198.83	4.04	268.29	3.68
Analgesics & Antipyretics	156.80	3.18	240.00	3.29
Urinary	126.56	2.57	195.11	2.67
Anti-Haemorrhages	71.81	1.46	81.39	1.11
Musculo-Skeletal Disorders	25.57	0.52	44.20	0.60
Oncology	9.84	0.20	-	-
<b>TOTAL</b>	<b>4916.06</b>	<b>100.00</b>	<b>7288.42</b>	<b>100.00</b>

➤ **Formulation Business**

**- Domestic Business :**

The domestic formulations business showed a decline of 31.1% during the 3<sup>d</sup> quarter ended December 2008 over corresponding period of last year. However, the products that did well are Cyclopam, Cloben-G, MCBM-69, Megachek, Cital, Carmicide, Speraflox, Sperogest, Aloha, Irivisc.

Sperogest 100 mg & Speraflox 250 mg were the new products launched during this quarter

➤ ***International business :***

During the quarter, the company participated in CPhI exhibitions held in Frankfurt in the month of October 2008. This is the 6<sup>th</sup> consecutive year that the Company has been participating in CPhI worldwide, which has helped us in spreading our network globally.

During the 3<sup>rd</sup> quarter December 2008, the international business for formulation has grown by 29.7% inspite of the global economic slowdown.

**Regulated Market :**

The exports to regulated markets during the 3<sup>rd</sup> quarter have registered an impressive growth of 29.7%. The sales for the 3<sup>rd</sup> quarter December 2008 is Rs. 20.37 Crores as compared to Rs. 15.70 Crores for the same period pervious year.

We have successfully cracked some deals for licensing of our dossiers, an activity which is gaining momentum. We have also signed a profit sharing agreement for Latanoprost dossier for European Markets. The dossier is ready for filing in EU countries under the new Decentralised Procedure (DCP).

First site transfer approval for Indo-Metformin in South Africa was obtained. This will pave the way for participation in the forthcoming tender.

We participated in the tender floated by AOK, Germany, through our German partner and are awaiting the formal announcement of the results. We are confident of bagging award for atleast one product, viz., Metformin tablets. On the basis of encouraging preliminary indication, we have commenced manufacturing of tablet so that we are in a position to commence supplies on the day we receive an official communication from AOK, Germany / our German partner. The expected business from this tender is US\$ 10 million spread over a period of two years.

**Semi-Regulated Market :**

The exports to semi-regulated markets during the 3<sup>rd</sup> quarter have registered a growth of 29.7%. The sales for the 3<sup>rd</sup> quarter December 2008 is Rs. 4.46 Crores as compared to Rs. 3.44 Crores for the same period pervious year.

During the quarter, Malaysian authorities approved our Metformin dossier and the first shipment was dispatched for commercialization. We could also commence business in Chile by sending the Ophthalmic formulation shipment to Chile.

We are now embarking on ambitious plans to have a huge basket of our own dossiers, covering the latest molecules coming off patent.

➤ **API Business :**

The company's API business recorded revenues of Rs. 4.49 Crores during the 3<sup>rd</sup> quarter ended December 2008 Lacs as compared to Rs. 1.57 Crores for the same period pervious 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. 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:

<b>Project Status</b>	<b>No of Projects</b>
<b>Under development</b>	8
<b>Scaled up and under validation</b>	2
<b>Ready for scale up with Lab validation completed</b>	2
<b>Contract Research Projects</b>	2
<b>Contract Research Manufacturing</b>	1
<b>Under Scale up and plant Validation</b>	-
<b>Novel Polymorphism Study</b>	2
<b>Scaled up and Plant Validated</b>	-
<b>Projects planned for the year 2009-10</b>	a. API : 6 b. Contract : 8

No. of projects are given solely pertaining to the work carried out at R & D, API for the period October 2008 to December 2008.

**IPR Status**

<b>Patents filed</b>	<b>No of Patents</b>
<b>India</b>	<b>6</b> <b>( 2 under process )</b>
<b>PCT application</b>	<b>2</b> <b>( 1 under process for PCT filing )</b>

**Analytical Status :**

<b>Project Status</b>	<b>No of Projects</b>
Analytical method development	More than 90 methods of RM, intermediates and final products
Analytical method validation	7 completed
Cleaning method validation	12 completed
DMF and COS filing related studies with mini validation	22 completed
Isolation and characterization of impurity standards	5
Working standards of impurities, intermediates and finished products	20
Novel Polymorphism Study	3

**DMF / COS filing status :**

<b>Project Status</b>	<b>No of Projects</b>
US DMF filed	2
EU DMF (COS) filed	1
US DMF under progress	1
EU DMF (COS) under progress	1
Other DMFs Filed	2
Other DMFs under progress	4
DMF / COS approval received	1 COS (Metformin HCL)
DMF/COS Nos. received	2

## **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:

<b>Project Status</b>	<b>No of Projects</b>
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 :**

<b>Patents filed</b>	<b>No of Patents</b>
India	5
PCT application	3 under process for PCT filing
USA	1 under process for filing



**Analytical Status :**

<b>Project Status</b>	<b>No of Projects</b>
Analytical method development	More than 50 methods of RM and final products
Analytical method validation	4 completed
Novel Polymorphism Study	2

**DMF / COS filing Status :**

<b>Project Status</b>	<b>No of Projects</b>
ANDA Filing	-
EU Dossier Filing	5
Non-Reg. Dossier Filing	30
Semi-Reg. Dossier Filing	5

**➤ *Peep into the Future:***

Company has completed several formulation / Dossier projects for various European companies' details as follows.

1. Metformin HCL-COS: (R0-CEP 2007-188-Rev 01 dated 30/10/2008) & USDMF No. 21097 dated 12/05/2007
2. Allopurinol – 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. 6 more products are under 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.

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 February 2009.

➤ ***Credit Rating :***

ICRA has re-affirmed an A1+ rating to Indoco's Commercial Paper Program of Rs. 25 Crores (Short Term Debt). The rating A1+ is the highest accorded by ICRA for a Short Term Debt Program.

During the quarter, ICRA accorded A1+ rating to the Company's Short Term Loan facilities (Working Capital Facilities from the Bank). This is the highest credit quality rating assigned by ICRA. Further, ICRA has also accorded LA+ rating to the Company's Long Term Loan Facility (Term Loan) . This is the adequate credit quality rating assigned by ICRA.

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