# INDOCO REMEDIES LIMITED MANAGEMENT DISCUSSION & ANALYSIS FOR THE 3<sup>RD</sup> QUARTER DECEMBER 2010

# > 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 10 – Dec 10	% to Net Sales	Oct 09 – Dec 09	% to Net Sales	% Gwth	Apr 10 – Dec 10	% to Net Sales	Apr 09 – Dec 09	% to Net Sales	% Gwth
Net Sales :										
Domestic – Formulation	7400.47	64.74	6662.66	69.62	11.07	23501.47	65.64	19891.22	68.71	18.15
- API	391.93	3.42	172.72	1.80	126.91	1043.63	2.91	603.03	2.08	73.06
Total Domestic (A)	7792.40	68.17	6835.38	71.42	14.00	24545.10	68.55	20494.25	70.79	19.76
Formulation Exports :										
- Regulatory	2667.75	23.33	2079.53	21.73	28.28	7883.13	22.01	6591.31	22.77	19.59
- Semi-Regulatory	691.87	6.05	408.97	4.27	69.17	2286.90	6.38	1196.58	4.13	91.11
Formul. Exports Total:	3359.62	29.39	2488.50	26.00	35.00	10170.03	28.40	7787.89	26.90	30.58
API's Export :	278.70	2.43	245.96	2.57	13.31	1087.48	3.03	664.91	2.29	63.55
Total Export (B)	3638.32	31.82	2734.46	28.57	33.05	11257.51	31.44	8452.80	29.20	33.18
Total Net Sales (A+B)	11430.72	100.00	9569.84	100.00	19.44	35802.62	100.00	28947.05	100.00	23.68
Other Operating Income	118.51		26.06		354.76	577.54		318.87		81.12
Total Income	11549.23		9595.90		20.36	36380.16		29265.92		24.31
EBIDTA	1704.38	14.91	1396.62	14.60	22.04	6106.76	17.06	5275.20	18.22	15.76
Operating Profit Profit After Tax	1302.76 881.35	7.71	1030.59 773.09	8.08	26.41	4928.98 3889.47	13.76	4177.75 3386.35	14.43	17.98

#### Financial Highlights:

During the 3rd quarter ended December 31, 2010, the net revenues were higher by 19% at Rs. 114.31 crores compared to Rs. 95.70 crores, over same quarter previous year. The increase in revenues was due to the impressive performance of international and API division. The domestic marketing divisions – Warren, Spera & Excel also performed quite well.

The revenues from domestic business (including API business) grew by 14% at Rs. 77.92 crores compared to Rs. 68.35 crores over the same quarter previous year. Domestic formulation business being the core business of the Company, going forward the management will continue to aggressively focus on the same. The revenues from international business grew impressively by 33 % at Rs. 36.38 crores compared to Rs. 27.34 crores. Both the regulated as well as emerging markets performed exceeding well. The growth in terms of US dollar by formulation exports during the current quarter over same quarter previous year is 41%. The business from regulated markets showed a good growth of 28.3% at Rs. 26.68 crores as against Rs. 20.80 crores over same quarter previous year. The business from emerging markets excelled showing a growth of 69% at Rs. 6.92 crores compared to Rs. 4.09 crores over the same quarter previous year. The API business has also performed exceeding well with a growth of 60.2% from Rs. 4.19 crores to Rs. 6.71 crores.

The material consumption to net sales is 44.6% compared to 43.4% during same quarter previous year. The staff cost to net sales is 14.2% compared to 14.8% during same quarter previous year. Research expenses are at Rs. 2.55 crores compared to Rs. 2.52 crores same quarter last year. Other expenses to net sales are 27.4% compared to 27.5% during same quarter previous year.

Measures taken by the company for continued efficiency in operations and cost curtailment across all the segments of business will ensure on-track performance in terms of profitability. During the quarter, the impact on profitability was mainly due to increase in the material cost and lower realization in exports on account of rupee appreciation against all major currencies. The marketing expenses, packing & delivery expenses and power & fuel expenses increased during the quarter. Manpower cost increased by Rs. 2.04 crores over same quarter previous year. This was due to normal annual increase in salary and new recruitments across the organization including additions in field staff for new division 'ETERNA'. The interest cost for this quarter has remained in line with that of same quarter last year despite the increase in the interest rates by all the banks in India. This control in interest cost has been a consistent feature for more than 5 quarters. The company's overall DSO has reduced to 74 days as on 31st Dec. 2010 from 82 days as on 31st March 2010. This is an outcome of better credit control measures. The inventory of the company is well within the control at 60 days.

The Earnings before Interest, Depreciation, Tax & Amortization (EBIDTA) works out to 14.9% compared to 14.6% during same quarter previous year. The Profit before Tax recorded for the quarter is Rs. 10.50 crores as against Rs. 7.80 crore during the same quarter previous year showing a growth of 34.6%. Finally the Profit after Tax recorded for the quarter is at Rs. 8.81 crores as against Rs. 7.73 crores during same quarter previous year.

#### > Credit Rating:

ICRA re-affirmed the A1+ rating for company's commercial paper program and working capital facilities. It also retained its LA+ rating for company's long term borrowings.

A1 + rating indicated highest credit quality rating and LA+ rating indicates adequate credit quality rating.

#### Finished Dosages:

#### - Domestic Business:

The domestic formulations business showed a growth of 11 % during the 3rd quarter ended Dec 2010 over corresponding period last year.

The performances of main products showing a positive trend in this quarter are as under:

(Rs. in Lacs)

Product Name	Therapeutic Segment	Oct10- Dec10	Oct09- Dec09
	. 0	Amount	Amount
SENSODENT-K	STOMATOLOGICALS	422.52	338.67
CYCLOPAM TAB	GASTRO INTESTINAL	417.86	376.24
KARVOL PLUS CAPSULES	RESPIRATORY	323.27	293.85
CLOBEN G CREAM	DERMATOLOGY	285.11	209.90
SENSODENT-KF	STOMATOLOGICALS	200.20	168.57
GLYCHEK-M TABLET	ANTIDIABETIC	197.65	165.00
METHYCAL TABLETS	VITAMINS / MINERALS / NUTRIENTS	110.00	53.02
CLAMCHEK 625 TABLETS	ANTI-INFECTIVE	75.76	69.29
DEXOREN-S	OPHTHAL / OTOLOGICALS	55.11	43.13
NOSIC	GASTRO INTESTINAL	37.18	25.92
IRIVISC	OPHTHAL / OTOLOGICALS	25.34	18.48
LOSAMAX-H	CARDIAC	19.87	14.57
MACUCHEK CAPSULES	OPHTHAL / OTOLOGICALS	17.48	9.21
OXIGAT EYE DROPS	OPHTHAL / OTOLOGICALS	9.52	5.58
IRIMIST	OPHTHAL / OTOLOGICALS	7.16	4.26

During the quarter, the company launched a new product in Warren - Snowdent Dental Cream

During the third quarter, the therapeutic segments which performed well are as under:

(Rs. In Lacs)

Particulars	OCT 2010 -	OCT 2009 -	GROWTH
1 at ticulars	DEC. 2010	DEC . 2009	%
Dental	1181.15	991.35	19.15
Gastro Intestinal	895.03	767.83	16.57
Diabetic & Cardiac	523.72	461.29	13.53
Ophthalmic	440.00	358.07	22.88
Dermatology	372.64	292.36	27.46
Vitamins / Minerals / Nutrients	326.29	186.39	75.06

# ORG Ranking:

The Company has been ranked by ORG Marg as under:

Secondary Sales Audit Ranking status:

SSA RANKING	Nov-10	Nov-09
MONTH	32	30
MAT	33	31

# Prescription Audit:

Rx RANKING	Nov-10	Nov-09
MONTH	24	23
MAT	23	22

The company has done well in generating a larger no. of prescriptions which is vital for the sustainable growth. The number of prescriptions generated in November' 09 was 47.6 million which has substantially increased to 50.12 million in November' 10.

#### - International Business:

On the International Formulation front, the business continued to perform well in the Qtr III, FY 2010-11 by registering a growth of 35.0% over the same quarter previous year. The revenues for the quarter under review are Rs. 33.60 crores as against Rs. 24.88 crores over the same quarter previous year. As mentioned earlier, the rise in revenues in dollar terms is around 41%.

#### **Regulated Markets:**

The revenues from regulated markets at the end of the 3rd quarter stood at Rs. 26.68 crores, inspite of the low exchange rate realizations. During the quarter, Indoco and Zumanta, a US based company, signed off a major development deal in the dermatology sector. The deal gives Indoco a platform to utilize its development strengths in the Dermatology segment with the US partner taking care of the Clinical and Regulatory requirements. The product will be marketed and distributed by Zumanta and will be supplied from Indoco's manufacturing facility in Goa.

Also during the quarter, Indoco and Aspen signed New Product Development deals where, Indoco will develop range of products for Aspen, for a wider territory including Europe and Australia.

#### **Emerging Markets:**

The revenues from emerging markets at the end of 3rd quarter ending Dec 2010 stood at Rs. 6.92 crore as compared to Rs. 4.09 crore in the same period last year, with an impressive growth of 69.2%. The regions which have contributed to the growth of the division are Africa and Asia.

The emerging market division has achieved 8 new product registrations in this quarter. These products will be commercialized in Q4 of this financial year. The registration process in Cameroon is nearing completion and commercial dispatches will start in the next quarter.

#### Bio equivalence Study

The Company successfully completed the pilot bio-study for an anti-diabetic product in fed conditions. This is a formulation in the category of NDDS and the company will now proceed with one more pilot study in fasting condition, before proceeding with pivotal biostudy.

This is the first time that we have signed with a CRO from Spain for conducting a bio study in Europe. The clinical part of the study will be conducted in Poland and analytical part will be handled from Spain.

#### > API Business:

The company's API business recorded revenues of Rs. 6.70 crores during the 3<sup>rd</sup> quarter ended December 31, 2010 as compared to Rs. 4.18 crores for the same period previous year showing a growth of 60.2%. The break-up of API revenues are as under:

(Rs. in Lacs)

Particulars	Oct 10 – Dec 10	Oct 09 – Dec 09	% Change
Domestic	391.93	172.72	126.91
Export	278.70	245.96	13.31
Total	670.63	418.68	60.18

In this quarter, the API division has been awarded CEP certificate for the API Gliclazide Ph. Eur by the Council of European Directorate for the Quality of Medicines (EDQM). This certification will facilitate the API division in promoting this product in European market.

#### ➤ Infrastructure :

The Company has initiated the expansion / modernization program at its various plants at an estimated cost of Rs. 65 crores to increase the output, improve productivity & manage the timely deliveries.

- Goa Plant III (Tablet Mfg.) New facility As scheduled, the facility will commence trial production and validation activities by February 2011. Project is 90 % completed and the plant will be commercialized in April 2011. Of this, the new facility will entail an investment of Rs. 48 crores.
- Goa Plant II (Ophthalmic facility) The plant is gearing up for Regulatory Audit of USFDA in February 2011. The sterile facility was originally approved in October 2005. The ophthalmic facility has undergone expansion recently by the commissioning of an ultramodern vial line.
- Goa Plant I (Tablet / Liquid / Ointment facility) The plant capacity has been enhanced by installation of a high capacity equipment in coating and blister packaging department.

- Waluj Plant (Tablet / Liquid / External facility) The liquid capacity line has been enhanced to increase the capacity by 4 lacs bottles per month. Expansion of Quality Control Dept is completed & functioning of the same will commence from January 2011.
- Baddi Plant (Tablet / Liquid / Toothpaste / Ointment facility) The plant has recently installed modern equipment to increase the total capacity. This initiative will help the company to save the cost on packaging material. The Baddi plant has cleared the Regulatory Audit MHRA successfully for the second time.

#### > 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 theart equipments, analytical instruments and latest databases.

#### 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 (APIs) projects is summarized below:

Project Status	No of Projects
Under development	12
Lab Validation completed and ready for Scale	4

Up, Plant Validation	
Under Scale Up and Plant Validation	3
Plant Validation Completed	1
Plant validation for projects under progress	Completed
after cost reduction	
Plant validation for projects completed after	Completed
cost reduction	
Total No. of Projects	20

Analytical Method Development: (APIs)

Project Status	No of Projects
Development Concluded	2
Under Development	4
Analytical method validation	2
Cleaning method validation	3
Stability Samples	9
DMF and COS filing related studies	3
Isolation and characterization of impurity standards	4
Working standards of impurities, intermediates and	12
finished products	
Analytical Method Transfer	1
Polymorphism Study	3

The project status of various R & D (Finished Dosages) projects is summarized below:

Project Status	No of Projects
Under development	27
Scaled up and under validation	3
Ready for scale up with Lab validation completed	6
Contract Research Projects	10
Under Scale up and plant validation	1
Novel Polymorphism Study	1
Scaled up and Plant Validated	3

Project under pipeline: 5

Analytical Method Development: (Finished Dosages)

Project Status	No of Projects	
Analytical method development	More than 35 methods of RM	
	and final products	
Analytical method validation	10 completed	
Novel Polymorphism Study	1	

# Regulatory Affairs:

Following is the status of regulatory submission / approval received in the quarter of Oct 2010 to Dec. 2010.

#### APIs:

- 1. Received CEP for Gliclazide Ph. Eur.
- 2. Submitted Brimonidine Tartarate EDMF to Greece Authority.
- 3. Submitted Betaxolol EDMF to Cyprus Authority.

#### **DMF/COS Filing Status till date:**

Project Status	No of Projects
US DMF	8
Canada	1
Cyprus	2
Germany	1
COS approval received	6
EU DMF under progress	3

# Finished Dosages:

The company has filed ANDAs for 2 formulations with USFDA during the quarter. In addition, the company has submitted CTD Dossiers for 4 formulations to customers for regulated markets and 20 dossiers of our own in emerging markets.

# Dossier Filing Status till date:

Project Status	No of Projects
US ANDA	7
EU CTD	21
Emerging Market	981
US ANDA under progress	-
EU CTD under progress	8
Emerging Market under progress	30

# Intellectual Property Rights (IPR)

<u>APIs</u>

Patents filed	Total Patents filed till date	Patents filed in Oct – Dec 2010 Quarter
India	17	1
PCT application	8	1
Total	25	2

Finished Dosages

Patents filed	Total Patents filed till date	Patents filed in Oct – Dec 2010 Quarter
India	10	-
PCT application	3	-
USA	1	-
Total	14	-

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