# **INDOCO REMEDIES LIMITED**

# **MANAGEMENT DISCUSSION & ANALYSIS**

# FOR THE 2<sup>nd</sup> QUARTER SEPTEMBER 2010

# > Revenue figures:

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

(Rs. in Lacs)

	2 <sup>ND</sup> Quarter			Half Yearly						
	Jul 10 – Sep 10	% to Net Sales	Jul 09 – Sep 09	% to Net Sales	% Gwth	Apr 10 – Sep 10	% to Net Sales	Apr 09 – Sep 09	% to Net Sales	% Gwth
Net Sales :										
Domestic – Formulation	8844	66.82	6448	67.56	37.15	16101	66.06	13229	68.27	21.70
- API	356	2.68	192	2.01	85.41	652	2.67	430	2.21	51.62
Total Domestic (A)	9200	69.51	6640	69.57	38.55	16753	68.73	13659	70.49	22.65
Formulation Exports :	7200	03101	0010	03101		10.00	000.0	10009	7013	
- Regulatory	2712	20.49	2265	23.73	19.73	5215	21.39	4511	23.28	15.60
- Semi-Regulatory	815	6.15	339	3.55	140.41	1595	6.54	788	4.06	102.41
Formul. Exports Total:	3527	26.65	2604	27.28	35.44	6810	27.94	5299	27.34	28.51
API's Export :	507	3.83	299	3.13	69.56	809	3.31	419	2.16	93.07
Total Export (B)	4034	30.48	2903	30.42	38.95	7619	31.26	5718	29.50	33.24
Total Net Sales (A+B)	13234	100	9543	100	38.67	24372	100	19377	100	25.78
Other Operating Income	310		64			459		293		
Total Income	13544		9607			24831		19670		
Total Tikolik	13344		2007			24031		15070		
EBIDTA	2302	17.40	1534	16.07	50.06	4402	18.06	3877	20.00	13.54
Operating Profit	1913	14.46	1178	12.34	62.39	3626	14.88	3146	16.23	15.26
Profit After Tax	1526	11.53	925	9.69	64.97	3008	12.34	2613	13.48	15.11

#### Financial Highlights:

During the 2nd quarter ended September 30, 2010, the overall performance of the Company has been very good showing an excellent growth of 38.7% to Rs. 132.34 crores from Rs. 95.43 crores, over same quarter previous year. The overall increase in the turnover is due to the impressive performance of all the divisions of the business.

The domestic business (including API business) has grown by 38.6% to Rs. 92.00 crores from Rs. 66.4 crores over the same quarter previous year. Along with this, the international business has also grown by 39.0 % to Rs. 40.34 crores from Rs. 29.03 crores. This quarter, the emerging markets also witnessed a record growth of 140.4% to Rs. 8.15 crores from Rs. 3.39 crores over the same quarter previous year. There has also been a remarkable growth of 75.8% in API Business from Rs. 4.91crores to Rs. 8.63 crores.

The material consumption to net sales is 45.8% compared to 42.7% during same quarter previous year. The staff cost is 14.0% compared to 15.2% during same quarter previous year. Research expenses are at Rs. 2.18 crores compared to Rs. 2.25 crores same quarter last year. Other expenses are 25.2% of net sales compared to 26.8% during same quarter previous year.

The increase in the profit is mainly on account of overall increase in the revenues. The profit could have been higher but got impacted due to increase in the material cost and lower realization in exports on account of rupee appreciation against all major currencies. However, the growth in business in terms of foreign currency (USD) was 48% during the current quarter over same quarter previous year. Also the marketing expenses and power & fuel expenses increased during the quarter. Manpower cost has increased by Rs. 4.08 crores over same quarter previous year. This is 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 has shown a reduction from Rs. 0.66 crores to Rs. 0.53 crores during the same quarter previous year. The reduction is mainly due to lesser borrowing & borrowings in foreign currencies at a very competitive rate. This reduction in interest cost has been a consistent feature for the past 4 to5 quarters. The company's overall DSO has reduced to 78 days as on 30<sup>th</sup> Sept'2010 from 82 days as on 31<sup>st</sup> March 2010. This is an outcome of better credit control measures.

The Earnings before Interest, Depreciation, Tax & Amortization (EBIDTA) works out to 17.4% compared to 16.1% during same quarter previous year. Finally the Profit after Tax recorded for the quarter at Rs. 15.26 crores is 11.5% of net sales compared to Rs. 9.25 crores i.e. 9.7% during same quarter previous year.

## > Credit Rating:

Company's Commercial Paper Programme is rated as A1+ by ICRA. Similarly, the working capital facilities are rated as A1+ and company's long term borrowings are rated as LA+.

A1+ rating indicates highest credit quality rating & LA+ rating indicates adequate credit quality rating.

## Finished Dosages:

#### - Domestic Business:

The domestic formulations business showed a growth of 37.2 % during the 2nd quarter ended Sept 2010 over same quarter previous year. During the quarter, the performance of all the products has been very good.

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

(Rs in Lacs)

D. L. W	TEL G	July To Sept 2010	July To Sept 2009	
Product Name	Therap. Seg.	Amount	Amount	
	Gastro -			
CYCLOPAM TAB	Intestinal	566.01	418.35	
FEBREX PLUS TAB	Respiratory	485.48	365.59	
FEBREX PLUS SYRUP	Respiratory	454.51	307.63	
SENSODENT-K	Stomatological	413.56	324.84	
CLOBEN G CREAM	Dermatology	337.72	259.55	
TUSPEL PLUS				
EXPECTORANT	Respiratory	292.51	215.41	
VEPAN 500 TAB	Anti-Infective	282.06	251.72	
KARVOL PLUS				
CAPSULES	Respiratory	261.57	144.27	
SENSODENT-KF	Stomatological	198.44	151.92	
OXIPOD 200	Anti-Infective	132.20	95.62	
CLAMCHEK 625				
TABLETS	Anti-Infective	116.37	69.06	
TRIZ TABLET	Respiratory	103.61	71.15	

Some new products of Xtend (a recently launched division) which have done well are Flamar-P, V-Cef-O, Osteoflam Inj.

New products launched in second quarter are Osteochek, Gemsharp, Zolorab/D, Pgb-12, Deflachek, Lorchek P, Lorchek MR.

The performance of main Therapeutic Segment is as under:

(RS. IN LACS)

D (1)	JULY 2010 -	JULY 2009 -	GROWTH
Particulars	SEPT. 2010	SEPT. 2009	<b>%</b>
Respiratory	2,129	1,390	53.17
Anti-Infective	1,828	1,372	33.24
Gastro Intestinal	1,244	875	42.17
Stomatologicals	1,178	916	28.60
Pain / Analgesics	513	339	51.33
Opthal / Otologicals	462	303	52.48
Gynaec	421	380	10.79
Dermatology	427	331	29.00
Diabetic & Cardiac	396	380	4.21
Vitamins / Minerals / Nutrients	265	176	50.57
Anti-Malarials	55	32	71.88

#### **ORG Ranking:**

The Company has been ranked by ORG Marg as under:

Secondary Sales Audit Ranking status:

SSA RANKING	Aug-10	Aug-09
MONTH	29	30
MAT	31	31

#### Prescription Audit:

Rx RANKING	Aug-10	Aug-09
MONTH	22	22
MAT	22	24

The company's rank in Prescription Audit has improved by 2 ranks which is a very encouraging sign. The company has done well in generating a larger no. of prescriptions which is vital for the sustainable growth. As per the ORG Prescription Audit report, the number of prescriptions generated in AUG 09 was 46.85 million which has substantially increased to 49.97 million in AUG 10.

#### - International Business:

The International Formulation Business continued its sprint forward in the Qtr II, FY 2010-11 by registering a growth of 35.4% over same quarter previous year. The revenues for the quarter under review are Rs. 35.27 crores compared to Rs. 26.04 crores over the same quarter previous year.

#### Regulated Markets:

The exports to regulated markets at the end of the 2<sup>nd</sup> Quarter stood at Rs. 27.12 crores as against Rs. 22.65 crores over same quarter previous year, this despite the low exchange rate realizations from all major currencies.

The Quarter saw Indoco's Levocetirizine Tablets getting a nod from the Hungarian regulatory authority. This opens up opportunities for Indoco to run Mutual Recognition Procedures in various countries in EU and get benefited by Out Licensing deals later on. Indoco also filed new product applications in Australia, UK and some other markets in the EU region via its marketing partners in these regions. Indoco's Paracetamol Tablets got registered in Denmark and the commercial supplies will begin from 3<sup>rd</sup> quarter.

Indoco and Aspen signed manufacturing contracts for a number of products, in the liquid orals, tablets & cream range to cater Aspen's requirement in the Latin American and Sub-Saharan African Markets including South Africa. This deal will give a major boost to the contract manufacturing business of Indoco from its MCC approved facilities in Goa.

Watson, the third largest U.S generic company has further strengthened its relationship with Indoco by expanding the product development and supply pipeline by four more products. The addendum to the agreement was recently signed. The current market size of these four products is USD 765 million.

Indoco's Goa facility for Oral Solids, Liquid Orals and Semi Solids renewed its GMP certification by the Therapeutic Goods Administration (TGA), Australia in the same Quarter. This approval will stand in good stead, now that Indoco and ASPEN/SIGMA deal is closing in for a number of products to be manufactured at the same facility.

#### Emerging Markets:

The exports to the emerging markets in the 2<sup>nd</sup> Quarter ending Sept 2010 is Rs. 8.15 crores as compared to Rs. 3.39 crores over the same quarter previous year showing a impressive growth of 140.4%. The regions which have contributed to the growth of the division are Africa and LATAM.

This quarter witnessed the commercialization of 2 new markets - viz Namibia and Botswana. This will enable us to further consolidate our presence in Africa.

The emerging market division has achieved 11 new product registrations in this quarter. These products will now be commercialized in Q3 of this financial year.

Out of the 15 products under registration in Philippines, we have received the registration for 5 products with another 6 products in the penultimate stage of registration. The registration process for 9 products in Cameroon is also nearing completion, with the target month of launch being Jan'11.

Indoco's Goa and Waluj facilities were audited and approved by SBD Yemen. This will facilitate the registration of several new products in ophthalmic, antibiotic and pain management range in Yemen and further consolidate our presence in the market.

#### > API Business:

During the 2<sup>nd</sup> Quarter ending Sept 2010, the Company's API business also witnessed a impressive growth of 75.8 % from Rs. 4.91 crores to Rs. 8.63 crores over the same period previous year.

WHO authorities recently audited our **Kilo Plant** at Rabale, **Mid-Volume** and **Multi-Ton** plant at Patalganga and awarded WHO: GMP certificate. WHO GMP certification is an important requirement and well accepted in most of the countries across Asia, Africa, CIS and Latin America. With this certification in hand, we have now initiated registration activities for our API products in Korea, Iran, Egypt, Ukraine, Mexico, Brazil etc which will boost our revenue from these markets in near future.

#### 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	10
Lab Validation completed and ready for Scale	5
Up, Plant Validation	
Under Scale Up and Plant Validation	2
Plant Validation Completed	-
Plant validation for projects under progress	Completed
after cost reduction	
Plant validation for projects completed after	Completed
cost reduction	
Total No. of Projects	17

Analytical Method Development: (APIs)

Project Status	No of Projects
Development Concluded	4
Under Development	10
Analytical method validation	4
Cleaning method validation	2
Stability Samples	9
DMF and COS filing related studies	3
Isolation and characterization of impurity standards	6
Working standards of impurities, intermediates and	6
finished products	
Analytical Method Transfer	2
Polymorphism Study	3

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

Project Status	No of Projects
Under development	15
Scaled up and under validation	6
Ready for scale up with Lab validation completed	5
Contract Research Projects	10
Under Scale up and plant validation	4
Novel Polymorphism Study	2
Scaled up and Plant Validated	6

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 July 2010 to Sept. 2010.

### APIs:

- 1. Submitted Olopatadine Hydrochloride DMF to US FDA.
- 2. Submitted Allopurinol EUDMF to Germany for Beta Pharma.
- 3. Submitted Documents for Japanese Accreditation of Patalganga site

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

Project Status	No of Projects
US DMF	8
Canada	1
Cyprus	1
Germany	1
COS approval received	5
EU DMF under progress	3

## Finished Dosages:

We have filed ANDAs for 2 formulations with USFDA during the quarter. In addition, we have submitted a number of dossiers of our own in emerging markets and through our customers in regulated markets.

Dossier Filing Status till date:

Project Status	No of Projects
US ANDA	5
EU CTD	20
Emerging Market	961
US ANDA under progress	3
EU CTD under progress	8
Emerging Market under progress	20

# Intellectual Property Rights (IPR)

# <u>APIs</u>

Patents filed	Total Patents filed till date	Patents filed in July-Sept 2010 Quarter
India	16	4
PCT application	7	1
Total	23	5

# Finished Dosages

Patents filed	Total Patents filed till date	Patents filed in July-Sept 2010 Quarter
India	10	-
PCT application	3	-
USA	1	-
Total	14	-

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