

Indoco Remedies Limited

Management Discussion & Analysis for the Fourth Quarter FY18

Financials (Stand-alone)

(₹ In Lakhs)

Particulars	Unaudited				Audited		
	Quarter Ended				Year Ended		
	Jan. 18 – Mar. 18	Oct. 17 – Dec. 17	Jan. 17 – Mar. 17	% Gwth	Apr. 17 - Mar. 18	Apr. 16 - Mar. 17	% Gwth
Gross Sales (Net of Sales Returns):							
Formulation :							
- Domestic	15109	15593	13009	16.1	59498	58501	1.7
- Export							
Regulated Market :	6475	7800	10310	(37.2)	27564	35125	(21.5)
Emerging Market :	2283	2147	1839	24.1	7169	6314	13.5
Export Total	8758	9947	12149	(27.9)	34733	41439	(16.2)
Total Formulation ... (A)	23867	25540	25158	(5.1)	94231	99940	(5.7)
API :							
- Domestic	636	454	320	98.8	2432	2515	(3.3)
- Export	911	1121	884	3.1	3655	3630	0.7
Total API ... (B)	1547	1575	1204	28.5	6087	6145	(0.9)
CRO & Analytical Services :							
- Domestic	472	304	193	-	1413	580	-
Total CRO ... (C)	472	304	193	-	1413	580	-
Total Gross Sales (A+B+C)	25886	27419	26555	(2.5)	101731	106665	(4.6)
Other Operating Income	1077	393	1139	(5.4)	2427	2741	(11.5)
Total Income from Operation	26963	27812	27694	(2.6)	104158	109406	(4.8)
EBIDTA	4942	4321	3257	51.8	13486	15662	(13.9)
Operating Profit	3854	3818	3257	18.4	9713	13890	(30.1)
Profit Before Tax	2580	2434	2038	26.6	4843	9133	(47.0)
Profit After Tax	2050	2266	1794	14.3	4120	7745	(46.8)

➤ Financial Highlights

Net revenues for the quarter were at ₹ 258.9 crores against ₹ 265.5 crores, same quarter last year. For the year, the net revenues were at ₹ 1017.3 crores as against ₹ 1066.7 crores, last year. Formulations business contributed to 92.6 % and API business contributed to 7.4%.

During the quarter, the material consumption was 33.8 % of the net sales, compared to 36.6 %, same quarter last year. Staff cost to net sales is 19.6 % compared to 21.4 %. Depreciation / Amortization are at ₹ 16.3 crores, compared to ₹ 15.4 crores. Research & Development (R&D) expenses to net sales are 5.3 % at ₹ 13.8 crores, compared to 5.2 % at ₹ 13.9 crores. Other expenses to net sales are 26.3 % at ₹ 68.1 crores, compared to 28.8 % at ₹ 76.5 crores.

For the year, the material consumption is 34.3 % of the net sales, as against 35.8 %, last year. Staff cost to net sales is 21.7 % as against 20.3 %. Depreciation / Amortization are at ₹ 67.7 crores, as against ₹ 63.3 crores. Research & Development (R&D) expenses to net sales are 5.3 % at ₹ 53.5 crores compared to 4.8 % at ₹ 51.7 crores. Other expenses to net sales are 27.9 % at ₹ 283.5 crores, as against 27.0 % at ₹ 288.1 crores.

Earnings Before Interest, Depreciation, Tax and Amortization (EBIDTA) to net sales for the quarter are 19.1 % at ₹ 49.4 crores, compared to 12.3 % at ₹ 32.6 crores, same quarter last year.

For the year, Earnings Before Interest, Depreciation, Tax and Amortization (EBIDTA) to the net sales is 13.3 % at ₹ 134.9 crores, as against 14.7 % at ₹ 156.6 crores, last year

Profit Before Tax (PBT) for the quarter is 10.0 % of net sales at ₹ 25.8 crores, as against 7.7 % at ₹ 20.4 crores, same period last year.

For the year, Profit Before Tax (PBT) is 4.8 % of net sales at ₹ 48.4 crores, as against 8.6 % at ₹ 91.3 crores, last year.

Profit After Tax (PAT) for the quarter is 7.9 % at ₹ 20.5 crores, as against 6.8 % at ₹ 17.9 crores, same quarter last year.

For the year, Profit After Tax (PAT) is 4.0 % of net sales at ₹ 41.2 crores, as against 7.3 % at ₹ 77.4 crores, last year.

➤ Rating

The Company's working capital facilities are rated as [ICRA] A1+ (Pronounce ICRA A One Plus) and long term borrowings are rated as [ICRA] A+ (Pronounce ICRA A Plus) by ICRA.

Instruments with A1+ rating are considered to have very strong degree of safety regarding timely payment of financial obligations. Such instruments carry lowest credit risk.

Instruments with A+ rating are considered to have adequate degree of safety regarding timely servicing of financial obligations. Such instruments carry low credit risk.

➤ **Finished Dosages**

As per AWACS, the growth of IPM for the fourth quarter is 8.7 % and for the year ending, the growth stands at 5.7 %. For the fourth quarter, IPM has added ₹ 29,858/- crores over same quarter last year. Inventory days of IPM for the month of March'18 were 38 days. Inventory days of Indoco in March'18 were 43 days, which has improved from 36 days in Dec'17.

Secondary Sales Audit Ranking

The Corporate rank is 30th in IPM with market share of 0.66 % as on Mar'18.
(Source: AWACs)

Prescription Ranking

The Company ranks 23rd with prescription (R_x) share of 0.89 % as on Feb'18 MAT basis. As per Strategic Marketing Solutions and Research Centre (SMSRC), the prescription (R_x) growth of 4 % registered by Indoco vis-à-vis industry growth of 2 % on Feb-18 MAT basis shows positive prospects for the Company. A double digit prescription growth is recorded in various targeted specialties viz., Pediatrician, Gynecologist, Consulting Physician, Cardiologist.
(Source: SMSRC).

Indoco's Domestic Formulation Business:

The revenues of domestic formulations business for the quarter grew at 16.1 % at ₹ 151.1 crores as against ₹ 130.1 crores for the same quarter last year. For the year, the revenues of domestic formulation business grew at 1.7 % at ₹ 595.0 crores, as against ₹ 585.0 crores, last year.

Details of revenues from major therapies are as follows:

(₹ In Lakhs)

Therapy	Q4FY18	Q4FY17	Gwth %
Respiratory	2848	2426	17.4
Stomatologicals	2406	2086	15.3
Anti-Infectives	2360	2023	16.6
Gastro Intestinal	2144	1891	13.4
Vitamins / Minerals	1020	837	21.9

Details of revenues from major brands are as follows:

(₹ In Lakhs)

Brand	Q4FY18	Q4FY17	Gwth %
Cyclopam	1718	1417	21.2
Febrex Plus	1563	1363	14.7
Cital	872	719	21.2
ATM	807	523	54.2
Oxipod	780	691	12.9
Sensodent K	760	632	20.3
Karvol Plus	507	383	32.4
Cloben G	455	448	1.5
Sensoform	445	385	15.4
Sensodent KF	442	369	19.8

New product introductions:

For the year, the Company has launched 9 new products, 6 in Chronic, 2 in Sub-Chronic and 1 in the Acute segment.

➤ **International Formulation Business**

During the quarter, the International formulations business revenues were at ₹ 87.6 crores as against ₹ 121.5 crores, same quarter last year. For the year, the international formulation business was at ₹ 347.3 crores, as against ₹ 414.4 crores, last year.

Europe contributed 51.5% of International formulation sales, America at 11.7%, South Africa, Australia & New Zealand at 16.2% and Emerging markets at 20.6%.

USA

During the quarter, the revenues were at ₹ 5.9 crores, as against ₹ 32.8 crores, same period last year. For the year, the revenues were at ₹ 40.5 crores, as against ₹ 125 crores, last year.

Current Status of ANDAs:

- ❖ 10 approvals till date
- ❖ 2 tentative approvals
- ❖ 36 filed, pending approval

For Goa Plant II, post the warning letter from USFDA, all the updates of the commitments were submitted to the agency and remediation actions are completed. The site now awaits a re-inspection by USFDA.

USFDA also inspected Goa Plant I (Solid Dosage) from 15th to 19th January'18 and had issued 8 observations (483s), for which initial response was submitted within the stipulated time of 15 days. Further to this response, updates to FDA are being submitted in timely manner.

Europe

During the quarter, the revenues were at ₹ 46.9 crores, compared to ₹ 54.1 crores, same quarter last year. For the year, the revenues were at ₹ 179.0 crores as against ₹ 156.2 crores, last year.

The Regulatory Authority of Hungary inspected our Goa Plant III between 20th to 24th November'17 and issued European GMP certification on 12.2.2018

to the facility which will enable the Company to export to all European countries, as well as to Canada, Australia and New Zealand.

The MHRA inspection was scheduled from 14th to 16th March'18 at Goa Plant I. At the end of the inspection, the Company received 3 critical and 4 major observations. A response was sent to the MHRA within the stipulated time with an outline of compliance plan. MHRA sought further information which is being responded to in a timely manner. Meanwhile, MHRA has issued a statement of non-compliance with EU GMP and restricted GMP Certificate permitting to manufacture and supply 50 SKUs critical to public health in the UK from Goa Plant I.

In addition to restricted supplies to UK from Goa Plant I, business to EU is serviced from Goa (Plant III) and Baddi (Plant I) as well. We are also getting our newly acquired facility at Baddi (Plant III) inspected by EU Regulatory Authority in the coming quarter. This will ensure continuity supplies to EU market, to a large extent.

The Company has taken concrete steps in shaping organization culture to ensure all data from our manufacturing sites is complete, consistent and accurate in all its forms, i.e., paper and electronic. The corrective actions are being implemented through a newly formed Compliance Cell headed by Chief Technical Officer (CTO). The Company has also engaged third party consultants and experts to correct the situation and comply with the expectations of USFDA and EU GMP guidelines.

South Africa, Australia and New Zealand Business

The revenues for the quarter were at ₹ 11.9 crores compared to ₹ 16.2 crores, same quarter last year. For the year, the revenues were at ₹ 56.1 crores, as against ₹ 70.1 crores, last year.

The business in these territories comprises of trade as well tender businesses. The trade business is growing consistently, however, the tender business which is not commercially viable is not being pursued.

Emerging Markets

The revenues for the quarter were at ₹ 22.8 crores, compared to ₹ 18.4 crores, same period last year. For the year, the revenues were at ₹ 71.7 crores, as against ₹ 63.1 crores, last year.

Sales show positive growth in Kenya as well as FWA markets. The Company launched Antimalarial tablets in Ivory Coast, Ophthalmic products in Tanzania.

➤ **Active Pharmaceutical Ingredients (APIs)**

The revenues of API business were at ₹ 15.5 crores, compared to ₹ 12 crores, same quarter last year. For the year, the revenues of API business were at ₹ 60.9 crores as against ₹ 61.4 crores, last year.

USFDA inspections were conducted at Indoco's API manufacturing facilities at Patalganga and Rabale, Navi Mumbai. The inspection at Patalganga facility was conducted from 7th to 11th May, 2018 and at Kilo Lab facility from 14th to 17th May, 2018. We are pleased to inform that both these inspections were successfully completed. During the audit, the FDA inspected the entire quality management systems to ensure compliance with federal regulations. The inspection included a review of production facility, processes and procedures, training records, quality systems and control procedures.

The Kilo lab facility received zero 483s from the agency, while the Patalganga facility cleared the inspection with 3 observations; none of them are critical or pertain to data integrity.

The Company's API Plant at Patalganga received Renewed Accreditation Certificate from The Pharmaceuticals and Medical Devices Agency (PMDA), Japan. The Accreditation is valid till May, 2023. The Company has filed 2 JDMFs in Japan for Allopurinol and Dicycloverine.

The Company received the IDMA BEST INDIAN PATENT AWARD on 20.1.2018 for 5 API Process Patents (4 Indian and 1 EU). The patents for manufacturing processes of Tapentadol, Rasagiline, Allopurinol Intermediate, Phenylacetic acid derivative (for Bromfenac & Nepafenac) and Imiquimod were considered for this award.

➤ **CRO & Analytical Services**

During the quarter, revenues from CRO and Analytical Services business were at ₹ 4.7 crores, compared to ₹ 1.9 crores, same quarter last year. For the year, the revenues were at ₹ 14.1 crores, as against ₹ 5.8 crores, last year.

➤ **Future Outlook**

The Company's Domestic business continues to focus on brand building, new product launches, thrust on sub-chronic (Speciality) segment and penetration in the North and East Region.

Going forward, the Company's business from US and EU is expected to grow speedily as ANDAs and Dossiers will be commercialized at regular intervals after resolution of USFDA's warning letter, reinstatement of the EU-GMP compliance certificate for Goa Plant I and EU-GMP approval of newly acquired solid dosages manufacturing facility at Baddi (Plant III). Indoco is also consolidating its position in the Emerging Markets through active brand promotion. Robust pipeline in multiple dosage forms will enable the Company to have an upper edge over its competitors in the international business.

Expertise in Research & Development, backward integration in API in select products, own CRO set-up, excellence in finished dosages manufacturing and a strong customer base makes the Company, a preferred partner, offering complete solutions to generic companies worldwide.

Safe Harbour

Statements made in this Management Discussion and Analysis (MDA) describing the Company's objective, projections, estimates and expectations may be 'Forward-looking statements' within the meaning of applicable securities laws & regulations. Actual results could differ from those expressed or implied due to risks, uncertainties and inaccurate assumptions.