

Indoco Remedies

04 June 2023

OAI classification at Goa Plant II facility jeopardises future growth in the US business

COMPANY UPDATE

Sector: Pharmaceuticals	Rating: HOLD
CMP: Rs 354	Target Price: Rs 385

Stock Info

Sensex/Nifty	62,547/18,534
Bloomberg	INDR IN
Equity shares	92mn
52-wk High/Low	Rs 423/307
Face value	Rs 2
M-Cap	Rs 32bn/ USD 0.4bn

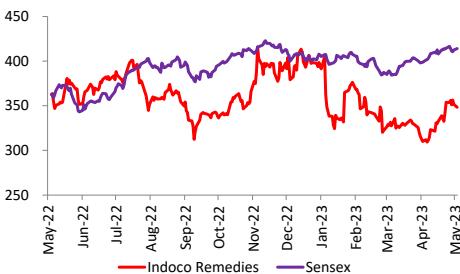
Financial Snapshot (Rs mn)

Y/E March	FY23	FY24E	FY25E
Sales	16,686	17,532	19,108
Gross profit	11,473	12,036	13,118
Gross Margin %	68.8%	68.7%	68.7%
EBITDA	2,861	2,944	3,399
Margin %	17.1%	16.8%	17.8%
PAT	1,423	1,442	1,772
EPS	15.4	15.7	19.2
DPS (Rs)	1.5	1.6	1.9
ROE (%)	13.8	12.5	13.4
P/E (x)	22.9	22.6	18.4
EV/EBITDA (x)	12.4	12.0	10.3

Shareholding pattern (%)

	Sep-22	Dec-22	Mar-23
Promoter	58.69	58.69	58.69
-Pledged	-	-	-
FII	1.07	1.11	1.55
DII	17.97	18.19	18.05
Others	22.27	22.01	21.71

Stock Performance (1-year)



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On 3rd June, 2023, Indoco Remedies (INDR) announced that its Goa Plant II sterile facility has been classified with an Official Action Indicated (OAI) status by the US FDA. The OAI status will preclude INDR from launching new products to the US market from this facility. The US FDA inspected the facility from 20th Feb, 2023 to 28th Feb, 2023. Post inspection, INDR was issued four observations by the US FDA. The OAI status on Goa Plant II facility was an unexpected event. As per our analysis of the observations and discussion with a regulatory consultant, an OAI status was not anticipated. The four US FDA observations do not seem to be complex in nature and we expect INDR to take around one year to resolve the compliance issues. Our US growth estimates are already conservative and we do not see significant downside risk. We had earlier built only 10% growth in the US as against company guidance of 30% in FY24. The 10% growth estimate assumed successful commercialization of oral products from Goa Unit 1, which recently received Voluntary Action Indicated (VAI) status from the US FDA. We have cut INDR's FY24 US revenue growth estimate from 10% to 0% to account for remediation led supply constraints at the Goa Plant II sterile facility. In FY23, the US business recorded revenue of Rs 2,658mn (~16% of sales). We estimate the impacted sterile facility (ophthalmic and injectables) to contribute ~70% of US sales. The OAI status implies that the existing products will continue to be shipped but new approvals should stall. Over the last one year, INDR has been facing manufacturing related issues in its sterile ophthalmic portfolio. INDR's Brinzolamide had a defect in its bottle dropper, wherein the nozzle of the dropper could break off and block the dropper, possibly resulting in the product not dispensing. Company has now resolved the issue and regained market share. However, another large product, gCombigan, which was expected to meaningfully ramp up in 4QFY23, has faced manufacturing challenges leading to decline in market share; INDR will be able to resume supplies of gCombigan in 3QFY24. We revise our US revenue growth estimates and downgrade INDR to "HOLD" with a lower target price of Rs. 385 (Rs. 403 earlier) based on 20x FY25E EPS.

OAI status can lead to downward revision in US growth guidance – As per the company, the US business is expected to deliver 30% revenue growth in FY24. Company was expecting 3-4 approvals in FY24, majority being ophthalmic products. The timeline for these approvals will get pushed until the OAI status is lifted.

Growth in US business is dependent on sterile injectables/ophthalmics – INDR has consistently indicated that sterile products and niche oral solids are the key focus area to grow their US business. As per our analysis, ~70-75% of products exported by INDR are sterile in nature. This has partly to do with the fact that its Goa Plant I (Oral Solids facility) was under warning letter since 2019. In May'23, the warning letter was lifted and INDR is expected to start receiving approvals for pending filings from this facility. However, the oral solids market in the US remains very competitive and less profitable. Nevertheless, a 10% revenue growth on a base of USD 32mn (US sales in FY23) in FY25 should be achievable.

Investors are advised to refer disclosures made at the end of the research report.

Scenario analysis indicates limited impact to revenues**Base case:** Expect US sales to remain flat in FY24 and grow by 10% in FY25.**Bull case:** Expect US sales to grow at 10% in FY24 and FY25.**Bear case:** Expect US sales to remain flat in FY24 and decline by 5% in FY25.**Exhibit 1: US portfolio**

Molecule	Dosage Form
Allopurinol	Oral Solid (Tablet)
Lacosamide	Injectable
Norepinephrine Bitartrate	Injectable
Brimonidine Tartrate and Timolol Maleate	Ophthalmic Solution
Brinzolamide	Ophthalmic Suspension
Phenylephrine HCL	Injectable
Isoproterenol HCL	Injectable
Lacosamide	Oral Solid (Tablet)
Glycopyrrolate	Injectable
Glimepiride	Oral Solid (Tablet)
Febuxostat	Oral Solid (Tablet)
Neostigmine Methylsulfate	Injectable
Ketotifen Fumarate	Ophthalmic Solution
Rasagiline	Oral Solid (Tablet)
Acetylcysteine	Injectable
Tranexamic Acid	Injectable
Succinylcholine Chloride	Injectable
Dorzolamide HCL	Ophthalmic Solution
Olanzapine	Oral Solid (Tablet)
Febuxostat	Oral Solid (Tablet)
Dorzolamide HCL and Timolol Maleate	Ophthalmic Solution
Difluprednate	Ophthalmic Emulsion
Ciprofloxacin and Dexamethasone	OTIC suspension
Brimonidine Tartrate	Ophthalmic Solution

*Source: Company, Systematix Institutional Research***Exhibit 2: Change in estimates**

Particulars (Rs mn)	New estimates		Old estimates		Change (%)	
	FY24E	FY25E	FY24E	FY25E	FY24E	FY25E
Net sales	17,532	19,108	17,803	19,406	-1.5	-1.5
EBITDA	2,944	3,399	3,049	3,518	-3.4	-3.4
Margin (%)	16.8	17.8	17.1	18.1	(33) bps	(34) bps
PAT	1,442	1,772	1,519	1,859	-5.1	-4.7
Margin (%)	8.2	9.3	8.5	9.6	(31) bps	(31) bps
EPS	15.7	19.2	16.5	20.2	-5.1	-4.7

Source: Systematix Institutional Research

FINANCIALS

Profit & Loss Statement

YE: Mar (Rs mn)	FY21	FY22	FY23	FY24E	FY25E
Net Revenues	12,415	15,408	16,686	17,532	19,108
YoY gr. (%)	12.2%	24.1%	8.3%	5.1%	9.0%
Cost of Goods Sold	3,541	4,568	5,213	5,495	5,989
Gross Profit	8,874	10,840	11,473	12,036	13,118
Margin (%)	71.5%	70.4%	68.8%	68.7%	68.7%
Employee Cost	2,740	2,937	3,219	3,509	3,824
Other Expenses	3,294	3,883	4,584	4,734	4,968
R&D Expenses	597	746	809	850	927
EBITDA	2,243	3,273	2,861	2,944	3,399
YoY gr. (%)	82.0%	46.0%	-12.6%	2.9%	15.5%
Margin (%)	18.1%	21.2%	17.1%	16.8%	17.8%
Depreciation and Amortization	731	790	706	752	803
EBIT	1,511	2,484	2,155	2,192	2,596
Margin (%)	12.2%	16.1%	12.9%	12.5%	13.6%
Net Interest	223	141	250	281	296
Other Income	31	23	23	11	62
Exceptional Items	-	-	-	-	-
Profit Before Tax	1,320	2,366	1,928	1,923	2,363
Margin (%)	10.6%	15.4%	11.6%	11.0%	12.4%
Total Tax	390	818	505	481	591
Effective tax rate (%)	30%	35%	26%	25%	25%
Minority Interest & Share of Loss from Associates	-	-	-	-	-
Profit after tax	930	1,548	1,423	1,442	1,772
EPS	10.1	16.8	15.4	15.7	19.2
YoY gr. (%)	286%	66%	-8%	1%	23%

Source: Company, Systematix Institutional Research

Cash Flow

YE: Mar (Rs mn)	FY21	FY22	FY23	FY24E	FY25E
PBT	1,320	2,366	1,928	1,923	2,363
Depreciation	731	790	706	752	803
Interest	228	148	250	281	296
Others	138	-66	-23	-11	-62
Working capital	-1,398	-1,088	-630	-280	-510
Direct tax	-197	-411	-505	-481	-591
Net cash from Op. activities	822	1,738	1,725	2,183	2,298
Net Capital expenditures	-769	-1,253	-1,478	-1,293	-1,293
Others	102	39	-590	-253	-202
Net Cash from Inv. activities	-667	-1,214	-2,068	-1,546	-1,495
Issue of share cap. / premium	-	-	-44	-	-
Debt changes	-31	-143	703	384	188
Dividend paid	-28	-138	-142	-144	-177
Others	-240	-163	-238	-239	-242
Net cash from Fin. activities	-299	-444	279	0	-231
Net change in cash	-143	80	-64	637	572

Source: Company, Systematix Institutional Research

Balance Sheet

YE: Mar (Rs mn)	FY21	FY22	FY23	FY24E	FY25E
Equity Share Capital	184	184	184	184	184
Reserves & Surplus (Ex OCI)	7,506	8,862	10,098	11,396	12,991
Net Worth	7,690	9,046	10,283	11,580	13,175
Short term debt	1,163	1,483	1,710	2,094	2,282
Long term debt	969	959	1,435	1,435	1,435
Trade payables	1,132	1,333	1,235	1,301	1,418
Other Provisions	469	475	495	520	567
Other liabilities	1,727	1,565	1,425	1,507	1,637
Total Liabilities	13,151	14,861	16,582	18,438	20,515

Source: Company, Systematix Institutional Research

Key Financial Metrics

YE: Mar (Rs mn)	FY21	FY22	FY23	FY24E	FY25E
Per Share(Rs)					
EPS	10.1	16.8	15.4	15.7	19.2
CEPS	18.0	25.4	23.1	23.8	27.9
BVPS	83.4	98.2	111.6	125.7	143.0
DPS	0.3	1.5	1.5	1.6	1.9
Return Ratio(%)					
RoCE	15.4	21.6	16.0	14.5	15.4
RoE	12.1	17.1	13.8	12.5	13.4
Balance Sheet					
Net Debt : Equity (x)	0.3	0.2	0.3	0.2	0.2
Net Working Capital (Days)	151.5	183.5	203.8	213.1	209.6
Valuation(x)					
PER	35.0	21.1	22.9	22.6	18.4
EV/EBITDA	15.4	10.6	12.4	12.0	10.3
EV/Sales	2.8	2.3	2.1	2.0	1.8

Source: Company, Systematix Institutional Research

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