



India

REDUCE (no change)

Consensus ratings*:	Buy 7	Hold 0	Sell 1
Current price:			Rs1,302
Target price:			Rs714
Previous target:			Rs714
Up/downside:			-45.2%
InCred Research / Cor	nsensus:		-53.0%
Reuters:			
Bloomberg:		AMI	ORG IN
Market cap:		U	S\$572m
		Rs4	47,423m
Average daily turnover	:	L	JS\$1.6m
		R	s136.7m
Current shares o/s:			36.0m
Free float: *Source: Bloomberg			27.2%



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Price performance	1M	ЗМ	12M
Absolute (%)	10.6	14.8	29.4
Relative (%)	11.8	9.5	17.7

Major shareholders	% held
Promoter & Promoter Group	72.8
UTI AMC	1.0
SBI Funds Management Ltd	0.8

Ami Organics Ltd

After vinylene, high hopes on darolutamide

- As vinylene carbonate prices have collapsed, market's new expectations have started to build on a darolutamide intermediate.
- Traditional business of Ami Organics is seeing a slowdown. Also, darolutamide has several other intermediates and for them there are multiple suppliers.
- We feel the consensus bullishness on growth is misplaced. Like all chemical companies, here also a consensus EPS cut is on the cards. Retain REDUCE.

Darolutamide alone cannot carry the load of consensus expectations

Darolutamide was developed jointly by Bayer and Orion Corporation. Please note that darolutamide is a successful product and its sales are likely to touch more than US\$3bn (US\$1.2bn currently) in the next four-to-five years. At the same time, darolutamide is not the only anti-prostate cancer drug, as enzalutamide (Xtandi) and apalutamide (Erleada) are also available and there are several drugs in the pipeline like- ARN-509-(Astellas Pharma), orbicularis (developed by Dendreon) and PT101 (developed by Protagonist Therapeutics). On the intermediate side as well, darolutamide has five-to-six different intermediates, which have multiple Indian and global suppliers. As is evident, while darolutamide is likely to face competition, at the same time, even the suppliers of intermediates will face stiff competition. The result is likely to be similar to what we have seen with multiple active pharmaceutical ingredient (API) suppliers.

Vinylene carbonate - at best, Rs0.35-0.4bn EBITDA at 100% utilization

When Ami Organics started its vinylene carbonate project, the product price was more than US\$70/kg but now it has fallen to US\$8/kg whereas the cost of production remained similar. The current EBITDA is ~ US\$0.5/kg, which means on 100% capacity utilization of its 8,000t plant, Ami Organics can make Rs0.35-0.4bn EBITDA.

Massive cut needed in consensus earnings estimates

Consensus appears to be building around Rs1bn EBITDA from vinylene carbonate and significant EBITDA addition from a darolutamide intermediate. At the same time, consensus appears to be quite sanguine about the base business. However, as we have shown in this report that base molecules - apixaban, trazodone, etc. are already facing the heat of pricing and competition from cheaper products. We believe that consensus EPS estimates for FY24F/25F/26F need to be cut by 20%, 30% and 40%, respectively. We retain our REDUCE rating on the stock with a target price of Rs714. Upside risk: A sudden rise in vinylene carbonate prices may lead to better-than-our-projected EPS.

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Financial Summary	Mar-22A	Mar-23A	Mar-24F	Mar-25F	Mar-26F
Revenue (Rsm)	5,201	6,167	7,092	7,802	9,362
Operating EBITDA (Rsm)	1,052	1,226	1,313	1,450	1,587
Net Profit (Rsm)	719	833	879	958	1,038
Core EPS (Rs)	20.0	23.1	24.4	26.6	28.8
Core EPS Growth	33.2%	15.8%	5.5%	9.0%	8.3%
FD Core P/E (x)	65.12	56.25	53.32	48.90	45.16
DPS (Rs)	0.0	0.0	0.0	0.0	0.0
Dividend Yield	0.00%	0.00%	0.00%	0.00%	0.00%
EV/EBITDA (x)	43.61	37.77	34.89	31.48	28.77
P/FCFE (x)	(17.49)	125.43	177.08	114.00	191.42
Net Gearing	(19.1%)	(9.3%)	(15.8%)	(16.5%)	(14.8%)
P/BV (x)	9.05	7.89	7.19	6.48	5.85
ROE	21.0%	15.0%	14.1%	13.9%	13.6%
% Change In Core EPS Estimates					
InCred Research/Consensus EPS (x)					

SOURCE: INCRED RESEARCH, COMPANY REPORTS



After vinylene, high hopes on darolutamide

Too high expectations from darolutamide intermediate

The name of darolutamide's intermediate which Ami Organics is selling for the last five years is methyl-5-acetal-1h-pyrazole-3-carboxylate. It is being exported since FY21 and as per the DRHP document, Ami Organics exported US\$1m worth of the intermediate in FY21.

Darolutamide is used for prostate cancer treatment

- Darolutamide is a drug that is used to treat non-metastatic castration-resistant prostate cancer (nmCRPC). It was approved for marketing in the US, Europe, and Japan in 2020.
- 2. Global sales of darolutamide were estimated to be US\$1.2bn in 2022. The sales are expected to grow to US\$3.4bn by 2026F. A major portion of the sales are expected to come from the US, followed by Europe and Japan.
- Darolutamide is a first-in-class drug and is seen to be effective in prolonging the lives of patients with nmCRPC. It is also well-tolerated with a favourable safety profile. These factors are contributing to the strong sales growth of darolutamide.

Can darolutamide be the saviour for Ami Organics? It's good, but the competition is also tough ➤

- 1. Other than darolutamide, there are two other next-generation androgen receptor (AR) inhibitors available in the market, namely enzalutamide (Xtandi) and apalutamide (Erleada).
- 2. Darolutamide is better than the other two alternatives because it has better tolerability, fewer side effects, and a higher survival rate.
- 3. The two main competitors in darolutamide are:
 - a. Xtandi (enzalutamide), which was approved by the US FDA in 2012. Xtandi has a similar safety profile to darolutamide, but it has a shorter mTTP and a lower overall survival rate.
 - b. Erleada (apalutamide), which was approved by the US FDA in 2018. Erleada has a slightly worse safety profile than darolutamide, but it has a longer mTTP and a higher overall survival rate.
- 4. It is still too early to say which drug will ultimately be the most successful in the nmCRPC treatment market. However, darolutamide is well-positioned to compete with Xtandi and Erleada due to its superior safety profile and longer mTTP.
- 5. In addition to Xtandi and Erleada, there are several other AR antagonists that are in development for the treatment of nmCRPC. These drugs include:
 - a. ARN-509, which is being developed by Astellas Pharma.
 - b. **Orbicularis**, which is being developed by Dendreon.
 - c. **PT101**, which is being developed by Protagonist Therapeutics.
- 6. These drugs are still at the early stage of development, but they could pose a threat to darolutamide's market share.

Bayer and Orion are marketing darolutamide under the brand name Nubeqa ➤

Bayer and Orion collaborated in 2015 to develop the drug Nubeqa. This drug
has been approved in all major geographies: Japan, Europe, and the US.
Investigations for developing new indications for the drug are currently
underway.



- 2. On 26 Jan 2023, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorization for the medicinal product darolutamide (Nubeqa). The CHMP adopted a new indication to include the treatment of adult patients with metastatic hormone-sensitive prostate cancer.
- 3. Bayer and Orion partnered to develop this molecule during the Phase-III clinical trials. This collaboration is aimed to bring out Bayer's strength in developing and launching new compounds to market and also Fermion's strengths in manufacturing and turning out large-scale production. Bayer has global marketing rights for the compound, and Orion and its subsidiary Fermion are handling the CMC and manufacturing from the early clinical stage to commercialization. Orion also has co-promotion rights for Europe.
- Orion manufactures the final drug product, and Fermion manufactures the API.
- 5. Nubeqa and Easyhaler are essential products for Orion and will be key growth drivers for the company in the coming years. The new Hanko plant of Fermion will be equipped and used to produce darolutamide, which is currently Orion's most significant product, and its sales are expected to grow strongly in the coming years. This assumption is based on an estimate by Orion's partner Bayer, according to which Nubeqa's annual global peak sales could exceed EUR3bn.

Does Ami Organics make darolutamide? No, it makes its intermediate called methyl-5-acetal-1h-pyrazole-3-carboxylate ➤

Ami Organics makes an intermediate of darolutamide, which is methyl-5-acetal-1h-pyrazole-3-carboxylate. The following are the names of some of the other intermediates used in the synthesis of darolutamide:

- 1. 4-bromo-2-chlorobenzonitrile
- 2. N-boc-L-alaninol
- 3. Ethyl 5-acetyl-1H-pyrazole-3-carboxylate
- 4. (S)-4-(1-(2-aminopropyl)-1H-pyrazol-3-yl)-2-chlorobenzonitrile
- 5. 2-chloro-4-(1H-pyrazole-5-yl)benzonitrile

There are multiple other companies who make these intermediates. We have listed one of them below:

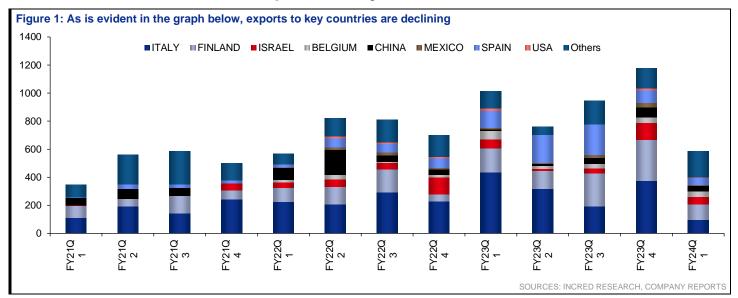
1. Aarti Pharma Labs

Apixaban, entacapone, nintedanib and rivaroxaban sales are likely to decline, which shows in their reduced export numbers >

- 1. Apixaban is the costlier anti-coagulant and may be because of high inflation, people in Europe are shifting to a lower-cost alternative. Ami Organic's main market for Apixaban appears to be Italy.
- Nintedanib is used to treat idiopathic pulmonary fibrosis this is again a typical medicine whose usage would have gone up during the post-Covid period. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8983072/). As the Covid-19 pandemic has subsided, so has the usage of this drug.
- Entacapone is an inhibitor of catechol-o-methyltransferase (COMT). It is used
 in combination with levodopa and carbidopa (Sinemet) to treat the end-ofdose 'wearing-off' symptoms of Parkinson's disease. It's a costly drug
 whereas a cheaper generic alternative is available (carbidopa/levodopa).
- 4. Rivaroxaban is used to treat and prevent deep vein thrombosis (DVT), a condition in which harmful blood clots form in blood vessels of the legs. Rivaroxaban and apixaban are an alternative to each other and both of them are very costly. There are multiple cheaper generics like dabigatran.



Exports to key countries are on the decline



Italy - Problems faced by both Apixaban and Quetiapine>

- Ami Organics exports its products to different companies in Italy. Some of them are Fabbrica Italiana Sintetici S.p.A, Organike s.r.l.a Socio Unico, and Novartis.
- 2. Fabbrica Italiana Sintetici S.p.A- This company produces Apixaban and Quetiapine. However, Apixaban is still in the trial phase as of now, and the main product is still Quetiapine.
- 3. Bristol-Myers Squibb is based in Rome and is one of the major Apixaban manufacturers under brand name Eliquis.

Apixaban sales are not rising at a good pace: According to IQVIA, global sales of Apixaban in 1Q2023 increased by 7% vs. the same quarter in 2022. This increase in global sales was driven by the US, where sales grew by 19%, whereas in RoW the sales declined by 18%. The decline in RoW sales is being attributed to several factors, including increased competition from generics and newer blood thinners, as well as changes in treatment guidelines.

Sales of quetiapine, a generic antipsychotic drug, is rising at a sedate pace in Italy: According to data from IQVIA, sales of quetiapine in Italy increased by 8% in the first quarter of 2023, compared to the same period in 2022. While branded drugs sales went up (led by Astra Zeneca), sales of generic quetiapine remained flattish.

Finland - Trazone sales are declining and Entacapone is banned ➤

- 1. Mostly the market for Trazone intermediate 2H-[1,2,4] Triazolo [4,3-A] Pyridin-3-One.
- 2. 3,4-di hydroxy 5-nitro benzaldehyde The drug Entacapone is used for Parkinson's disease.

Trazodone sales are falling in Finland in 2023. According to the Finnish Medicines Agency, Trazodone sales fell by 13% in the first quarter of 2023, compared to the same period in 2022. This decline is likely due to a number of factors, including the rising availability of newer antidepressants, the growing awareness of the risks associated with Trazodone, and the rising cost of the drug.

According to the Finnish Statistics on Medicines 2023, the sales of entacapone in Finland in 2023 were 20,000 defined daily doses (DDD). This represents a decrease of 10% from the sales in 2022. Entacapone is a drug used to treat Parkinson's disease. It works by increasing the levels of dopamine in the brain. The sales of entacapone are expected to continue to decline in Finland in the



coming years, as the drug becomes more widely available as a generic. However, entacapone is still a popular drug for treating Parkinson's disease, and it is likely to remain a significant market for many more years.

Israel >

The bright spot as nintedanib sales are rising. Boehringer Ingelheim reported a strong performance, with net nintedanib sales rising by 10.5 per cent (currency-adjusted). The company also expects to present additional data from its pipeline throughout 2023, which could further boost nintedanib sales. Fermion OY is one of the leading clients of Ami Organics.

Vinylene carbonate- much ado about nothing

Vinylene carbonate (VC) is a colourless, liquid organic compound with the formula C3H2O3. It is the simplest unsaturated cyclic carbonic acid ester. Vinylene carbonate can also be thought of as the cyclic carbonate of the hypothetical (Z)-ethene-1,2-diol. The activated double bond in this five-membered oxygen-containing heterocycle makes the molecule a reactive monomer for homopolymerization and copolymerization and a dienophile in Diels-Alder reactions.

Vinylene carbonate has a variety of uses >

- As an electrolyte additive for lithium-ion batteries: VC promotes the
 formation of an insoluble film between the electrolyte and the negative
 electrode, which prevents the reduction of the electrolyte at the negative
 (graphite) electrode and contributes significantly to the long-term stability of
 the battery.
- 2. **As a solvent for organic and inorganic compounds:** VC is a highly polar solvent that is miscible with a wide range of solvents, including water, alcohols, ketones, and amines.
- As a monomer for the production of polymers: VC can be polymerized to form a variety of polymers with different properties, including elastomers, plastics, and fibres.
- 4. **As a chemical intermediate:** VC is used in the production of other chemicals, such as ethylene carbonate, propylene carbonate, and divinyl carbonate.
- VC is a safe and non-toxic compound, but it is flammable and can be harmful if inhaled or ingested. It is important to handle VC with care and to use it in a well-ventilated area.

Vinylene carbonate usage in a lithium-ion batteries is for the following characteristics: ▶

Vinylene carbonate (VC) is used in lithium-ion batteries as an electrolyte additive because it has a number of beneficial properties, including:

- It promotes the formation of a solid electrolyte interphase (SEI) on the negative electrode: The SEI is a thin layer of protective film that forms on the electrode surface during the first few cycles of the battery. It helps to prevent the electrolyte from reacting with the electrode material and degrading the battery's performance.
- 2. **It reduces the reactivity of the electrolyte:** The electrolyte in a lithium-ion battery is a flammable liquid that can be easily reduced by the negative electrode. VC helps to stabilize the electrolyte and prevent it from reacting with the electrode.
- It improves the conductivity of the electrolyte: The conductivity of the electrolyte is important for the performance of the battery. VC helps to increase the conductivity of the electrolyte and improve the battery's power output.
- 4. **It reduces the polarization of the negative electrode:** Polarization is a phenomenon that occurs when the voltage across an electrode is increased.



It can lead to a decrease in the battery's capacity and efficiency. VC helps to reduce the polarization of the negative electrode and improve the battery's performance.

Following are the disadvanatges of using VC in an electrolyte >

Vinylene carbonate (VC) is a widely used electrolyte additive in lithium-ion batteries, but it also has some disadvantages, including:

VC is flammable: VC is a colourless, flammable liquid with a low flash point. This means that it can easily catch fire if exposed to a spark or flame. This can be a safety hazard, especially in high-power applications.

VC can decompose at high temperatures: VC decomposes at high temperatures, releasing carbon monoxide and other harmful gases. This can be a safety hazard, especially in batteries that are exposed to high temperatures, such as those used in electric vehicles.

VC can increase the viscosity of the electrolyte: VC can increase the viscosity of the electrolyte, which can slow down the charging and discharging of the battery. This can lead to longer charging times and decreased battery performance.

VC can interact with other electrolyte additives: VC can interact with other electrolyte additives, such as ethylene carbonate (EC) and dimethyl carbonate (DMC). This can lead to the formation of precipitates, which can clog the battery and reduce its performance

VC is an integral part of LiPF6-based batteries but they are getting replaced by LiFSi ➤

LiFSi has several advantages over the traditional LiPF6 electrolyte, including:

- Higher ionic conductivity: LiFSi has a higher ionic conductivity than LiPF6, which means that it can transport lithium ions more easily. This can lead to faster charging and discharging speeds, as well as improved performance at high temperatures.
- Higher thermal stability: LiFSi is more thermally stable than LiPF6, which
 means that it can withstand higher temperatures without breaking down. This
 is important for batteries that are used in high-temperature environments,
 such as electric vehicles.
- 3. **Better cycling stability**: LiFSi batteries have better cycling stability than LiPF6 batteries, which means that they can retain their capacity for more cycles. This is important for batteries that are used in applications where they are cycled frequently, such as electric vehicles and power tools.
- 4. Less corrosive to aluminum: LiFSi is less corrosive to aluminum than LiPF6, which is important for batteries that use aluminum current collectors. This can help to improve the battery's lifespan and safety.

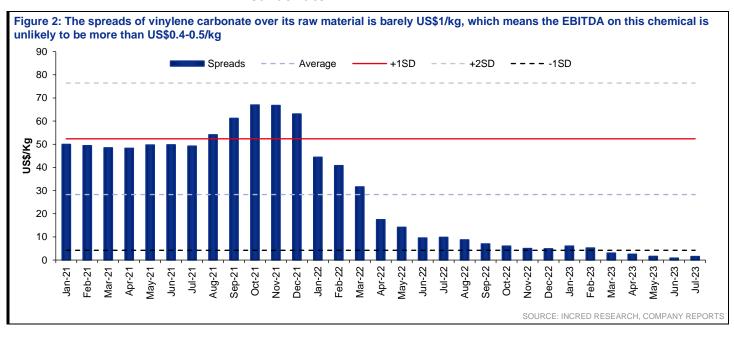
However, VC is not essential in LiFSi electrolyte-based batteries ➤

- VC (vinylene carbonate) is not essential in LiFSi batteries, but it can be beneficial in some cases. VC is a non-flammable, low-viscosity solvent that is compatible with LiFSi. It has a high ionic conductivity and can improve the electrochemical performance of LiFSi batteries. VC can also help to form a protective SEI layer on the electrodes, which can further improve the battery's performance.
- 2. However, some studies have shown that the addition of VC to LiFSi electrolytes can lead to increased electrolyte decomposition and capacity fading. This is likely due to the fact that VC is a strong nucleophile and can react with the LiFSi salt. As a result, the use of VC in LiFSi batteries should be carefully considered and the electrolyte composition should be optimized to minimize the negative effects of VC.



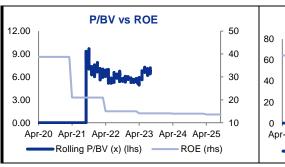
3. In the case of Tesla 4860 batteries, it is not yet known whether they will use VC. However, it is possible that they will, as VC has been shown to be beneficial in LiFSi batteries in some cases. It is also possible that Tesla will use a different solvent, such as DME (dimethoxyethane), which has also been shown to be compatible with LiFSi and can improve the battery performance

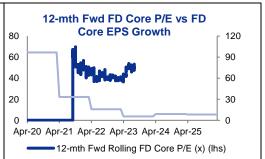
Huge overcapacity in China is eroding the prices of vinylene carbonate ➤





BY THE NUMBERS





(Rs mn)	Mar-22A	Mar-23A	Mar-24F	Mar-25F	Mar-26F
Total Net Revenues	5,201	6,167	7,092	7,802	9,362
Gross Profit	2,473	2,858	3,121	3,433	3,745
Operating EBITDA	1,052	1,226	1,313	1,450	1,587
Depreciation And Amortisation	(101)	(123)	(152)	(183)	(214)
Operating EBIT	951	1,103	1,161	1,267	1,373
Financial Income/(Expense)	(64)	(24)			
Pretax Income/(Loss) from Assoc.					
Non-Operating Income/(Expense)	28	43	14	14	14
Profit Before Tax (pre-EI)	915	1,122	1,175	1,281	1,387
Exceptional Items					
Pre-tax Profit	915	1,122	1,175	1,281	1,387
Taxation	(195)	(289)	(296)	(323)	(350)
Exceptional Income - post-tax					
Profit After Tax	719	833	879	958	1,038
Minority Interests					
Preferred Dividends					
FX Gain/(Loss) - post tax					
Other Adjustments - post-tax					
Net Profit	719	833	879	958	1,038
Recurring Net Profit	719	833	879	958	1,038
Fully Diluted Recurring Net Profit	719	833	879	958	1,038

Cash Flow					
(Rs mn)	Mar-22A	Mar-23A	Mar-24F	Mar-25F	Mar-26F
EBITDA	1,052	1,226	1,313	1,450	1,587
Cash Flow from Invt. & Assoc.					
Change In Working Capital	(915)	(443)	(231)	(230)	(507)
(Incr)/Decr in Total Provisions					
Other Non-Cash (Income)/Expense	(18)				
Other Operating Cashflow	76	43	14	14	14
Net Interest (Paid)/Received	(64)	(24)			
Tax Paid	(228)	(245)	(296)	(323)	(350)
Cashflow From Operations	(97)	557	801	911	745
Capex	(328)	(657)	(500)	(500)	(500)
Disposals Of FAs/subsidiaries		(181)			
Acq. Of Subsidiaries/investments					
Other Investing Cashflow	(897)	632			
Cash Flow From Investing	(1,225)	(205)	(500)	(500)	(500)
Debt Raised/(repaid)	(1,358)	21	(36)		
Proceeds From Issue Of Shares	3,000				
Shares Repurchased					
Dividends Paid		(109)	(250)	(250)	(250)
Preferred Dividends					
Other Financing Cashflow	(239)	(56)			
Cash Flow From Financing	1,403	(144)	(286)	(250)	(250)
Total Cash Generated	81	208	15	161	(5)
Free Cashflow To Equity	(2,680)	374	265	411	245
Free Cashflow To Firm	(1,258)	377	301	411	245

SOURCE: INCRED RESEARCH, COMPANY REPORTS

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BY THE NUMBERS...cont'd

Balance Sheet					
(Rs mn)	Mar-22A	Mar-23A	Mar-24F	Mar-25F	Mar-26F
Total Cash And Equivalents	996	587	1,031	1,192	1,187
Total Debtors	1,637	2,303	2,232	2,455	2,947
Inventories	1,122	1,192	1,530	1,682	2,019
Total Other Current Assets	761	620	620	620	620
Total Current Assets	4,515	4,701	5,413	5,950	6,772
Fixed Assets	1,808	2,473	2,820	3,137	3,423
Total Investments	17	17	17	17	17
Intangible Assets					
Total Other Non-Current Assets	205	479			
Total Non-current Assets	2,031	2,969	2,837	3,154	3,440
Short-term Debt	3	30			
Current Portion of Long-Term Debt					
Total Creditors	1,184	1,420	1,457	1,603	1,924
Other Current Liabilities	106	178	178	178	178
Total Current Liabilities	1,293	1,628	1,636	1,781	2,102
Total Long-term Debt	6	6			
Hybrid Debt - Debt Component					
Total Other Non-Current Liabilities					
Total Non-current Liabilities	6	6			
Total Provisions	67	95	95	95	95
Total Liabilities	1,366	1,730	1,731	1,876	2,197
Shareholders Equity	5,180	5,940	6,519	7,227	8,015
Minority Interests					
Total Equity	5,180	5,940	6,519	7,227	8,015

Key Ratios					
	Mar-22A	Mar-23A	Mar-24F	Mar-25F	Mar-26F
Revenue Growth	52.7%	18.6%	15.0%	10.0%	20.0%
Operating EBITDA Growth	31.2%	16.6%	7.1%	10.4%	9.5%
Operating EBITDA Margin	20.2%	19.9%	18.5%	18.6%	17.0%
Net Cash Per Share (Rs)	27.42	15.30	28.65	33.12	32.98
BVPS (Rs)	143.89	164.99	181.08	200.75	222.63
Gross Interest Cover	14.84	45.71			
Effective Tax Rate	21.3%	25.7%	25.2%	25.2%	25.2%
Net Dividend Payout Ratio					
Accounts Receivables Days	99.79	116.58	116.69	109.65	105.30
Inventory Days	115.41	127.59	125.04	134.17	120.26
Accounts Payables Days	135.69	143.65	132.23	127.84	114.58
ROIC (%)	26.0%	19.3%	15.9%	17.0%	16.8%
ROCE (%)	23.4%	19.5%	18.3%	18.2%	17.8%
Return On Average Assets	14.4%	12.0%	11.0%	11.0%	10.7%

SOURCE: INCRED RESEARCH, COMPANY REPORTS



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