

Dishman Carbogen Amcis

BUY

INDUSTRY PHARMA CMP (as on 22 Dec 2017) Rs 307 **Target Price** Rs 435 Nifty 10,493 33,940 Sensex **KEY STOCK DATA** Bloomberg DCAL IN No. of Shares (mn) 161 MCap (Rs bn) / (\$ mn) 49/773 6m avg traded value (Rs mn) **STOCK PERFORMANCE (%)** 52 Week high / low Rs 368/275 3M 12M 6M Absolute (%) (2.2)Relative (%) (9.5)**SHAREHOLDING PATTERN (%) Promoters** 61.4 FIs & Local MFs 11.2 **FPIs** 9.6

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Source : BSE

Public & Others

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17.8

On the fast track

One of the molecules from Dishman Carbogen Amcis' (DCAL) pipeline, crenolanib (disclosed by us in our IC note 'Highly potent'), has received fast track designation from the US FDA for the indication of relapsed or refractory (R/R) acute myeloid leukemia (AML). A drug program with Fast Track status is afforded greater access to the FDA for the purpose of expediting the drug's development, review, and potential approval. With this, crenolanib is in three expedited Phase III trials for the US market - two for AML and one for GIST.

Developments such as fast track designations reinforce our belief in the quality of DCAL's development pipeline. We believe that DCAL is steadily carving out a reputation for itself as a reliable partner for innovators to entrust even the most complex of projects to. With 8 to 10 products in late phase III and 12-15 in early phase III, the flow of lucrative commercial launches has just begun and 2-3 launches are likely annually.

We re-iterate our positive stance on DCAL with the company poised to supply APIs for several other potential commercial launches over the next 12-18 months. We expect this to not only drive further growth and profitability, but also reduce dependence on single blockbuster products (like niraparib), leading to lower earnings risk. Maintain BUY with a revised TP of Rs 435 (11x Dec-19E EV/EBITDA).

Crenolanib launch possible in FY20E: Crenolanib is being developed by a small company, Arog

Pharmaceuticals, in the US. It is currently undergoing clinical trials for several indications, (1) gastrointestinal stromal tumors (GIST), (2) acute myeloid leukaemia (both R/R and newly diagnosed) and, (3) glioma. The US FDA had previously granted fast track designation to crenolanib for the indication of GIST, indicative of the therapeutic potential of this product. Per the information on clinicaltrials.org (link), the phase III trial for GIST is scheduled to be completed by Aug-19, making a late FY20/early FY21 commercial launch possible. We have not considered the same in our estimates.

- Niraparib update: Niraparib has now been launched in the EU after marketing approval from the EC. Post commercial launch in the US in Apr-17, niraparib is likely to deliver sales of ~US\$ 120mn in CY17. Tesaro had peggged the global opportunity size of the current indication at US\$1bn. Tesaro's Dec-17 investor presentation outlines its further plans for niraparib, the highlights of which are on page 4 and 5 of this report.
- View and valuation: At CMP, DCAL is trading 9.1x FY19 EBITDA and 7.2x FY20E EBITDA, at ~25% discount to the sector average. Foresee 13% revenue CAGR and 36% earnings CAGR over FY1720E. Maintain BUY.

Financial Summary

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YE Mar (Rs bn)	FY17	FY18E	FY19E	FY20E
Net Sales	17,137	17,690	20,745	24,689
EBITDA	4,534	5,092	6,112	7,406
APAT	1,454	1,903	2,689	3,692
Adj. EPS (Rs/sh)	9.0	11.8	16.7	22.9
EV/EBITDA (x)	12.8	11.2	9.1	7.2
Adj. RoE (%)	11.6	12.8	15.2	17.2

Source: Company, HDFC sec Inst Research

HDFC securities Institutional Research is also available on Bloomberg HSLB <GO> & Thomson Reuters

Crenolanib is currently undergoing clinical trials for use in a variety of indications like Acute Myeloid Leukemia (AML), Gastro-intestinal Stromal Tumor (GIST) and Glioma

Crenolanib Besylate: Huge Opportunity

- Crenolanib, a next-gen tyrosine kinase inhibitor, is currently undergoing clinical trials for use in a variety of indications like Acute Myeloid Leukemia (AML), Gastro-intestinal Stromal Tumor (GIST) and Glioma.
- GIST: GIST is a disease in which abnormal cells form in the tissues of the gastrointestinal tract. Crenolanib is planned for use in the treatment of GIST with a specific mutation (D842V) in the PDGFRA gene. A Phase III trial (approximately 120 patients), aimed at finding out how safe and effective crenolanib is, compared with a placebo, in prolonging the amount of time patients avoid disease progression, has been initiated. Median overall survival is reported to be only 12.8 months in patients whose tumors bear the D842V mutation compared to 48-60 months in large series of imatinib-treated (current first-line) patients with other types of GIST mutations. The US FDA has granted fast-track designation to the drug for this indication, confirming crenolanib's potential to address this unmet medical need.

Expert Speak On FLT3 Inhibitors At Annual ASH Meeting (Picture Linked To Video



Prof. Mark Levis | ASH 2017 | Overview of FLT3 inhibitors in AML

Source: HDFC sec Inst Research

- AML: AML is a type of cancer in which the bone marrow makes abnormal myeloblasts (a type of white blood cell), red blood cells, or platelets and is lifethreatening due to its rapid progression and its 5-year survival of approximately 22% with current treatments. Crenolanib is being tried in FLT3-mutated AML. Arog has multiple clinical trials on going for this indication, including phase III trials for newly diagnosed FLT3 Mutated AML (vs Rydapt) and R/R AML (in combination with chemotherapy vs chemotherapy alone). Besides this, there are ongoing trials for combination therapies and other specific situations of AML.
- Crenolanib works much in the same way as midostaurin (a recently approved FLT3 inhibitor for treatment of AML). Evaluation of crenolanib's Phase II clinical trials for the treatment of newly diagnosed AML showed high tolerability, no significant adverse events and extremely high efficacy (76% complete remission after 1 cycle, 86% after 2 cycles), which compares very favourably to midostaurin (59% within 60 days of treatment start).

Expert Speak On Crenolanib At Annual ASH Meeting (Picture Linked To Video



Prof. Eunice Wang | ASH 2017 | Crenolanib and SC in young newly diagnosed FLT3 mutated AML



With a variety of indications being explored, this could be a significant opportunity for DISH. While it is too early for peak sales estimates, crenolanib could translate to a double-digit US\$mn product for DISH

- The US FDA recently awarded fast track designation to crenolanib for the indication of R/R AML, while the European Union has previously granted orphan drug status to crenolanib for the treatment of AML and soft tissue sarcoma. AML affects 1 in 10,000 people in the EU, soft tissue sarcoma affects 2.8 in 10,000. Orphan drug designation provides incentives designed to facilitate development, including protocol assistance, reduced fees for regulatory activities and up to 10 years of market exclusivity in the EU upon approval for the designated indication.
- Non-small cell lung cancer (NSCLC): Lung cancer itself is a prominent type of cancer and about 14% of all new cancers are lung cancers. There are two types of lung cancers; non-small cell lung cancer (~85% of total) and small cell lung cancer. In 2017, 225,000 new cases of lung cancer were reported in the US, extrapolating to ~190,000 new cases for NSCLC. Crenolanib is currently undergoing phase II clinical trials for the treatment of NSCLC.
- Glioma: Glioma is a type of tumour that starts in the brain or spine. It is called glioma because it arises from glial cells. They form 80% of all malignant brain tumours. There is currently no cure, with the first-line therapy being radiotherapy and chemotherapy. The global market for glioma is estimated to be US\$ 700mn currently. A phase II proof of concept study to investigate crenolanib monotherapy in patients with recurrent/refractory glioblastoma with PDGFRA gene amplification is ongoing. Most drugs are at this stage of development, with none in phase III. Hence, crenolanib stands a good chance of being the first to market for treatment of this cancer.
- Other clinical trials underway for crenolanib include Phase II for Glioblastoma (the most aggressive form of glioma with around 12,000 new cases every year) and Phase I for Esophageal cancer.
- With a variety of indications being explored, this could turn out to be a significant opportunity for DCAL. While it is too early for peak sales estimates, we believe that crenolanib could translate to a double-digit USSmn product for DCAL.

Indication	No of new cases	Survival rate	Annual cost (US\$)	Existing therapies	In pipeline
GIST	5,000- 6,000	80% five years	25,000-75,000	Gleevec (primary), Sutent (secondary) and Stivarga (tertiary)	Nilotinib, Masitinib, Crenolanib
AML	20,000- 25,000	27% five years	25,000-60,000	First line - 7+3 chemotherapy Regimen. Rydapt (for FLT3 +ve AML)	Gilteritinib, Quizartinib, Crenolanib
Glioma	25,000	20% two years	80,000-100,000	Temodar, Avastin	Crenolanib
NSCLC	190,000- 200,000	Varies by stage, ranging from 92% for Stage IA to less than 1% for Stage IVB.	N/A	Vary according to stage	Many



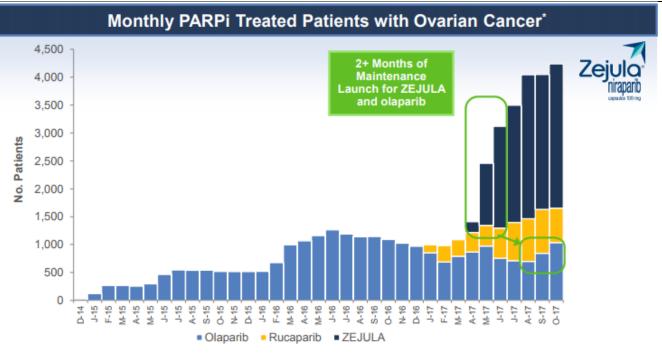
Niraparib: A Long Way To Go

- Niraparib has begun its commercial journey with a successful launch in the US market, already capturing 65% market share. However, this is only the beginning. Tesaro is determind to expand niraparib's indications beyond the current maintenance therapy setting and into the first-line of ovarian cancer treatment. This opportunity has been pegged at US\$ 4bn by the company.
- Another key driver of ovarian cancer revenues as highlighted in Tesaro's Dec-17 presentation is the potential for increase in duration of maintenance therapy from ~9 months currently to 15 months+.
- Further, clinical trials are being done for a variety of indications outside ovarian cancer. The furthest along would be the trials for triple negative breast cancer and lung cancer, which are Tesaro's focus after ovarian cancer. Tesaro has pegged the total opportunity for niraparib at US\$ 8bn post expansion into these two indications as well.
- At peak sales of US\$ 5bn, we estimate that niraparib could fetch as much as Rs 11/sh in EPS (~120% of FY17 EPS) for DCAL, outlining the signficance of the drug.

Competitive dynamics:

Despite indication expansion for olaparib into maintenance therapy earlier this year, it has been unable to gain market share owing to niraparib's higher efficacy. Rucaparib too has now been afforded a label expansion into maintenance therapy regardless of BRCA mutation, which would be a key monitorable going forward. We believe that niraparib's strong efficacy profile will continue to secure its market *leadership*

Niraparib Has Achieved Rapid Uptake And Leading Market Share





Current phase III trials include PRIMA (broaden maintenance indication) and FIRST (expand 1L indication in combination with another Tesaro novel product, TSR-042)

At peak sales of US\$ 5bn, we estimate that niraparib could fetch as much as Rs 11/sh in EPS (~120% of FY17 EPS) for DCAL, outlining the signficance of the drug.

Three Strategic Imperatives To Maximize Value Of Niraparib In Ovarian Cancer



Establish Broad Leadership Position in First-line Treatment of OvCa Through Successful Registrations from PRIMA, and in Combination Use

> PRIMA (Ph3)

 Broaden maintenance indication

> OVARIO (Ph2)

 Generate rapid proof-ofconcept in combination with bevacizumab

> FIRST (Ph3)

 Expand 1L indication in combination with TSR-042 (± Bev) 2

Strengthen Leadership Position in Recurrent Platinum-responsive Ovarian Cancer

> QUADRA (Ph2)

- Broaden indication to include treatment of 4L+
- Evaluate all comers and biomarker/clinical marker subset
- ISTs to build on niraparib backbone with combination regimen
 - AVANOVA: Chemo free P2 Nir and Nir+Bev
 - · Others in planning

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Advance Standard of Care in Platinum-resistant Recurrent Ovarian Cancer (PROC)

> TOPACIO (Ph1/2)

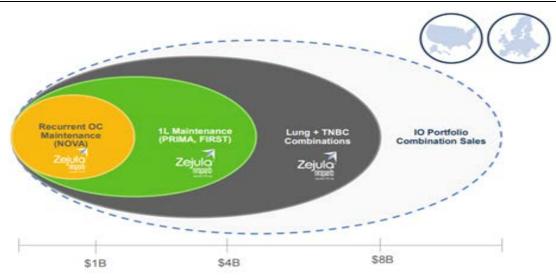
· Build on Phase 1/2 signal

> OPAL (Ph1/2)

- Signal seeking to identify promising breakthrough combinations
- Prioritize triple combination (Nir+Bev+TSR-042)

Source: HDFC sec Inst Research

Large Development Opportunities Beyond Current Indication





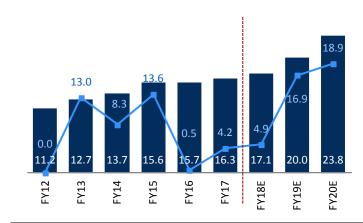
The start of commercial launches from DISH's deep pipeline will drive top-line growth over FY17-20E

With commercial manufacturing for high volume drugs like Niraparib done in India, commercial launches will drive growth in this segment

Dishman Carbogen In Charts

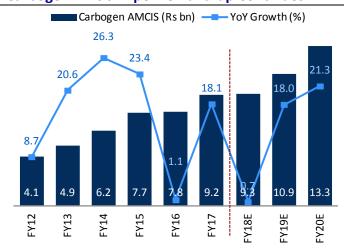
Revenue: 14% CAGR Over FY17-20E





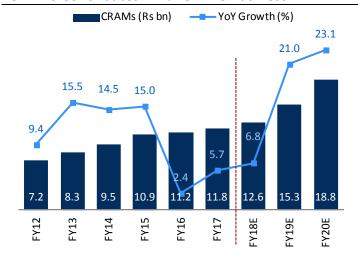
Source: Company, HDFC sec Inst Research

Carbogen Amcis: Pipeline Build-up Continues



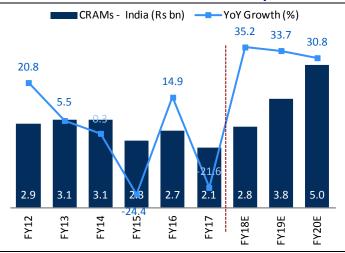
Source: Company, HDFC sec Inst Research

CRAMS Contributes ~72% Of The Business



Source: Company, HDFC sec Inst Research

CRAMS India: Commercial Launches Key

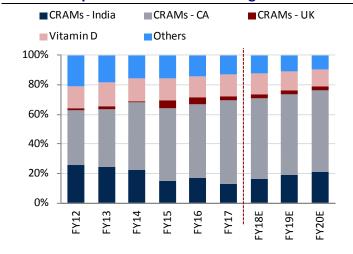


With rising contribution from CRAMs, profitability is likely to improve.

High employee costs are a part of the business of DISH, with a requirement of many highly qualified scientists.
With a base built in Carbogen Amcis, we expect the faster revenue growth to lead to operating leverage for DISH

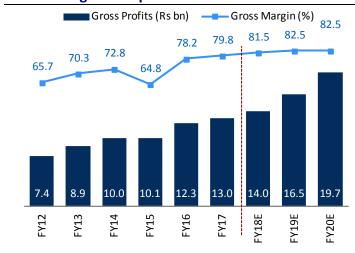
Margin expansion will also be driven by commercial launches like Niraparib, which are very high margin products

Revenue Split: CRAMS Pie Increasing



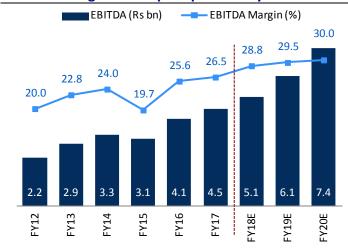
Source: Company, HDFC sec Inst Research

Gross Margin To Expand



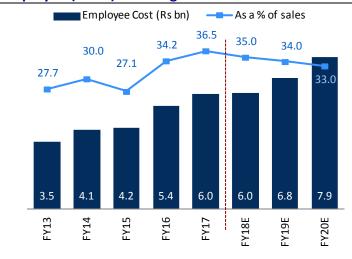
Source: Company, HDFC sec Inst Research

EBITDA Margin: ~400bps Expansion By FY20E



Source: Company, HDFC sec Inst Research

Employee (Fixed) Costs Significant





Foresee ~36% earnings CAGR over FY17-20E, driven by highly profitable commercial launches

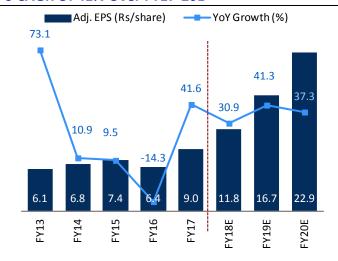
DISH sees an asset turnover of 1.25x to be the maximum realistic target, considering the nature of the business

FCF generation will improve going forward, with lucrative commercial launches and prudent capex spending. Net debt levels are under control

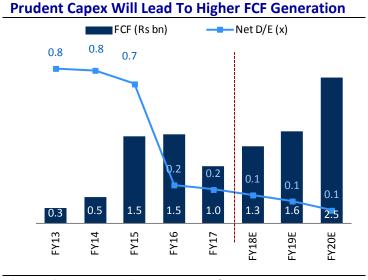
High fixed costs and a low asset turnover have impacted the return ratios. However, we expect these to see an upward trajectory going forward

The return rations are also negatively skewed on account of the high intangible additions from FY16

EPS CAGR Of 41% Over FY17-20E

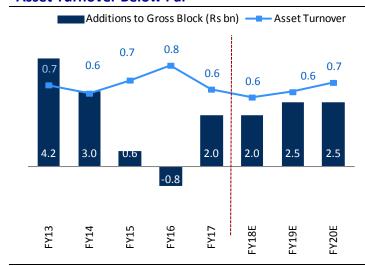


Source: Company, HDFC sec Inst Research



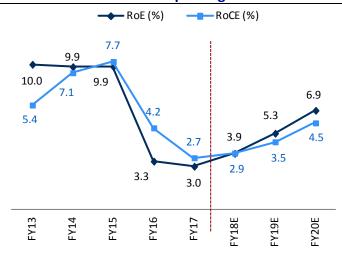
Source: Company, HDFC sec Inst Research

Asset Turnover Below Par



Source: Company, HDFC sec Inst Research

Return Ratios: Poor But Improving



^{*}Gross block figures for FY15 onwards are adjusted similarly to the table on page 21.

^{**}Gross block numbers from FY16 onwards are as per IND AS.



Peer Valuations

	Mcap CMP	СМР	D		Doco		Adj EPS	(Rs/sh)			EV/EBIT	TDA (x)			RoE	(%)	
	(Rs bn)	(Rs/sh)	Reco	TP	FY17	FY18E	FY19E	FY20E	FY17	FY18E	FY19E	FY20E	FY17	FY18E	FY19E	FY20E	
Sun Pharma	1,276	531	NEU	485	26.0	14.6	20.9	28.5	13.1	22.5	17.2	13.4	17.9	9.4	12.5	15.2	
Cipla	483	601	NEU	630	12.5	21.2	27.6	35.2	20.6	16.3	13.3	11.0	8.4	12.8	14.7	16.3	
Cadila Healthcare	434	423	BUY	540	14.5	12.6	19.2	25.9	25.2	18.8	16.3	13.5	23.5	16.9	21.6	24.0	
Aurobindo Pharma	399	681	NEU	800	39.3	37.7	46.7	53.7	12.3	10.6	10.0	8.9	27.6	21.3	21.5	20.3	
Dr Reddy's Labs	396	2,333	NEU	2,400	72.7	71.0	117.5	161.2	17.0	16.3	11.9	9.1	9.5	9.2	14.0	16.9	
Lupin	392	872	BUY	1,125	56.9	36.7	46.6	66.0	10.2	14.2	11.7	8.8	20.9	11.8	13.6	17.0	
Divi's Labs	289	1,090	NEU	1,100	39.9	35.9	46.5	53.1	20.0	22.7	17.8	15.6	22.0	16.8	19.4	19.8	
Alkem Laboratories	258	2,155	BUY	2,100	74.6	65.9	87.6	107.4	26.2	24.6	19.2	15.8	21.9	16.5	19.1	20.1	
Torrent Pharma	231	1,366	BUY	1,480	51.2	46.9	60.7	79.0	17.9	18.6	15.3	12.4	22.1	17.8	20.6	22.7	
Glenmark	160	568	BUY	1,000	29.6	25.1	41.9	54.6	9.6	10.2	8.5	6.9	18.1	13.1	18.4	20.0	
Jubilant Life Sciences	122	769	BUY	850	37.0	40.7	54.6	69.6	11.9	10.4	8.6	7.3	18.0	17.4	19.7	20.9	
Alembic Pharma	100	529	NEU	555	21.4	21.1	24.7	31.1	16.0	16.3	13.2	10.6	23.0	19.5	19.6	21.0	
Strides Shasun	75	837	BUY	1,200	34.0	35.0	51.6	67.5	14.3	13.6	11.2	8.8	13.1	11.7	16.0	18.2	
Dishman Carbogen Amcis	49	307	BUY	435	9.0	11.8	16.7	22.9	12.8	11.2	9.1	7.2	11.6	12.8	15.2	17.2	
Granules India	34	132	BUY	170	7.5	6.9	9.0	12.2	12.9	12.6	9.5	8.0	21.0	15.5	16.0	19.1	



Income Statement (Consolidated)

Year ending March (Rs mn)	FY16	FY17	FY18E	FY19E	FY20E
Net Revenues	16,017	17,137	17,690	20,745	24,689
Growth (%)	0.8	7.0	3.2	17.3	19.0
Material Expenses	3,419	3,293	3,171	3,508	4,172
Employee Expenses	5,355	5,960	5,999	6,815	7,867
Selling and Administration Expenses	1,726	1,814	1,971	2,405	2,980
Other Operating Expenses	1,413	1,537	1,457	1,904	2,265
EBITDA	4,103	4,534	5,092	6,112	7,406
EBITDA Margin (%)	25.6	26.5	28.8	29.5	30.0
EBITDA Growth (%)	31.2	10.5	12.3	20.0	21.2
Depreciation	1,975	2,135	2,241	2,386	2,479
EBIT	2,128	2,399	2,851	3,726	4,927
Other Income (Including EO Items)	265	261	270	350	450
Interest	944	490	440	367	319
РВТ	1,449	2,170	2,681	3,709	5,058
Tax (Incl Deferred)	421	707	777	1,020	1,366
RPAT	1,028	1,463	1,903	2,689	3,692
Minority Interest	(1)	(9)	-	-	-
APAT	1,027	1,454	1,903	2,689	3,692
APAT Growth (%)	-14.3	41.6	30.9	41.3	37.3
Adjusted EPS (Rs)	6.4	9.0	11.8	16.7	22.9

Source: Company, HDFC sec Inst Research

Balance Sheet (Consolidated)

Year ending March (Rs mn)	FY16	FY17	FY18E	FY19E	FY20E
SOURCES OF FUNDS					
Share Capital - Equity	161	161	161	161	161
Reserves	48,853	47,979	49,592	51,992	55,298
Total Shareholders Funds	49,014	48,140	49,753	52,153	55,459
Long Term Debt	5,126	4,601	4,101	3,601	3,101
Short Term Debt	5,327	4,790	5,250	4,500	4,750
Total Debt	10,453	9,391	9,351	8,101	7,851
Net Deferred Taxes	818	803	150	350	450
Other Non-current Liabilities & Provns	2,474	2,263	2,299	2,549	2,799
TOTAL SOURCES OF FUNDS	62,759	60,597	61,553	63,153	66,559
APPLICATION OF FUNDS					
Net Block	51,450	48,473	47,994	48,108	48,129
CWIP	1,330	1,329	1,100	950	800
Investments	53	46	46	46	46
Other Non-current Assets	1,815	2,169	2,200	2,500	2,825
Total Non-current Assets	54,648	52,017	51,340	51,604	51,800
Cash & Equivalents	1,043	1,270	2,344	2,388	4,415
Inventories	3,399	4,266	4,475	5,234	6,224
Debtors	3,153	2,856	2,996	3,503	4,166
Other Current Assets	5,349	5,335	5,371	5,854	6,407
Total Current Assets	11,901	12,457	12,842	14,590	16,797
Creditors	1,144	856	825	912	1,085
Other Current Liabilities & Provns	3,690	4,290	4,148	4,518	5,369
Total Current Liabilities	4,834	5,147	4,973	5,430	6,454
Net Current Assets	7,067	7,310	7,869	9,160	10,343
TOTAL APPLICATION OF FUNDS	62,759	60,596	61,553	63,153	66,558



Cash Flow

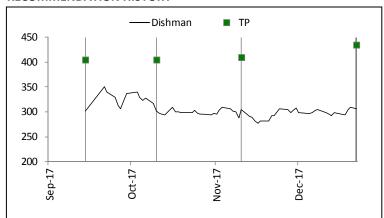
Casiiiioii					
Year ending March (Rs mn)	FY16	FY17	FY18E	FY19E	FY20E
Reported PBT	2,334	2,170	2,681	3,709	5,058
Non-operating & EO items	(74)	(15)	(653)	200	100
Interest net	846	229	170	17	(131)
Depreciation	1,091	2,135	2,241	2,386	2,479
Working Capital Change	(835)	(807)	(554)	(1,341)	(1,258)
Tax Paid	(575)	(707)	(777)	(1,020)	(1,366)
OPERATING CASH FLOW (a)	2,786	3,005	3,108	3,951	4,882
Capex	(1,239)	(2,008)	(1,771)	(2,350)	(2,350)
Free cash flow (FCF)	1,548	997	1,336	1,601	2,532
Investments	-	41	-	-	-
Non-operating Income	(290)	1,007	270	350	450
INVESTING CASH FLOW (b)	(1,529)	(960)	(1,501)	(2,000)	(1,900)
Debt Issuance/(Repaid)	101	(1,062)	(40)	(1,250)	(250)
Interest Expenses	(720)	(490)	(440)	(367)	(319)
FCFE	639	493	1,126	334	2,413
Dividend	(323)	(232)	(290)	(290)	(386)
Others	(66)	-	238	-	-
FINANCING CASH FLOW (c)	(1,007)	(1,784)	(532)	(1,906)	(955)
NET CASH FLOW (a+b+c)	251	262	1,074	44	2,027
EO Items, Others	-	-	-	-	-
Closing Cash & Equivalents	613	874	1,948	1,992	4,019
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Source: Company, HDFC sec Inst Research

Key Ratios

key katios					
	FY16	FY17	FY18E	FY19E	FY20E
PROFITABILITY (%)					
GPM	78.2	79.8	81.5	82.5	82.5
EBITDA Margin	26.2	27.7	29.7	30.5	31.1
APAT Margin	6.6	8.9	11.1	13.4	15.5
Adj. RoE	N/A	11.6	12.8	15.2	17.2
Adj. RoIC (or Core RoCE)	N/A	8.1	8.9	11.1	13.6
Adj. RoCE	N/A	7.7	8.3	10.1	12.0
EFFICIENCY					
Tax Rate (%)	29.1	32.6	29.0	27.5	27.0
Fixed Asset Turnover (x)	0.3	0.3	0.3	0.3	0.3
Inventory (days)	79.1	95.3	95.3	95.3	95.3
Debtors (days)	73.4	63.8	63.8	63.8	63.8
Other Current Assets (days)	98.3	97.8	<i>85.2</i>	77.4	68.9
Payables (days)	26.6	19.1	17.6	16.6	16.6
Other Current Liab & Provns (days)	84.0	91.6	84.1	<i>79.5</i>	79.5
Cash Conversion Cycle (days)	140.3	146.1	142.6	140.3	131.8
Debt/EBITDA (x)	2.5	2.1	1.8	1.3	1.1
Net D/E (x)	0.2	0.2	0.1	0.1	0.1
Interest Coverage (x)	2.5	5.4	7.1	11.1	16.9
PER SHARE DATA (Rs)					
EPS	6.4	9.0	11.8	16.7	22.9
Dividend	1.0	1.2	1.5	1.5	2.0
Book Value	303.7	298.3	308.3	323.1	343.6
VALUATION					
P/E (x)	48.3	34.1	26.1	18.5	13.4
P/BV (x)	1.0	1.0	1.0	1.0	0.9
EV/EBITDA (x)	14.5	12.8	11.2	9.1	7.2
EV/Revenues (x)	3.8	3.6	3.3	2.8	2.2
OCF/EV (%)	4.7	5.2	5.4	7.1	9.1
FCF/EV (%)	2.6	1.7	2.3	2.9	4.7
FCFE/Mkt Cap (%)	1.3	1.0	2.3	0.7	4.9
Dividend Yield (%)	0.3	0.4	0.5	0.5	0.6

RECOMMENDATION HISTORY



Date	CMP	Reco	Target
14-Sep-17	301	BUY	405
10-Oct-17	317	BUY	405
11-Nov-17	306	BUY	410
26-Dec-17	307	BUY	435

Rating Definitions

BUY : Where the stock is expected to deliver more than 10% returns over the next 12 month period NEUTRAL : Where the stock is expected to deliver (-)10% to 10% returns over the next 12 month period : Where the stock is expected to deliver less than (-)10% returns over the next 12 month period



Disclosure:

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