

BSE SENSEX 77,379 S&P CNX 23,432



Bloomberg	BIOS IN
Equity Shares (m)	1201
M.Cap.(INRb)/(USDb)	433.4 / 5
52-Week Range (INR)	396 / 244
1, 6, 12 Rel. Per (%)	3/5/20
12M Avg Val (INR M)	2032

Financials & Valuations (INR b)

Y/E March	FY25E	FY26E	FY27E
Sales	148.1	167.2	195.3
EBITDA	29.8	35.5	44.0
Adjusted PAT	2.3	5.6	11.6
EBIT Margin (%)	9.0	10.7	13.2
Cons. Adj EPS (INR)	2.0	4.7	9.6
EPS Gr. (%)	8.3	140.0	105.6
BV/Sh. (INR)	170.8	174.1	180.9

Ratios

Net D-E	0.8	0.7	0.7
RoE (%)	1.2	2.7	5.4
RoCE (%)	2.6	3.5	4.8
Payout (%)	29.3	29.3	29.3

Valuation

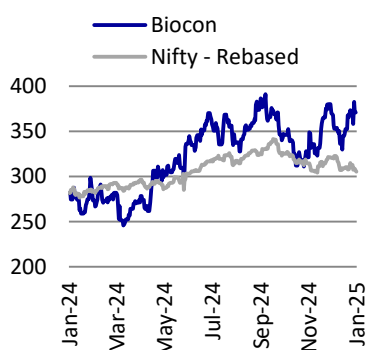
P/E (x)	184.3	76.8	37.4
EV/EBITDA (x)	18.4	15.4	12.5
Div. Yield (%)	0.6	0.3	0.7
FCF Yield (%)	3.8	5.5	7.9
EV/Sales (x)	3.7	3.3	2.8

Shareholding pattern (%)

As On	Sep-24	Jun-24	Sep-23
Promoter	60.6	60.6	60.6
DII	14.4	14.3	14.1
FII	6.2	6.2	8.4
Others	18.8	18.9	16.9

FII Includes depository receipts

Stock's performance (one-year)



CMP: INR360 TP: INR430 (+20%) Upgrade to BUY

'VAI' status for Malaysian site provides regulatory boost

B-Aspart – Potential product from the Malaysian site

- Biocon (BIOS) has received 'Voluntary Action Indicated' (VAI) status for its Malaysian site.
- With this, BIOS now has all critical sites for biosimilars under USFDA compliance, improving its business prospects in the US market.
- Regulatory compliance at the Malaysian site paves the way for commercial opportunities for B-Aspart. We believe the contractual cycle will pose a limited hurdle, as there is currently no biosimilar competition for this product.
- BIOS has experienced a significant earnings decline over the past two years (a 50% compounded decline over FY22-24), led by a lack of potential approvals for the US market and increased financial leverage.
- BIOS has implemented considerable remediation measures to overcome regulatory issues over the past two years. With compliance in place for the Biocon Park/Malaysian site, we expect product approvals/launches to boost the company's growth outlook over the next 2-3 years. We expect a 21% EBITDA CAGR over FY25-27. We re-rate the biologics business to 22x 12M forward EV/EBITDA (from 18x earlier) to factor in regulatory compliance. Accordingly, we arrive at an SOTP-based TP of INR430 (22x EV/EBITDA for the biologics business, 53% stake in Syngene, 14x EV/EBITDA for the generics business). Upgrade to BUY.

VAI classification for Malaysian site

- BIOS filed a Biologic License Application (BLA) for B-Aspart for the USFDA market from its Malaysian site in mid-CY20.
- The Malaysia site inspection was classified as Official Action Indicated (OAI) in Oct'23. The company also received a Complete Response Letter (CRL) for B-Aspart in Oct'23. Interestingly, the CRL did not cite scientific issues with this product.
- With the VAI now in place at the Malaysian site and the CRL containing very limited product-specific queries, it implies that the product approval was stuck due to manufacturing site compliance issues.
- The US market size for this product is about USD800m. Timely approval/biosimilar acceptance by the doctor community/patients remain critical to the product's prospects. Potential sales for BIOS from this product can be at least USD80-100m.

Supply constraints in the US further boost the outlook for B-Aspart

- Currently, insulin is in short supply in US markets. This is partly due to Novo-Nordisk building/allocating manufacturing capacity toward GLP-1, as these drugs (Ozempic/Vegovy) have posted a strong CAGR of 60% over CY19-24.
- Despite stable demand, Insulin Aspart has witnessed an 8% compounded decline over CY19-24. Interestingly, there has been a 19% YoY sales growth over the past 12M.

BIOS could become an early entrant for B-Aspart in the US market

- Currently, no biosimilar has been approved for Insulin Aspart. Apart from BIOS, two other companies have pending approvals from USFDA.
- Another competitor (Sanofi) has a product in Phase 1 clinical trials.

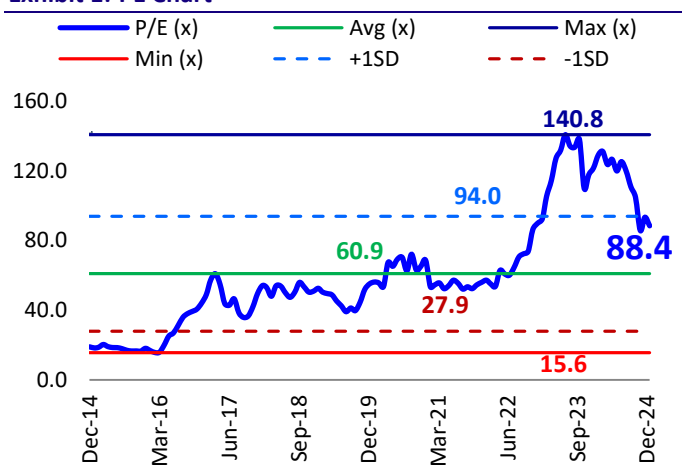
Strong progress in regulatory compliance across sites for biologics

- Over the past six months, BIOS has achieved significant regulatory milestones, despite multiple observations issued by the USFDA at its sites (drug substance/drug product manufacturing plants, analytical QC lab, microbiology lab at Biocon Park, and the Malaysian site).
- In Nov'24, it received the VAI classification at its Biocon Park site. Subsequently, it received approval for b-Ustekinumab in Dec'24.
- The recent VAI classification at the Malaysian site reinforces the company's efforts toward compliance, providing improved visibility for commercial success.

Upgrade to BUY

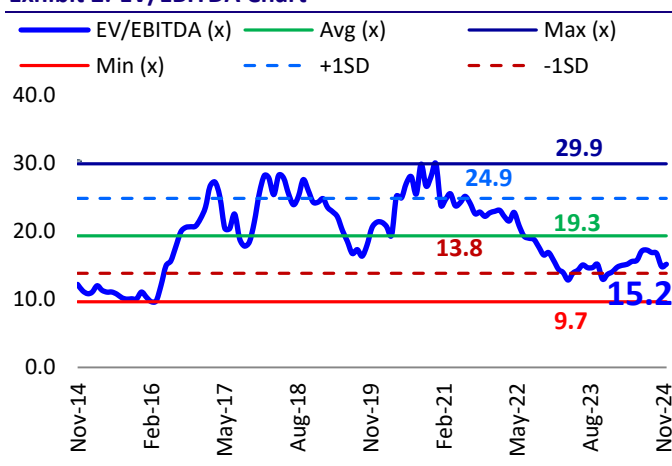
- Delayed compliance at the Biocon Park/Malaysian site and increased debt (due to the Viartis deal) led to a significant earnings decline for BIOS over the past two years.
- Compliance at Biocon Park also provides potential opportunities for BIOS from Liraglutide.
- Additionally, the Malaysian site enhances the scope for broadening BIOS's biosimilar offerings in the US market.
- Overall, we expect a 16% CAGR in biologics sales over FY25-27.
- On an overall basis, we expect 21% EBITDA CAGR over FY25-27. Considering the efforts toward compliance and potential business from upcoming products, we increase the EV/EBITDA multiple for the biologics business to 22x on a 12M forward basis. We further add 53% stake of Syngene and value the generics business at 14x EV/EBITDA to arrive at an SOTP-based TP of INR430.
- The timely approval for B-Aspart can provide further potential upside to biologics sales over FY25-27. Upgrade to BUY.

Exhibit 1: PE Chart



Source: Company, MOFSL, Bloomberg

Exhibit 2: EV/EBITDA Chart



Source: Company, MOFSL, Bloomberg

B-Aspart – Potential opportunity from Malaysian site

- BIOS's Malaysian site received an OAI classification from the USFDA in Oct'22 resulting in delays for product approvals from this site, including B-Aspart. CRL in Oct'23 further pushed B-Aspart for BIOS
- However, the recent VAI classification for the Sep'24 inspection clears the pathway for manufacturing plant compliance for B-Aspart.
- Interestingly, the shift of production capacity toward GLP-1 products by existing manufacturers (primarily innovators such as Novo Nordisk) has led to supply constraints for Insulin Aspart.
- Apart from BIOS, two other companies have approvals pending from the USFDA for B-Aspart.
- We expect potential opportunities for BIOS from B-Aspart to range between USD80 and 100m, subject to timely approval.

Improved compliance to enhance prospects in the US market

- BIOS filed for B-Aspart from the Malaysian site in mid-CY20, which triggered the Pre-Approval Inspection (PAI) of the site.
- Following this, BIOS's Malaysian site was inspected (PAI) in Aug'22. BIOS completed its comprehensive Corrective and Preventive Action (CAPA) plan in Feb'23, implementing remediation measures to address the issues highlighted in the Form 483 issued in Aug'22.
- However, BIOS received a Complete Response Letter (CRL) for its BLA of B-Aspart in Oct'23. Interestingly, the CRL did not cite any scientific issues with this product.

Exhibit 3: USFDA history of Biocon

Company name	City	Inspection End Date	Classification
Biocon Biologics	Johor, Malaysia	Sep-24	VAI
Biocon Biologics	Bengaluru	Jul-24	VAI
Biocon Limited	Paravada	Jun-24	VAI
Biocon Biologics	Electronics City, Bengaluru	Feb-24	VAI
Biocon Pharma	Bengaluru	Jun-23	NAI
Biocon Limited	Sangareddy	May-23	NAI
Biocon Biologics	Johor, Malaysia	Aug-22	OAI
Biocon Biologics	Bengaluru	Aug-22	Form 483 with 11 observations
Biocon Generics	Cranbury	Feb-22	VAI
Biocon Limited	Bangalore	Feb-20	VAI

Source: MOFSL, USFDA

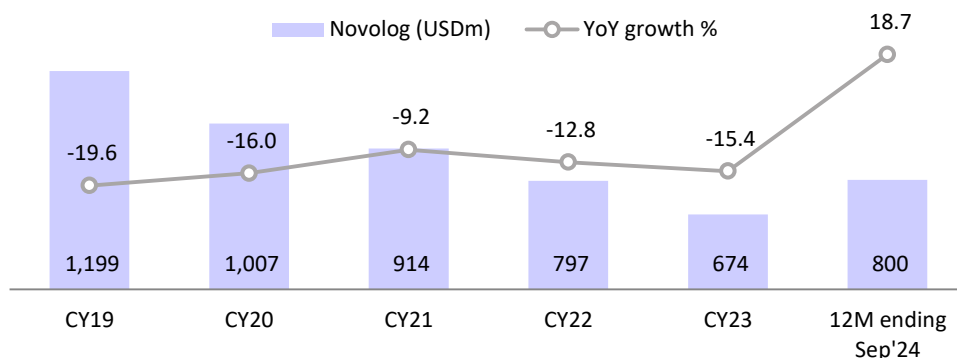
- With VAI classification in place for the Malaysian site, the scope of approval has considerably improved for B-Aspart.

Robust market size for Novolog in the US

- Novo Nordisk launched Novolog (Aspart) in Aug 2000.
- It has achieved USD800m sales from this product over the past 12M, clocking a 19% YoY growth. This was after a downtrend over CY19-23.
- Insulin Aspart is used to treat type 1 diabetes (a condition in which the body does not produce insulin and, therefore, cannot control the amount of sugar in the blood) in both adults and children.
- This is the only fast-acting insulin approved in the US market, while other insulins, such as Insulin Glargine, are slow-acting drugs.

- BIOS’s potential sales from this product could range at least between USD80 and 100m, subject to timely approval.

Exhibit 4: 19% YoY growth in Novolog sales over the past 12M

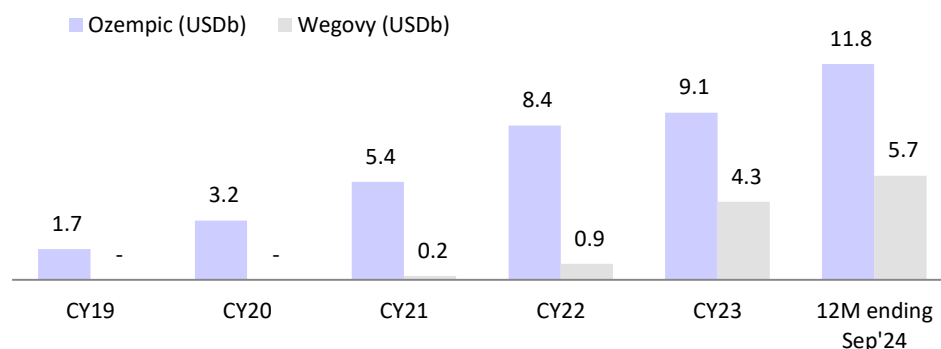


Source: Company, MOFSL

Shift toward GLP-1 leading to a shortage of Insulin Aspart supply

- Currently, Insulin Aspart is in shortage in US markets due to a shift of production capacities toward other potential drugs, such as Ozempic/Wegovy.
- The sharp increase in demand for Ozempic/Wegovy has led Innovator (Novo Nordisk) to re-prioritize its manufacturing capacities.
- Wegovy is the first USFDA-approved weight management medicine that also reduces the risk of major cardiovascular events. Interestingly, Ozempic is also often prescribed off-label for weight loss.

Exhibit 5: GLP-1 drugs posted a 60% CAGR over CY19-24



Source: Company, MOFSL

- Novo Nordisk’s GLP-1 products witnessed a strong 60% CAGR over CY19-24. Insulin Aspart witnessed an 8% compounded decline in sales over the same period.
- Despite this, the demand for the drug has remained stable, providing BIOS with an opportunity to capture market share for the product.

Early entrant advantage potential for BIOS

- BIOS filed for B-Aspart in the US market in mid-CY20.
- Currently, no biosimilars are approved for Insulin Aspart. Apart from BIOS, two other companies have pending approvals from the USFDA.
- Another competitor (Sanofi) is under Phase 1 clinical trials.

Exhibit 6: Three players awaiting approval for B-Aspart

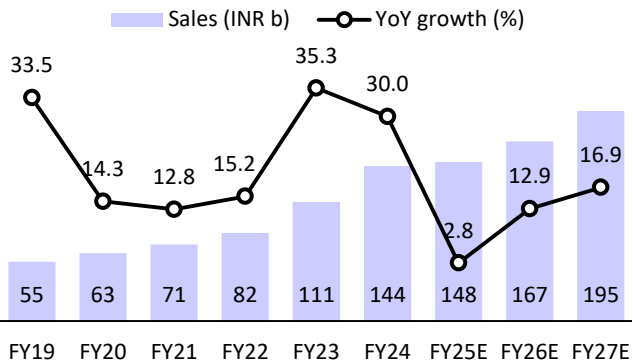
Product	Company	Biosimilar Name	USFDA status/Approval date	Market size USDm
Aspart	Novonordisk	NovoLog	Originator	800
	Gan & Lee Pharma/Sandoz Inc.	Rapilin	Pending approval	
	Amphastar Pharma	AMP-004	Pending approval	
	Biocon	MYL-1601D	Pending approval	
	Sanofi	SAR341402	Phase 1 complete	

Source: Company, MOFSL, Cardinal Health, USFDA

- Stable demand and supply constraints create a favorable outlook for BIOS in the US market. If BIOS receives timely approval, it could gain a first-mover advantage and capture considerable market share in the US.
- Currently, we expect a 16% sales CAGR in biologics over FY25-27. Timely approval for B-Aspart could provide additional upside to biologics sales during this period.

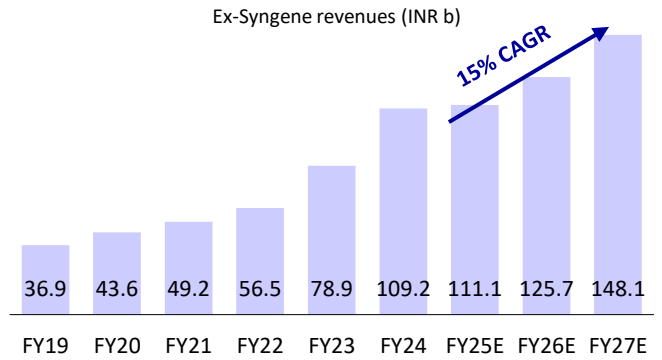
Story in charts

Exhibit 7: Expect revenue CAGR of ~15% over FY25-27



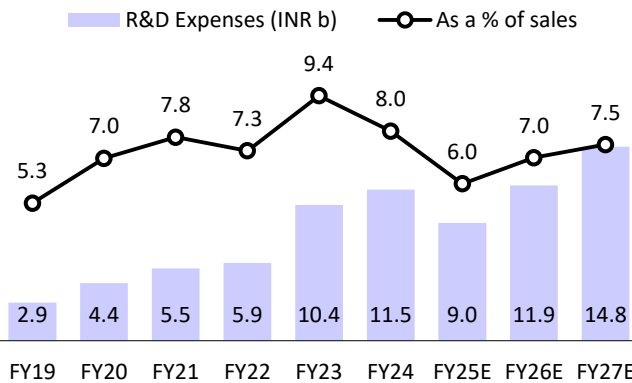
Source: Company, MOFSL

Exhibit 8: New launches/ramp-up to drive ex-Syngene revenue



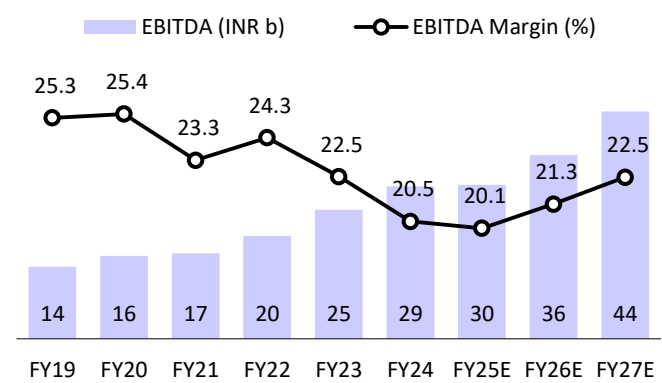
Source: Company, MOFSL

Exhibit 9: R&D spend to grow 150bp as % of sales in FY25-27



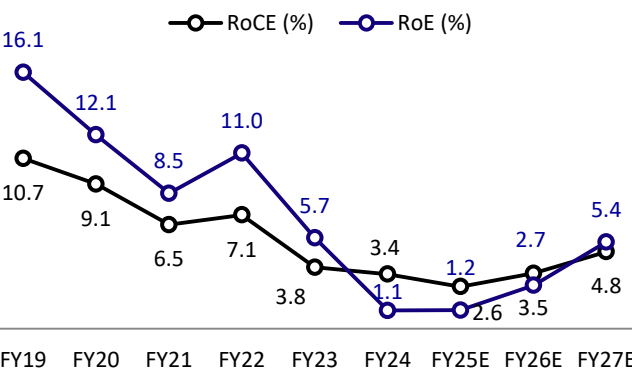
Source: Company, MOFSL

Exhibit 10: EBITDA margin to expand over FY25-27



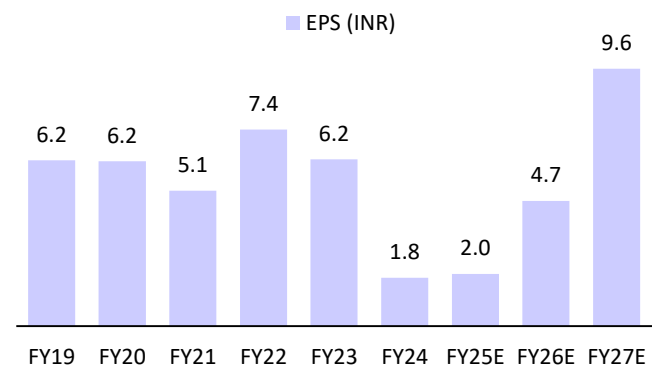
Source: Company, MOFSL

Exhibit 11: ROE at inflexion point



Source: Company, MOFSL

Exhibit 12: Expect EPS to jump 2.2x over FY25-27



Source: Company, MOFSL

Financials and valuations

Income Statement (Consolidated)									(INR m)
Y/E March	FY19	FY20	FY21	FY22	FY23	FY24	FY25E	FY26E	FY27E
Net Income	55,144	63,005	71,058	81,845	1,10,774	1,44,051	1,48,077	1,67,162	1,95,343
Change (%)	33.5	14.3	12.8	15.2	35.3	30.0	2.8	12.9	16.9
Total Expenditure	41,211	46,974	54,504	61,922	85,810	1,14,580	1,18,261	1,31,621	1,51,375
EBITDA	13,933	16,031	16,554	19,923	24,964	29,471	29,816	35,542	43,968
Change (%)	68.0	15.1	3.3	20.4	25.3	18.1	1.2	19.2	23.7
Margin (%)	25.3	25.4	23.3	24.3	22.5	20.5	20.1	21.3	22.5
Depreciation	4,478	5,522	7,145	8,150	11,131	15,690	16,552	17,682	18,214
EBIT	9,455	10,509	9,409	11,773	13,833	13,781	13,264	17,860	25,754
Int. & Finance Charges	709	649	577	686	4,183	9,750	8,749	7,632	7,155
Other Income - Rec.	1,444	1,614	1,005	2,674	2,674	4,100	2,100	2,300	2,320
Extraordinary income	1,946	675	910	-3,946	-1,042	7,940	11,153		
Share in Profits in JV					-1,666	-840	0	0	0
PBT	12,136	12,149	10,747	9,815	9,616	15,231	17,768	12,528	20,918
Tax	2,123	3,151	2,222	2,116	2,560	2,280	4,442	2,944	4,602
Tax Rate (%)	17.5	25.9	20.7	21.6	26.6	15.0	25.0	23.5	22.0
Minority Interest	964	1,227	1,051	1,220	1,810	2,750	3,300	3,960	4,752
Adjusted PAT	7,441	7,410	6,077	8,825	7,491	2,164	2,344	5,624	11,564
PAT	9,053	7,769	7,438	6,479	5,246	10,201	10,026	5,624	11,564
Change (%)	101.7	-0.4	-18.0	45.2	-15.1	-71.1	8.3	139.9	105.6
Margin (%)	16.4	12.3	10.5	7.9	4.7	7.1	6.8	3.4	5.9

Consolidated Balance Sheet									(INR m)
Y/E March	FY19	FY20	FY21	FY22	FY23	FY24	FY25E	FY26E	FY27E
Equity Share Capital	3,000	6,000	6,000	6,003	6,000	6,000	6,000	6,000	6,000
Revaluation Reserves	0	0	0	0	0	0	0	0	0
Other Reserves	57,980	61,058	70,269	78,322	1,72,670	1,91,830	1,98,925	2,02,905	2,11,088
Net Worth	60,980	67,058	76,269	84,325	1,78,670	1,97,830	2,04,925	2,08,905	2,17,088
Loans	18,028	19,797	36,783	51,466	1,80,190	1,62,760	1,61,260	1,59,760	1,58,260
Minority Interest	6,089	6,773	8,807	10,375	46,220	54,910	58,210	62,170	66,922
Deferred liabilities	5816	13,794	24,212	25,827	52,440	17,480	17,480	17,480	17,480
Capital Employed	90,913	1,07,422	1,46,071	1,71,993	4,57,520	4,32,980	4,41,875	4,48,315	4,59,750
Gross Block	68,240	85,167	93,959	1,03,295	1,27,440	1,44,540	1,51,040	1,57,540	1,64,040
Less: Accum. Deprn.	25,713	31,235	38,386	46,528	54,670	70,360	86,912	1,04,594	1,22,808
Net Fixed Assets	42,527	53,932	55,573	56,767	72,770	74,180	64,128	52,946	41,232
Capital WIP	12,869	15,765	22,535	34,203	25,880	39,850	39,850	39,850	39,850
Investments	10,118	9,661	19,519	15,879	20,700	10,000	38,687	40,165	32,824
Intangibles	8,303	11,974	13,533	15,824	2,69,200	2,72,850	2,72,850	2,83,764	3,12,140
Curr. Assets	44,860	49,426	70,986	78,334	1,28,880	1,61,180	1,50,907	1,66,693	1,88,908
Inventory	10,316	14,359	18,666	22,982	42,440	49,440	49,089	53,583	59,941
Account Receivables	12,918	12,237	12,176	20,582	35,730	62,310	61,259	67,323	75,461
Cash and Bank Balance	10,572	9,986	20,154	17,475	24,010	22,590	4,868	5,496	6,422
Loans & Advances	11,054	12,844	19,990	17,295	26,700	26,840	35,691	40,291	47,084
Curr. Liability & Prov.	27,764	33,336	36,075	29,014	59,910	1,25,080	1,24,547	1,35,104	1,55,204
Account Payables	26,959	32,306	34,981	27,709	58,420	1,17,310	1,15,622	1,25,028	1,43,430
Provisions	805	1,030	1,094	1,305	1,490	7,770	8,925	10,076	11,774
Net Current Assets	17,096	16,090	34,911	49,320	68,970	36,100	26,360	31,590	33,704
Appl. of Funds	90,913	1,07,422	1,46,071	1,71,993	4,57,520	4,32,980	4,41,875	4,48,315	4,59,750

E: MOFSL Estimates

Financials and valuations

Ratios

Y/E March	FY19	FY20	FY21	FY22	FY23	FY24	FY25E	FY26E	FY27E
Basic (INR)									
EPS	6.2	6.2	5.1	7.4	6.2	1.8	2.0	4.7	9.6
Cash EPS	11.3	11.1	12.2	12.2	13.6	21.6	22.1	19.4	24.8
BV/Share	50.8	55.9	63.6	70.3	148.9	164.9	170.8	174.1	180.9
DPS	0.5	1.6	0.0	1.3	1.1	2.1	2.1	1.2	2.4
Payout (%)	7.8	29.3	0.0	29.3	29.3	29.3	29.3	29.3	29.3
Valuation (x)									
P/E	58.1	58.3	71.1	49.0	57.7	199.6	184.3	76.8	37.4
Cash P/E	31.9	32.5	29.6	29.5	26.4	16.7	16.3	18.5	14.5
P/BV	7.1	6.4	5.7	5.1	2.4	2.2	2.1	2.1	2.0
EV/Sales	7.8	6.9	6.0	5.5	5.1	3.9	3.7	3.3	2.8
EV/EBITDA	30.8	27.0	25.9	22.6	22.7	19.1	18.4	15.4	12.5
Dividend Yield (%)	0.1	0.4	0.0	0.4	0.3	0.6	0.6	0.3	0.7
Return Ratios (%)									
RoE	16.1	12.1	8.5	11.0	5.7	1.1	1.2	2.7	5.4
RoCE	10.7	9.1	6.5	7.1	3.8	3.4	2.6	3.5	4.8
RoIC	14.5	12.0	9.6	9.8	4.1	3.1	2.8	3.8	5.4
Working Capital Ratios									
Fixed Asset Turnover (x)	1.4	1.3	1.3	1.5	1.7	2.0	2.1	2.9	4.1
Debtor (Days)	86	71	63	92	118	158	151	147	141
Inventory (Days)	68	83	96	102	140	125	121	117	112
Creditors (Days)	178	187	180	124	192	297	285	273	268
Working Capital (Days)	43	35	76	142	148	34	53	57	51
Leverage Ratio (x)									
Current ratio	1.6	1.5	2.0	2.7	2.2	1.3	1.2	1.2	1.2
Net Debt/Equity	0.1	0.1	0.2	0.4	0.9	0.7	0.8	0.7	0.7

Consolidated Cash Flow Statement

(INR m)

Y/E March	FY19	FY20	FY21	FY22	FY23	FY24	FY25E	FY26E	FY27E
Oper. Profit/(Loss) before Tax	10,026	8,709	8,462	7,716	6,430	12,978	29,816	35,542	43,968
Interest/Dividends Recd.	-908	-824	-770	-1,121	-1,124	-1,613	2,100	2,300	2,320
Direct Taxes Paid	-2,915	-3,441	-1,938	-2,620	-2,286	-2,923	-4,442	-2,944	-4,602
(Inc)/Dec in WC	-291	-1,651	-4,238	-7,895	-5,010	-6,352	-7,982	-4,602	-1,188
CF from Operations	11,546	12,831	11,597	11,766	18,525	29,539	22,963	30,296	40,498
(Incr)/Dec in FA	-14,924	-18,436	-17,559	-19,269	17,242	-24,615	-6,500	-6,500	-6,500
Free Cash Flow	-3,378	-5,605	-5,962	-7,503	35,767	4,924	16,463	23,796	33,998
(Pur)/Sale of Investments	6,984	1,844	-18,512	2,314	-1,60,060	14,570	-28,687	-12,392	-21,035
CF from investments	-7,138	-15,589	-36,247	-16,991	-1,42,818	-10,045	-35,187	-18,892	-27,535
Change in Net Worth	-692	25	314	425	12,016	307	7,683	2	1
(Inc)/Dec in Debt	75	186	5,872	3,213	1,24,159	-13,130	-1,500	-1,500	-1,500
Interest Paid	-1,007	-912	-1,160	-1,096	-4,856	-8,474	-8,749	-7,632	-7,155
Dividend Paid	-793	-701	0	0	-718	-2,030	-2,932	-1,645	-3,382
CF from Fin. Activity	-2,417	3,988	26,176	2,154	1,31,527	-21,915	-6,398	-10,776	-12,036
Inc/Dec of Cash	1,991	1,230	1,526	-3,071	7,234	-2,421	-18,622	627	927
Add: Beginning Balance	4,490	6,481	7,711	9,237	6,166	13,400	10,979	-7,643	-7,015
Closing Balance	6,481	7,711	9,237	6,166	13,400	10,979	-7,643	-7,015	-6,088
FX	112	536	71	33	29	1,030	1,930	1,930	1,930
Bank balances/Overdraft	3,979	1,739	10,846	11,276	10,581	10,581	10,581	10,581	10,581
Total Cash and cash Eq	10,572	9,986	20,154	17,475	24,010	22,590	4,868	5,496	6,423

E: MOFSL Estimates

Investment in securities market are subject to market risks. Read all the related documents carefully before investing.

Explanation of Investment Rating	
Investment Rating	Expected return (over 12-month)
BUY	>=15%
SELL	< - 10%
NEUTRAL	> - 10 % to 15%
UNDER REVIEW	Rating may undergo a change
NOT RATED	We have forward looking estimates for the stock but we refrain from assigning recommendation

*In case the recommendation given by the Research Analyst is inconsistent with the investment rating legend for a continuous period of 30 days, the Research Analyst shall within following 30 days take appropriate measures to make the recommendation consistent with the investment rating legend.

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