



Claris Lifesciences

Relative to Sector: **Outperformer**

Life Sciences

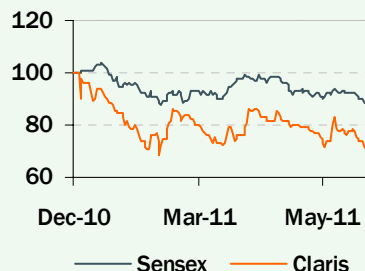
Stock Data

No. of shares	: 63.8 mn
Market cap	: Rs 10.1 bn
52 week high/low	: Rs 232/ Rs 152
Avg. daily vol. (6 mth)	: 206,100 shares
Bloomberg code	: CLAR IB
Reuters code	: CLAI.BO

Shareholding (%)

	Mar-11	QoQ chg
Promoters	: 69.0	0.0
FIs	: 10.0	0.9
MFs / UTI	: 0.4	0.0
Banks / FIs	: 1.1	0.0
Others	: 19.5	(0.9)

Relative Performance



Source: ENAM Research, Bloomberg

Specialized Play on Injectables

Financial Summary

Y/E Dec	Sales (Rs mn)	PAT (Rs mn)	EPS (Rs.)	Change (YoY %)	P/E (x)	RoE (%)	RoCE (%)	EV/EBITDA (x)	DPS (Rs)
2009	7,435	1,304	20.4	-	-	31.4	27.4	-	1.9
2010	7,523	1,489	23.3	14	-	20.9	24.0	-	1.6
2011E	8,028	1,525	23.9	2	6.7	15.5	18.7	4.3	2.0
2012E	9,325	1,872	29.3	23	5.4	16.4	16.3	3.3	2.0

Source: Company, ENAM estimates

Milind Bhangale

Sr VP - Life Sciences

milind.bhangale@enam.com (+91 22 6754 7615)

Deepak Khetan

Asst VP - Life Sciences

deepak.khetan@enam.com

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Investment Summary

❖ **Claris Lifesciences (Claris) is a play on the specialized injectables market (~USD 143 bn)**

- ❑ **Limited competition** given high entry barrier such as dedicated facilities, high cost of setting up facilities & operations
- ❑ **Large manufacturing facilities approved by various overseas regulators** – US FDA, MHRA (UK), TGA (Australia) & GCC FDCA
- ❑ **Wide product basket & strong registration pipeline** across mkts – Regulated markets (RMs): 172 (133 pending); Emerging Markets (EMs): 1,014 (184 pending)

❖ **Growth drivers**

- ❑ **With domestic healthcare industry growing at ~15% p.a. and wide product basket ranging from IV fluids to clinical nutrition to critical care, we believe Claris can grow at CAGR of 17% over CY10-CY12E**
- ❑ **New launches including Propofol (~USD 750 mn) in CY11E & Iron Sucrose (~USD 400 mn) in CY13E will lead the growth in RMs**
- ❑ **Supply deal with Pfizer, for 15 injectable products, would lead to significant ramp-up in RM sales**
 - ▶ **Positioned as an ideal partner for innovators – one large deal with Pfizer – lends global acceptability to Claris' manufacturing capability and product pipeline, thus paving way for more such deals**
- ❑ **Has a basket of 128 products of which only 48 are being sold in EMs. Claris is aggressively expanding this basket across EMs**

❖ **Risks to our call**

- ❑ **Delay in resolution of US FDA import alert may derail the US plans**
- ❑ **Delay in regulatory approvals for products may adversely impact sales ramp-up**
- ❑ **Dependency on Pfizer to ramp-up RM sales; lower-than-expected licensing income could impact profitability**

❖ **We initiate coverage with a BUY rating for a TP of Rs 293 (10x CY12E EPS of Rs 29.3, ex-US) implying 84% upside**

- ❑ **Assuming resolution of US FDA issues and 9-months of US sales in CY12, TP could be Rs 375 (12x CY12E EPS of Rs 31.3) implying 136% upside**

Claris: Play on specialized injectables market...

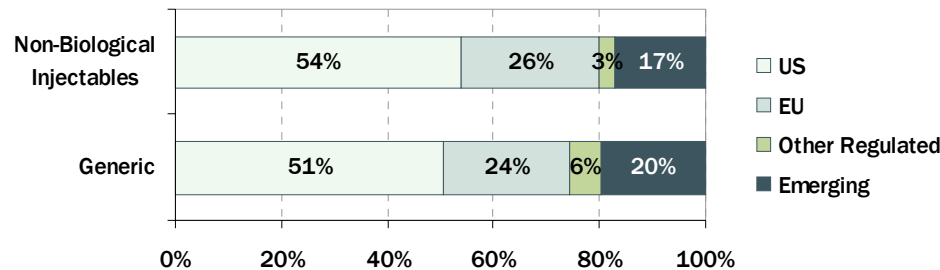
Huge opportunity

- Global injectables market is ~USD 143 bn (~20% of global pharma market) with generics contributing ~15% (USD 20 bn)
- With large number of drugs going off-patent, the global generic injectable market is expected to reach USD 33 bn by 2014 (CAGR of 11%)

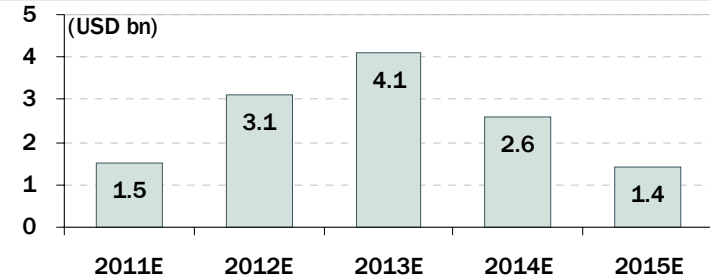
Niche market – Limited competition -> High margin

- High entry barriers – Complexity of products (multiple technology platforms and delivery mechanisms), capital intensive nature, dedicated facility, strict regulatory standards
- Thus, most of the products have limited number of suppliers
 - 86% of the molecules in the market have fewer than five injectable generic competitors
- Limited price erosion even after genericisation of product leading to higher margins compared to oral products

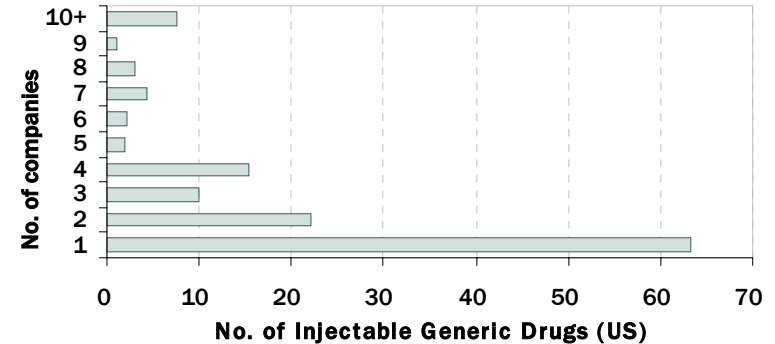
US/EU forms ~75% of global injectable market



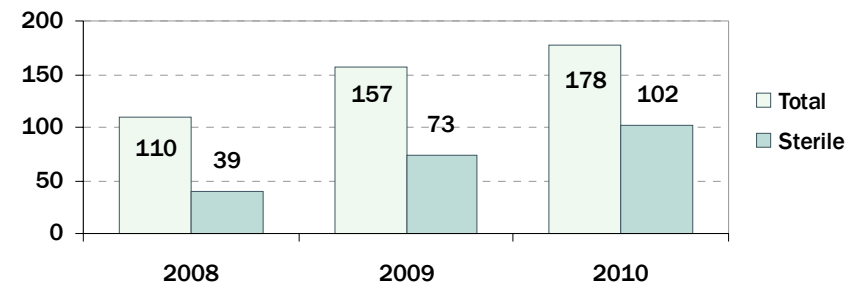
Upcoming Injectable patent expiries



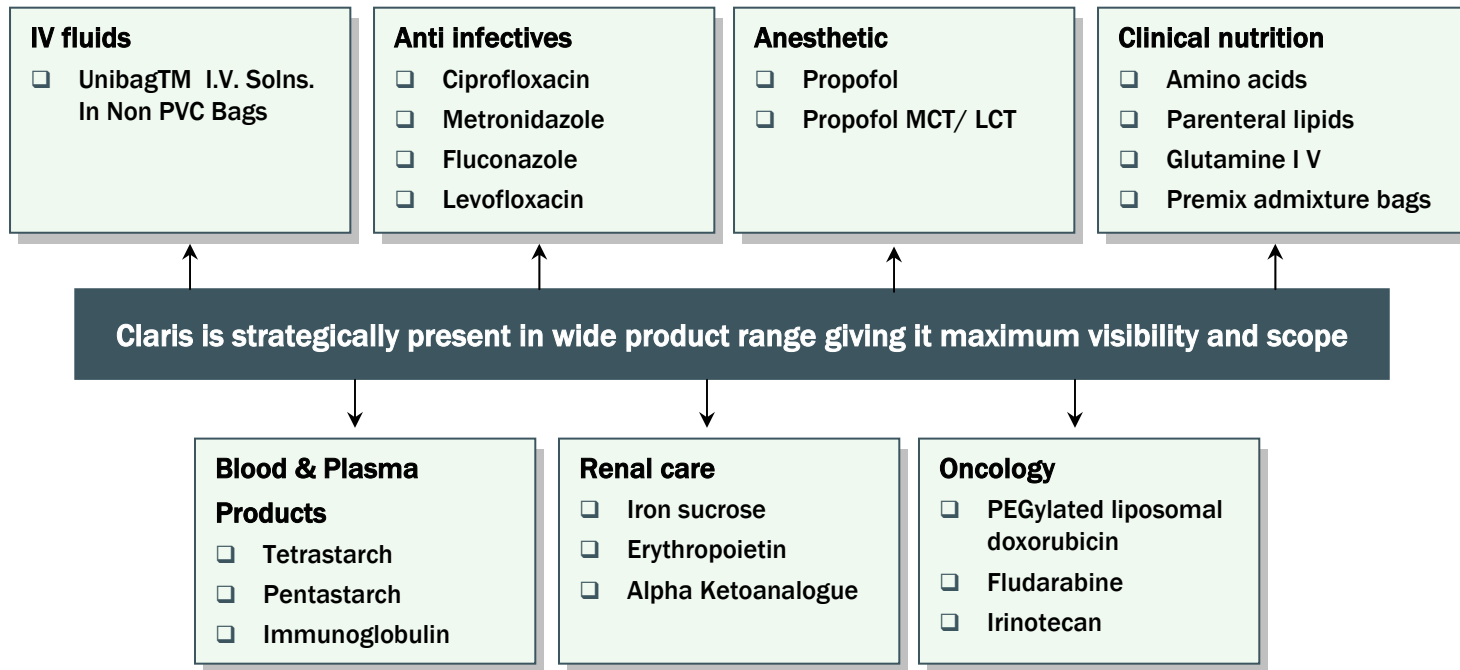
Limited manufacturers for most of the drugs



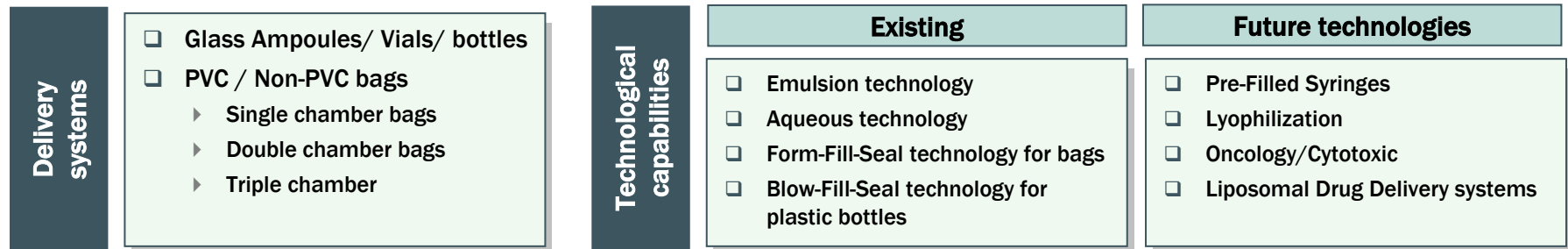
US drug shortages – Sterile’s percentage on rise



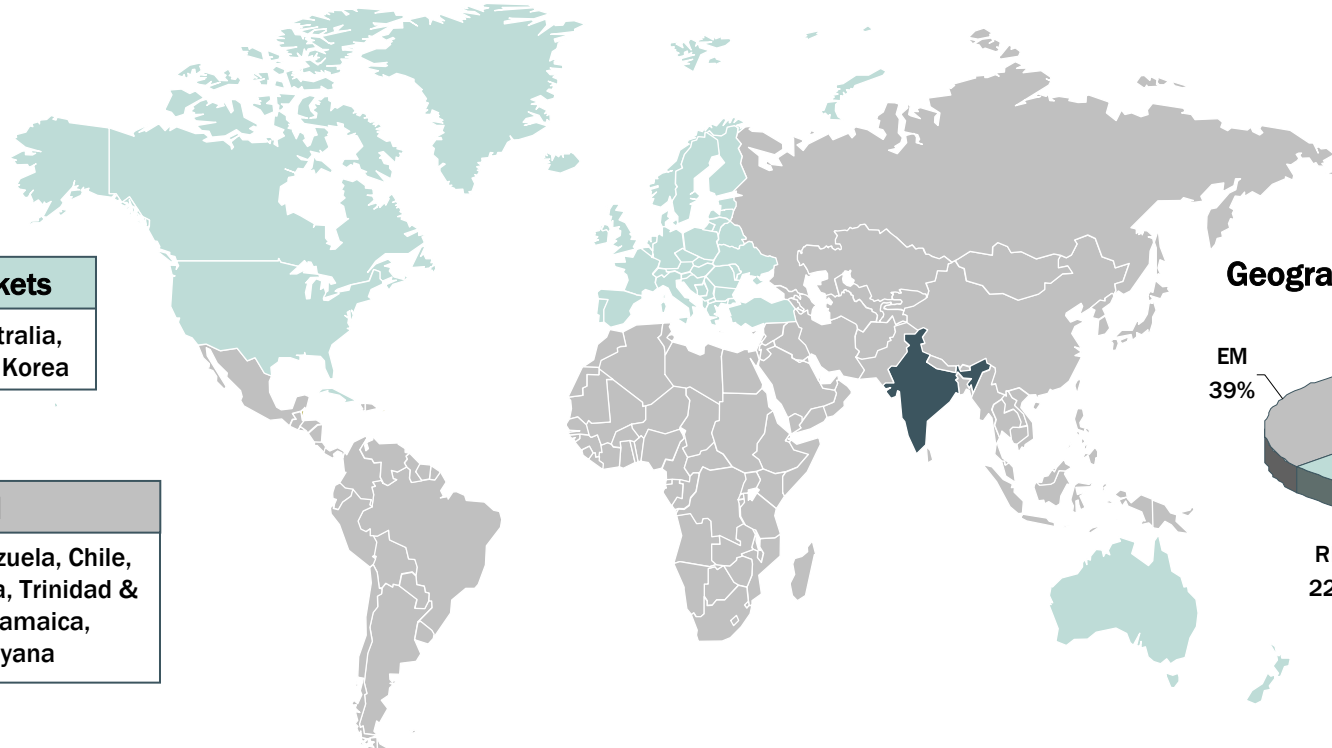
...with presence across wide therapeutic areas...



...and delivery systems with expanding technical capabilities



...and global foot-print



Regulated Markets
 US, EU, Canada, Australia,
 New Zealand, South Korea

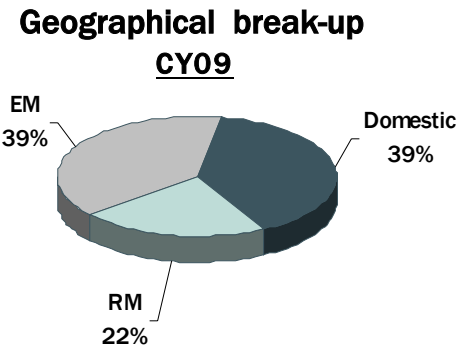
LATAM
 Brazil, Mexico, Venezuela, Chile,
 Nicaragua, Colombia, Trinidad &
 Tobago, Argentina, Jamaica,
 Costa Rica, Peru, Guyana

Africa
 Tanzania, Algeria, Mozambique,
 Uganda, Kenya, Madagascar, Ghana,
 Mauritius, Malawi, Angola, Ethiopia,
 Zimbabwe, Zambia, Comoros,
 Nigeria, Rwanda, Senegal, Sierra

Gulf + Middle East
 Saudi Arabia, Bahrain,
 Jordan, Qatar, Lebanon,
 UAE, Oman, Kuwait,
 Afghanistan, Syria, Yemen

Asia
 Vietnam, Srilanka, Nepal,
 Indonesia, Philippines,
 Singapore, Cambodia,
 Thailand, Bangladesh

CIS
 Uzbekistan, Kazakh,
 Kyrgyzstan, Turkmenistan,
 Tajikistan, Georgia,
 Azerbaijan, Russia, Ukraine



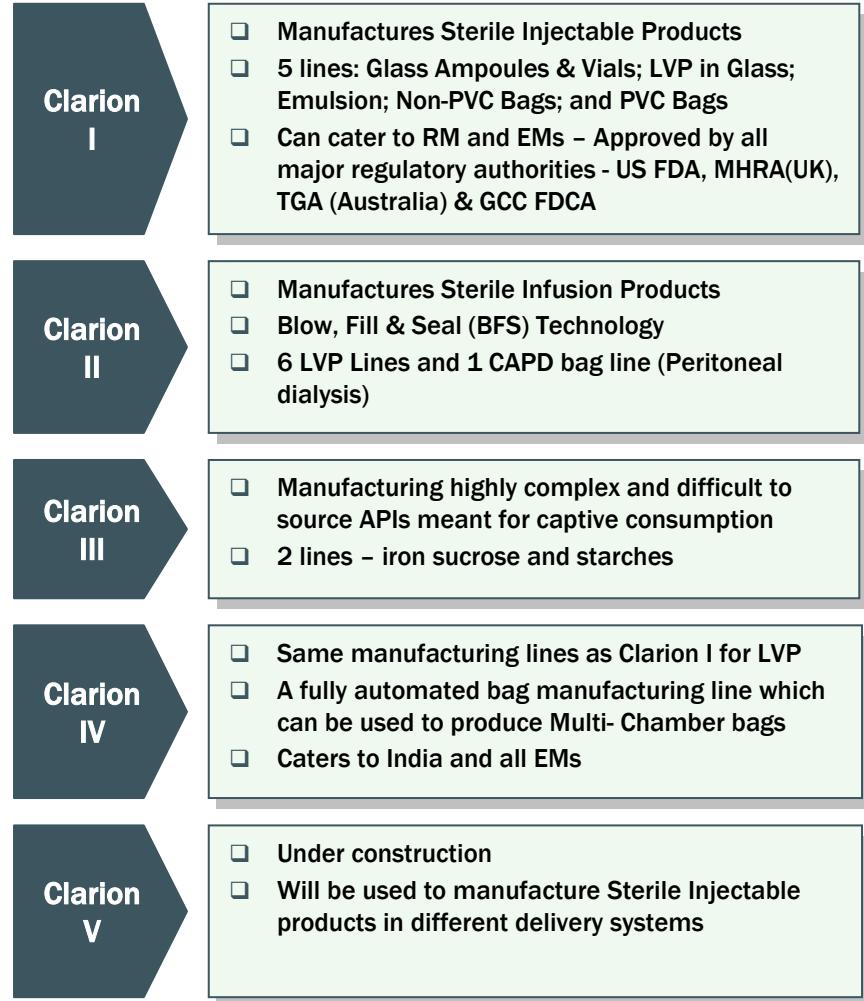
Manufacturing and R&D in place

❖ Manufacturing facilities approved by major regulatory authorities

- ❑ Four operational manufacturing plants across a 78 acre campus
- ❑ Approvals - US FDA, MHRA (UK), TGA (Australia) & GCC FDCA
- ❑ One of the few manufacturers to have facilities approved by multiple regulatory authorities in the regulated markets for:
 - ▶ Large volume parenterals in glass bottles
 - ▶ Emulsions manufacturing and
 - ▶ Bag manufacturing (PVC & Non PVC)

❖ R&D – Strong and proven capabilities

- ❑ Dedicated facility with 75 scientists; expertise in developing
 - ▶ complex products such as propofol, iron sucrose, hydroxyl ethyl starch and glutamine I.V.; and
 - ▶ delivery systems such as multi-chamber bags etc.
- ❑ 116 registered trademarks and 85 trademarks applied-for in India; 38 registered trademarks and 39 pending applications internationally
- ❑ 3 registered process patents and 15 pending applications for process patents in India



Continuously investing in R&D and capacity to fuel future growth

Domestic market – Strong foothold

Domestic healthcare industry growing at 15% p.a.

- ▶ India's rising population and income levels, along with a growing preference for private health services
- ▶ India has one of the largest number of Joint Commission International (JCI)-approved hospitals outside US
- ▶ Disease pattern shifting towards non-communicable and lifestyle-related diseases

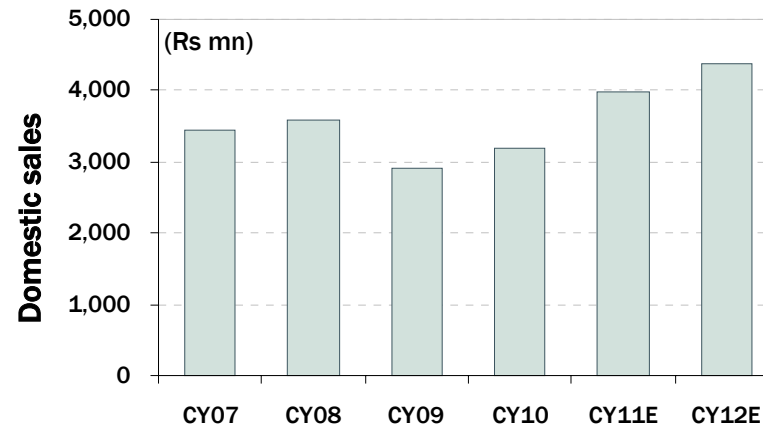
Brand, products & reach

- ▶ Claris has been present in domestic injectable market since 1999 and has a strong brand recall
- ▶ 128 products across therapies with innovative delivery systems
- ▶ ~440 MRs covering 22,000+ hospitals/ nursing homes

Growth to be mix of volume and value

- ▶ Capex of Rs 350 mn over next two years
- ▶ Employing contract manufacturers for lower-end infusion products
- ▶ Innovative delivery systems (like multiple chamber bags) to improve value and margins

Dip in CY09 was due to shifting of focus towards international market and lack of investment in domestic capacities



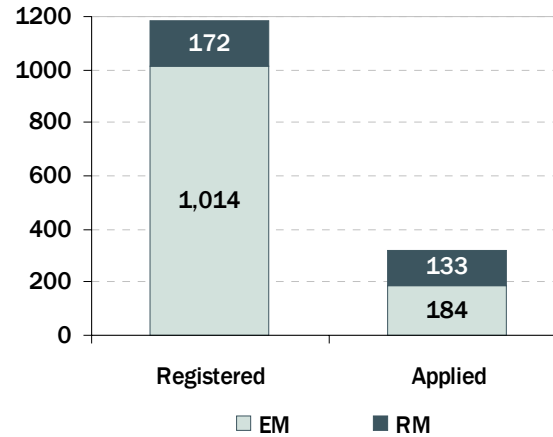
With increased investment in domestic capacities, we expect domestic business to show a CAGR of 17% over CY10-CY12E

International market – to rebound in CY12

Regulated Markets – growth to explode

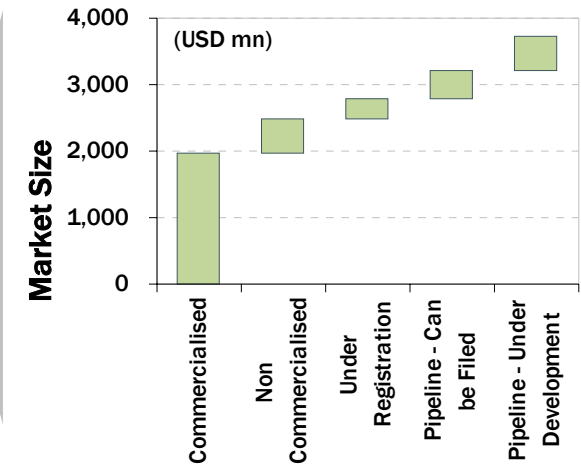
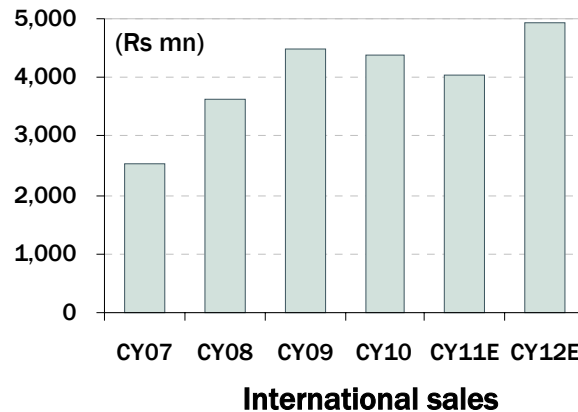
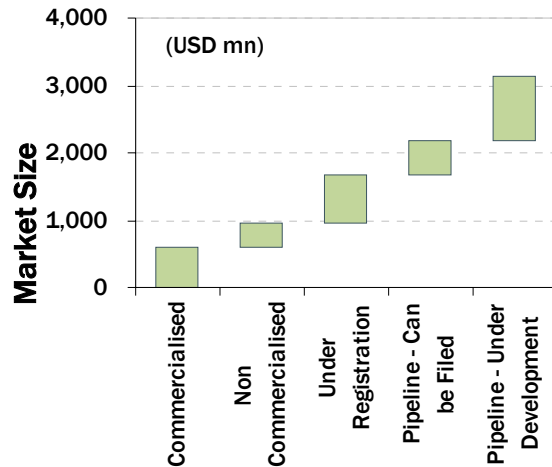
- Product launches including - Propofol (~USD 750 mn) in CY11/CY12 and Iron Sucrose (~USD 400 mn) in CY13
- Supply agreement with Pfizer to aid sales ramp-up
- Clearance from US FDA to boost sales as US forms more than 50% of injectable market worldwide

Registrations



Emerging markets

- 184 registrations pending approval
- To commercialize 20-25 registrations p.a. over next 3-4 years
- Due to political turmoil in ME+GCC the company has partially shifted base business sales to domestic markets
- However, CY12 onwards growth would be on track



CY12 onwards, we expect Claris to witness strong growth in International market

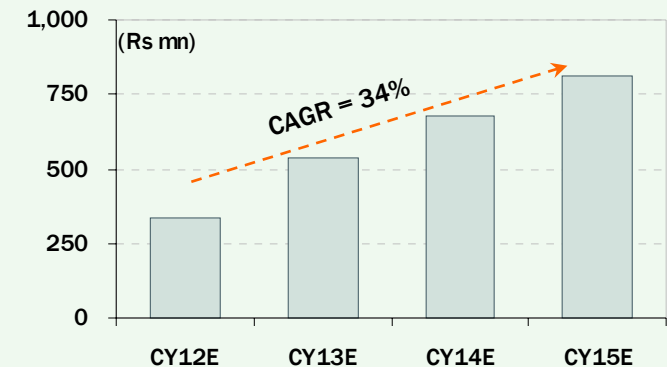
Propofol – A big opportunity

- ❖ **Propofol is a short acting, intravenous hypnotic agent (anesthetic product)**
 - ❑ Achieves its anesthetic or sedative effect by depressing respiratory and cardiac function
- ❖ **Usage – Induction and maintenance of general anesthesia, sedation for mechanically ventilated adults, and procedural sedation**
- ❖ **Benefits:**
 - ❑ Does not cause nausea or other side effects often associated with opioid medications
 - ❑ Recovery is more rapid and clear
- ❖ **Limited number of manufacturers on account of complex manufacturing process**

Market	Market size (USD mn)	% Growth (units)	Suppliers
Worldwide	750	8	-
US	450	6	Fresenius
Europe	150	5	Fresenius, B Braun

Clarix is one of the few suppliers worldwide

- ❑ **Currently sells in 48 countries**
 - ▶ Total registration – 95; 60 more in pipeline
 - ▶ Has received approval in EU (to be launched soon)
 - ▶ Has applied in the US
- ❑ **Clarix' revenue from Propofol in EU**
 - ▶ Given its alliance with Pfizer and limited suppliers, we believe Clarix can garner 12-15% market share in EU



Supply deal with Pfizer lends global credibility

Deal with Pfizer to scale-up revenues across RMs

- ❑ Claris supplies 15 injectable products to Pfizer in the US, EU, Australia, Canada and New Zealand
- ❑ Supply commenced in CY09 with ramping-up of supplies every year
- ❑ Claris receives licensing income related to development and filing of products

Lends support to Claris brand

- ❑ Strengthens Claris' presence in the US and other RMs
- ❑ Benefits from Pfizer's global distribution reach and leverages Claris' diversified product basket
- ❑ Claris to have low incremental expense on filings as most are existing products
- ❑ Supply arrangement covers only RMs leaving scope for arrangement to be extended to EMs or a separate deal with some other MNC

Injectable supply deals by Indian pharma players

Pfizer – Strides Arcolab	US	45 sterile injectables (oncology) & orals
Pfizer - Claris	US, Canada, New Zealand, Europe, Australia	15 sterile injectables
Pfizer - Aurobindo	US, Canada, EU, Rest of Europe, ROW, Australia, NZ	Orals and injectables

We believe there is minimal product overlap for Claris

Risks to call

❖ Delay in resolution of US FDA issue

- ❑ Claris' facility Clarion-I is under import alert from US FDA (Received in May'10)
 - ▶ In May'10, Claris had re-called some batches of Ondansetron, Ciprofloxacin and Metronidazole after contamination was found due to leakage of bags. Following this, US FDA issued a warning Letter and Import Alert on Clarion-I
 - ▶ The cost of recall amounted to Rs 74 mn
 - ▶ Any delay in implementation of corrective action plan or clearance from US FDA may hold up US sales and affect ANDA approvals

❖ Update

- ❑ The company is working on corrective action plan and hopes to re-invite US FDA by Q3CY11E
- ❑ Management is hopeful of resolving the issue in CY11E

❖ Delay in regulatory approvals for products may adversely impact sales ramp-up

❖ Dependency on Pfizer

- ❑ Ramp-up in RMs is largely dependant on Pfizer
 - ▶ The supply agreement with Pfizer is non-exclusive (Pfizer can source from other suppliers). However due to complexity of products, we do not foresee any significant risk to revenues
- ❑ Claris generates ~10–15% of its PAT from licensing income under supply agreement from Pfizer
 - ▶ Lower licensing income on account of delay in R&D and regulatory approvals can adversely affect bottom-line

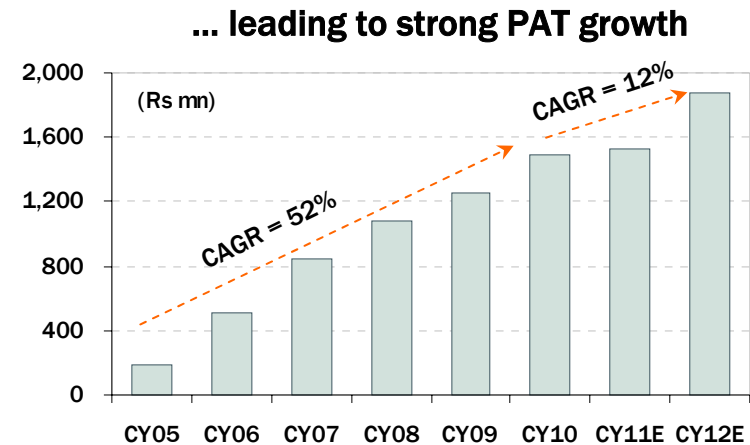
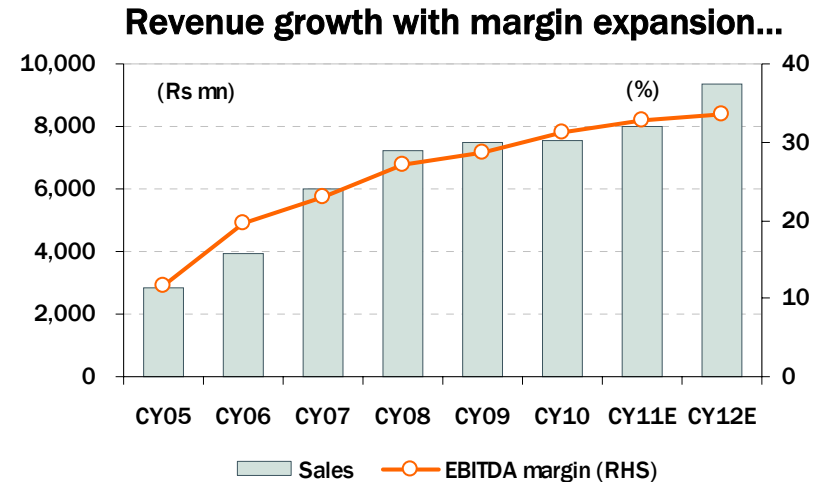
Financials: robust growth record...

- ❖ **Strong growth track record: Sales has grown at 21% CAGR (CY05-CY10) with bottomline growing at 52% CAGR over the same period. Going forward, sales would be driven by:**
 - ❑ launch of major products (Propofol and Iron Sucrose) in RMs
 - ❑ launch of new products in EMs
 - ❑ focus on domestic base business

- ❖ **EBITDA margin – expansion to be driven by Propofol launch in EU markets and improving product & geographic mix, despite licensing income contribution remaining constant going forward**

- ❖ **Interest Cost – We expect Claris’ net interest outgo to decline – cash of ~Rs 3.0 bn on books; debt to go down gradually over next 2-3 years**

- ❖ **Net Profit – to rise at a CAGR of 12% over CY10-CY12E, largely led by 10% annual growth in sales.**
 - ❑ Clearance from US FDA may push PAT growth to 16% (CAGR over CY10-CY12E)



...with strong upside potential once US FDA clearance is received

Recommend BUY for TP of Rs 293

Peer valuation

Company Name	Y/E	Mcap (USD mn)	PER (x)		EV/Sales (x)		EV/EBITDA (x)		EPS CARG (%)	RoE (%)
			CY11E/ FY12E	CY12E/ FY13E	CY11E/ FY12E	CY12E/ FY13E	CY11E/ FY12E	CY12E/ FY13E	CY10-CY12E/ FY11-FY13E	CY10/ FY11
Aurobindo Pharma	Mar	1,108	8.8	7.4	1.3	1.1	6.6	5.5	12.0	24.0
Strides Arcolab	Dec	425	10.2	7.4	1.8	1.5	8.6	7.0	29.9	11.9
Claris Lifesciences	Dec	225	6.7	5.4	1.4	1.1	4.3	3.3	12.1	20.9

Source: ENAM Research; Bloomberg

- ❖ Claris is currently trading at 5.4x CY12E EPS (~28% discount to its closest peers – Aurobindo and Strides Arcolab)
- ❖ Both Aurobindo and Strides Arcolab are injectable manufacturers
 - ❑ Aurobindo has received import alert on Unit-VI and Warning letter on Unit-III and Unit-VI
 - ❑ Strides Arcolab is awaiting US FDA approval for major injectable products
- ❖ We value Claris at Rs 293 (10x CY12E EPS of Rs 29.3, ex-US) implying an upside potential of 84% from CMP of Rs 159
- ❖ We have not built-in any US sales for CY12. However, given the management confidence on resolution of US FDA issue, we present a sensitivity here
- ❖ Assuming US sales begin in Apr'12
 - ❑ EPS can be as high as Rs 31.3 implying 16% PAT CAGR over CY10-CY12E
 - ❑ Target price can be as high as Rs 375 (12x CY12E EPS implying an upside potential of 136% from CMP of Rs 159)

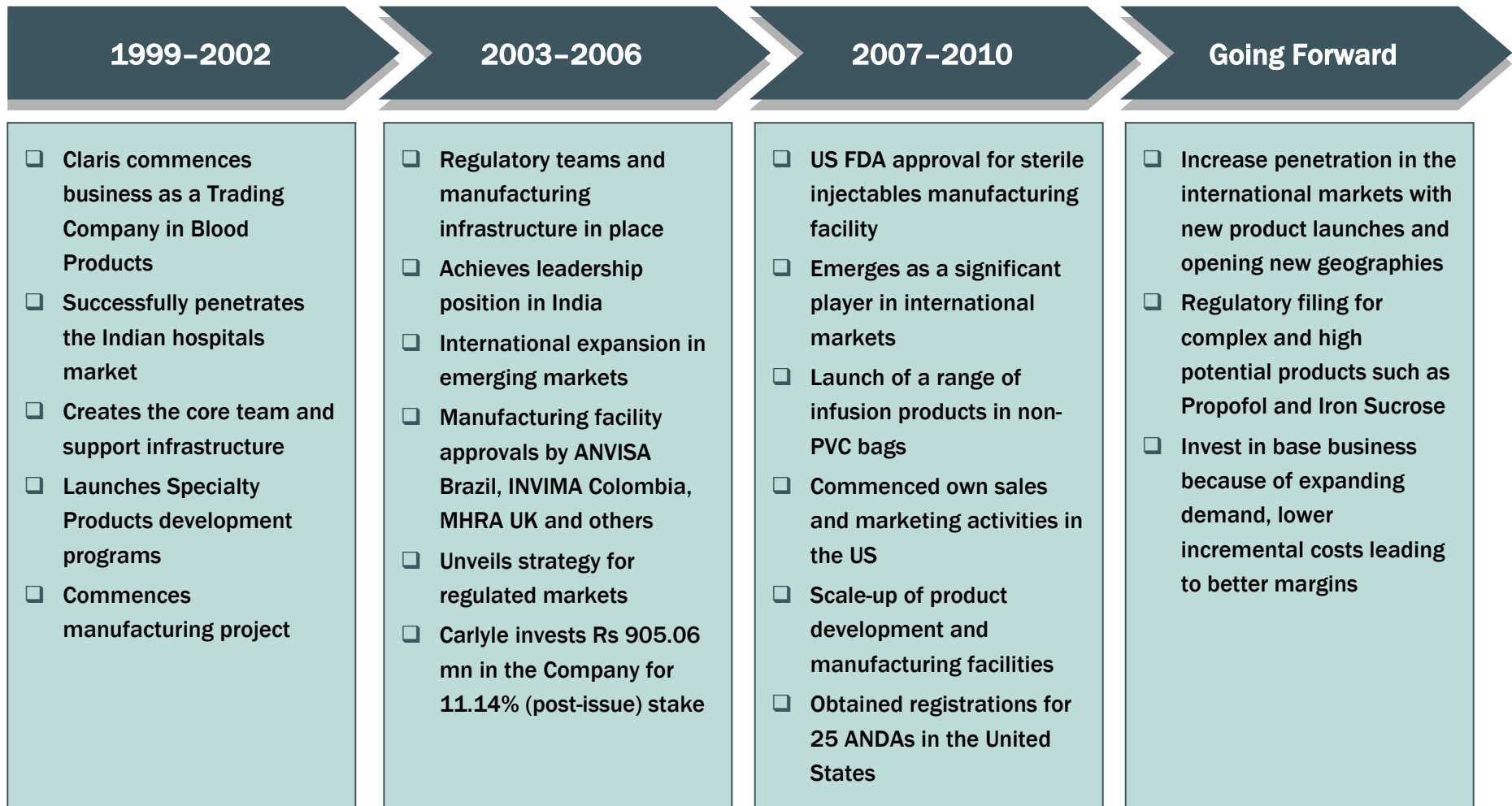
Sensitivity to CY12E US sales and PE multiple

		9months	6months	3months	NIL
		9,775	9,625	9,475	9,325
Target Multiple (x)	9.0x	281	276	270	264
	10.0x	313	306	300	293
	11.0x	344	337	330	323
	12.0x	375	367	360	352



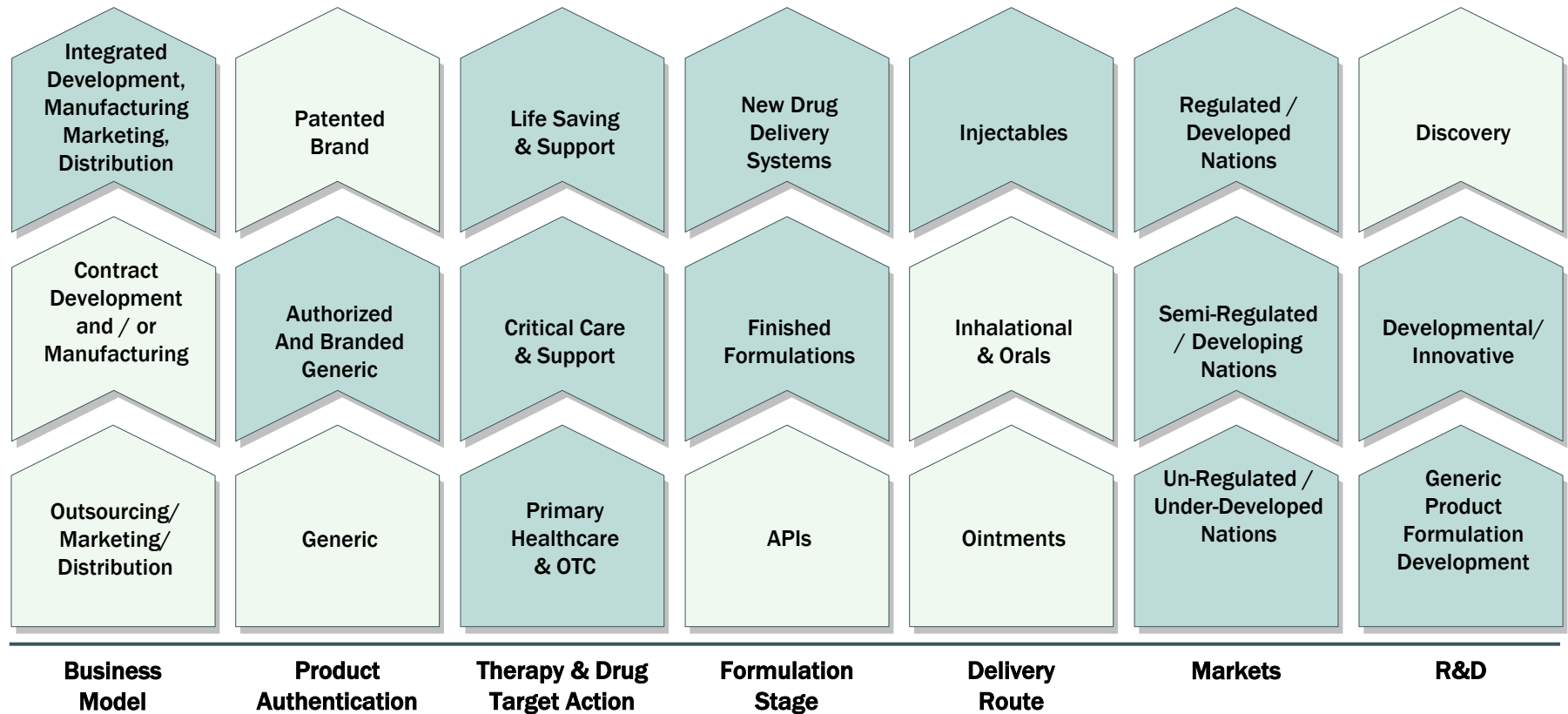
Annexure

Evolution of Claris Lifesciences



Claris has evolved from an EM focused company to one of the leading pure play global injectables players

Integrated business model



 Claris' presence

Claris has a well integrated business model with presence across value chain

Company Financials

Profit & Loss

(Rs mn)

Y/E Dec	2009	2010	2011E	2012E
Net sales	7,435	7,523	8,028	9,325
Other operating income				
Total income	7,435	7,523	8,028	9,325
Cost of goods sold	2,831	2,876	3,034	3,497
Contribution (%)	38	38	38	38
Advt/Sales/Distrn O/H	2,468	2,293	2,368	2,695
Operating Profit	2,136	2,354	2,625	3,133
Other income	159	154	79	79
PBIDT	2,295	2,508	2,704	3,212
Depreciation	448	467	530	580
Interest	410	362	380	350
Pre-tax profit	1,437	1,679	1,794	2,282
Tax provision	133	190	269	411
Adjusted PAT	1,304	1,489	1,525	1,872
E/o income / (Expense)	0	(74)	0	0
Reported PAT	1,304	1,414	1,525	1,872

Key ratios

(%)

Y/E Dec	2009	2010	2011E	2012E
Sales growth	2.9	1.2	6.7	16.2
OPM	28.7	31.3	32.7	33.6
Oper. profit growth	8.8	10.2	11.5	19.4
COGS / Net sales	38.1	38.2	37.8	37.5
Overheads/Net sales	33.2	30.5	29.5	28.9
Depreciation / G. block	7.4	7.0	6.1	5.4
Effective interest rate	12.7	10.7	10.8	10.9
Net wkg.cap / Net sales	30.1	35.6	34.5	33.6
Net sales / Net block (x)	1.3	1.1	0.9	1.0
RoCE	27.4	24.0	18.7	16.3
Debt / equity (x)	0.6	0.4	0.3	0.2
Effective tax rate	9.3	11.9	15.0	18.0
RoE	31.4	20.9	15.5	16.4
Payout ratio (Div/NP)	2.5	8.6	8.6	8.6
EPS (Rs.)	16.1	20.4	23.3	23.9
EPS Growth	22.8	27.3	14.2	2.4
CEPS (Rs.)	21.8	27.4	30.6	32.2
DPS (Rs.)	1.9	1.6	2.0	2.0

Source: ENAM Research

Company Financials

Balance sheet

(Rs mn)

Y/E Dec	2009	2010	2011E	2012E
Total assets	8,760	13,273	14,479	15,747
Gross block	7,539	9,486	11,888	12,747
Net fixed assets	6,152	7,641	9,513	9,792
Wkg. cap. (excl cash)	237	1,675	2,768	3,137
Cash / Bank balance	2,369	3,956	2,198	2,817
Others/Def tax assets	0	0	0	0
Capital employed	8,760	13,273	14,479	15,747
Equity capital	341	638	638	638
Reserves	4,761	8,508	9,902	11,613
Borrowings	3,140	3,606	3,418	2,975
Others	517	521	521	521

Cash flow

(Rs mn)

Y/E Dec	2009	2010	2011E	2012E
Sources	1,551	5,004	1,736	1,848
Cash profit	1,733	1,982	2,055	2,452
(-) Dividends	32	128	131	160
Retained earnings	1,701	1,855	1,924	2,291
Issue of equity	621	2,683	0	0
Borrowings	(772)	466	(188)	(443)
Others				
Applications	1,551	5,004	1,736	1,848
Capital expenditure	930	1,946	2,402	859
Investments	0	0	0	0
Net current assets	(1,581)	1,438	1,092	370
Change in cash	2,202	1,620	(1,758)	619

Source: ENAM Research

ENAM Securities Pvt. Ltd.

7, Tulsiani Chambers, Free Press Journal Marg, Nariman Point, Mumbai – 400 021, India..

Tel:- Board +91-22 6754 7600; Dealing +91-22 2280 0167;

Fax:- Research +91-22 6754 7679; Dealing +91-22 6754 7575

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2. Firm ownership of the stock	No
3. Directors ownership of the stock	Yes
4. Investment Banking mandate	No
5. Broking relationship	No

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