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INDIA RESEARCH

Strides Arcolab

Rs294
UNRATED

Visit Note

Mkt Cap: Rs11.8bn; US$261m

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Strides Arcolab (Strides) is a promising business model in the small cap Indian pharma space with scale-up potential. Given superb capabilities in the generic steriles space (123 ANDA filings including a whopping 91 sterile ANDAs; 45 ANDAs filed in 2009), we believe Strides is nearing a tipping point in its growth trajectory. Strides plans to file another 40 sterile ANDAs each for the next two years to create a 200+ sterile ANDAs portfolio by 2012 – one of the largest injectable portfolios in the global generics industry. Strides' ability to enter into partnering deals with global players like Pfizer (for 40 oncology steriles for US market) and GSK (10 sterile drugs for emerging markets) enhances comfort in its execution capabilities. Strides aims to cut yet another outlicensing deal for injectables targeted at another therapy segment during CY10. With only three steriles ANDAs commercialized till 2009 and ~10x sterile capacity likely to be opertionalized post FDA inspection in 2010, Strides' injectables-led growth story has just begun to unfold. On the flip side, Strides' leveraged balance sheet (~2.2x net gearing as of December 2008) has been a concern but we expect gearing to progressively come down, aided by strong cash inflows in the coming quarters (propelled by upfront licensing fee from Pfizer deal) as well as recent restructuring exercise. Strides is prepared to redeem its $34m 2010 FCCB issue which takes care of immediate cash flow concerns. Further, the recent restructuring exercise which has split the business into specialty (injectables), branded formulations and pharma will simplify the business and enable Strides to unlock value across different divisions. It will aid the company's objectives to be one of the top five steriles company in the world and to be debt free over the next few years.

Key financials

As on 31 December	CY05	CY06	CY07	CY08
Net sales (Rs m)	5,237	7,430	7,443	10,203
Net profit (Rs m)	484	402	(501)	1,080
Shares in issue (m)	35	35	35	40
EPS (Rs)	13.9	11.5	(14.3)	27.0
% growth	-	*(17.1)*	*(224.4)*	*(288.1)*
PE (x)	21.2	25.5	n/a	10.9
Price/Book (x)	3.0	2.4	3.5	2.0
EV/EBITDA (x)	13.1	12.5	(95.0)	37.4
RoE (%)	28.1	10.4	(13.9)	24.3
RoCE (%)	21.1	9.6	(4.4)	1.6

Source: IDFC-SSKI Research

STRIDES ARCOLAB: A PROMISING BUSINESS MODEL

Strides, established in 1990, has recorded a CAGR of 30% over the last six years with sales of $226m in 2008. For 9MCY09, the company has recorded ~$200m in sales with PBT (pre-exceptional items) of $7.4m. Over the years, Strides has aggressively invested in building capacities – as reflected in ~4x growth in gross block over CY04-08 which has significant strained the balance sheet. As on 31 December 2008, Strides has net debt of $276 and net gearing of 2.2x.

With most of its large-ticket capex behind, significant new capacities likely to be USFDA approved in 2010 and a large pipeline of regulatory filings poised for approval in key markets, Strides is now likely approaching a tipping point in its growth trajectory.

Exhibit 1: Strides has been investing in building an impressive body of regulatory market filings, particularly in USA

Market	Dossier filed	Approvals received	Dossier under review	Products commercialized
Australia	21	11	4	1
Canada	7	5	1	8
New Zealand	2	2	0	0
South Africa	96	23	9	7
USA	123	31	3	17
WHO	17	9	0	9
Europe	23	3	14	0
Total	**289**	**84**	**31**	**42**

Source: Company

Strides has a global manufacturing footprint with operations across 14 sites in Asia, Latin America and Europe and marketing presence across 60 countries. The company has undergone 15 successful inspections by USFDA/ EMEA/ PIC over the last 12 months including a recent inspection of the sterile site.

Strides is headed by Mr Arun Kumar, a first generation entrepreneur, supported by an experienced management team based out of Bangalore.

❑ Focus on niche product development and manufacturing with marketing partnerships

Since inception, Strides has had a clear focus on niche segments – as reflected in its decision to build up soft gel capabilities in the orals space during the initial phase, followed by a clear focus on injectables (steriles) in the later phase of growth. Unlike most other peers, Strides does not have API integration and instead relies on its expertise of complex formulation delivery technologies to create competitive advantage across products. Typically, Strides focuses on formulations, where API costs are less than 30% of the overall formulation cost – and which significantly reduces the importance of API backward integration.

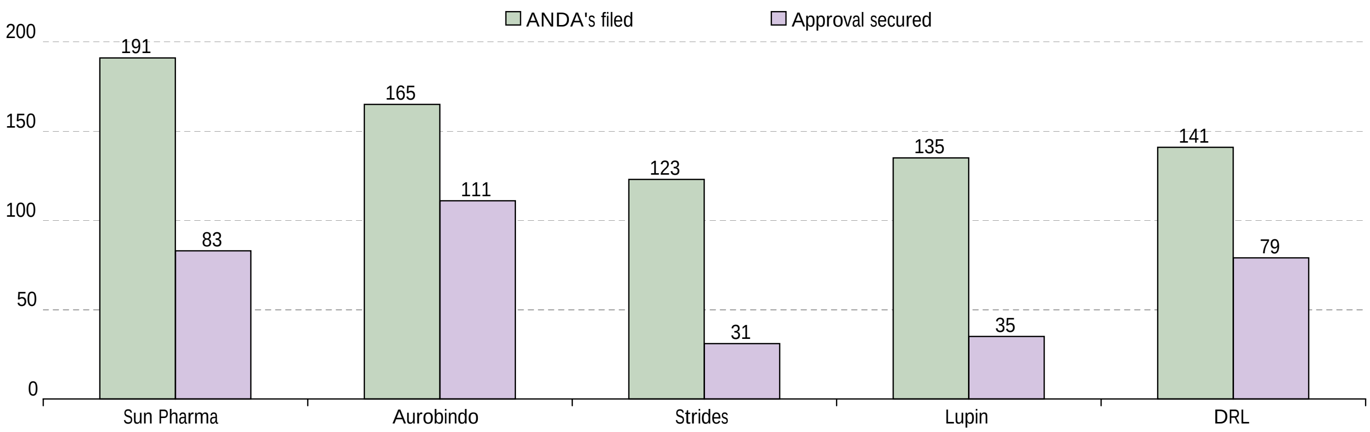
Barring its limited presence in the branded formulations space in South East Asia and Africa, Strides has remained focused largely on product development and manufacturing of niche drugs while entering into marketing tie-ups across geographies. Strides' attractive product portfolio has made it a partner of choice for global pharma players like Pfizer, GSK and Aspen etc.

Licensing income from these partnerships has enabled Strides to bankroll its R&D expenditure in the previous years, thereby enabling it to invest aggressively in building up its future product pipeline.

❑ Impressive US ANDA filings portfolio

Currently, Strides has filed 123 ANDAs including 91 steriles with USFDA. It filed 51 ANDAs in 2009, the highest in the Indian pharma industry. Till date, Strides has received approval for 31 ANDAs. This filings data compares favorably with peers, and clearly underlines the value of IP that Strides has attained.

Exhibit 2: Summary of ANDA filings

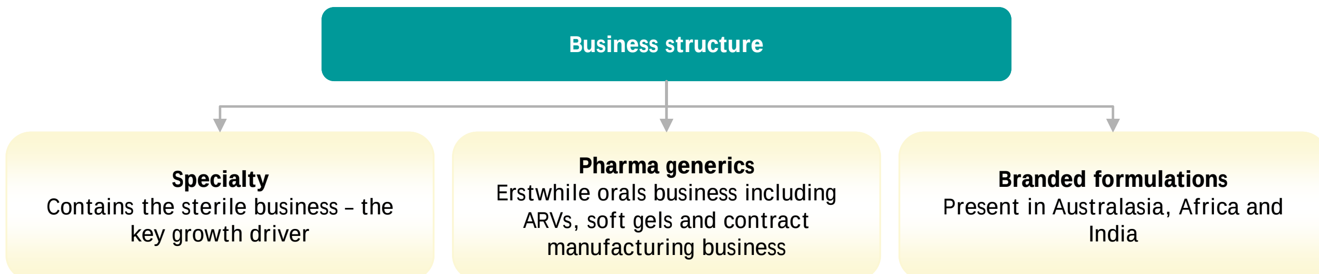


Source: IDFC-SSKI Research

❑ Recent restructuring exercise to create a simplified business structure

Till recently, Strides had a relatively complex corporate structure with a string of JVs across geographies and multiple subsidiaries. The management has undertaken a business restructuring exercise to consolidate several subsidiaries as well as to broadly split the business across three divisions.

Exhibit 3: Strides – business structure post the recent restructuring



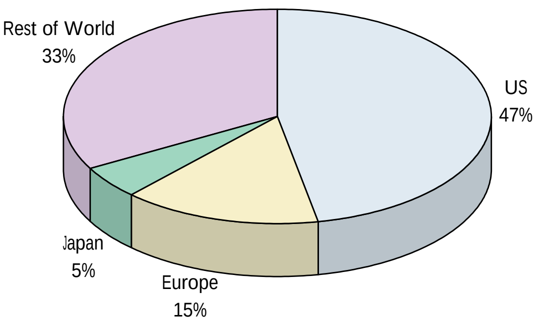
Source: Company, IDFC-SSKI Research

As part of this exercise, Strides has also undertaken measures like re-evaluation of assets, adjustment of goodwill, etc – which will likely strengthen the overall balance sheet. This restructuring has been recently approved by the courts and details are expected to be shared by the management post the announcement of Q4CY09 results. We believe this exercise will simplify the overall corporate structure for Strides and enable investors to track the progress of different business groups. Earlier during November 2007, Strides had also sold its Latin American business to Aspen as part of its efforts to streamline the business as also generate cash to fund future growth.

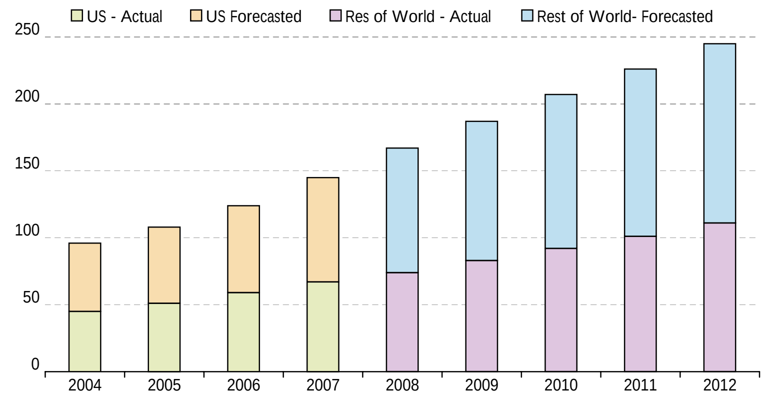
STERILES: THE CROWN JEWEL

Globally, injectables market is estimated to be $145bn with estimated CAGR of 11% over FY08-12. The injectable generics market is estimated to be $15bn and expected to grow at 10% per annum. Among therapies, oncology injectables are a key segment with $9 bn worth of drugs expected to go off patent by 2015.

Exhibit 4: Injecitbles market – sales by region



Growth looking one way – up



Source: Company, IDFC-SSKI Research

Given the complexities of manufacturing high-potency oncology injectables, there are relatively limited manufacturers of these drugs globally. Strides believes it can generate 25-30% operating margins in this segment on a sustainable basis.

Strides is poised to become one of the most competitive steriles players in the global pharma scene. It is focused on developing and manufacturing steriles across multiple therapeutic segments with focus on anti-infectives, oncology, ophthalmology and peptides. Strides' strategy revolves around focusing on select therapies and then developing an entire suite of products that covers at least 80-90% of that therapy. Thereafter, the company seeks to outlicense this entire "domain" to a global pharma player that has an interest in the therapy and can thereby garner a significant market share. In line with this strategy, Strides has partnered out its oncology injectables portfolio in the US to Pfizer earlier during the year, and seeks to outlicense one more domain to a big pharma player during CY10.

Currently, Strides has filed 91 sterile ANDAs with the USFDA including 45 ANDAs filed during 2009. Strides believes that it can file another 40 sterile ANDAs each for the next two years – thereby creating a potential injectable ANDA portfolio of ~200 products. If executed to plan, this will be by far the largest injectable portfolio across any company in India and among the largest globally.

Till date, Strides has obtained approval for 18 sterile ANDAs and has commercialized three of these products including Vancomycin, Rifampicin and Azithromycin. Strides has been constrained by the limited capacity of its existing USFDA to commercialize more products as well as ramp up sales of the already commercialized ones.

Exhibit 5: Strides' sterile filings in the US

ANDAs filed	91
ANDAs approved	18
ANDAs commercialized	3

Source: Company

❑ Recent Pfizer partnering deal underlines Strides' sterile credentials

As part of this recent deal, Pfizer will source 40 generic products (primarily oncology injectables) from Strides and Onco Therapies (a 50: 50 JV between Aspen and Strides) to market them in the US. These drugs cover ~60% of the $9bn oncology injectables likely to go off patent by 2015. While the arrangement is currently exclusive to the US, we believe that it may get extended to other geographies and may even include a larger number of products going forward.

In an interview, David Simmons (President and General Manager, Established Products Unit, Pfizer) has stated that:

- ***Strides is a powerhouse in the steriles injectables arena***
- ***Pfizer looked at more than 100 companies before settling on the deal with Strides***
- ***We view this as a beginning of a partnership and look at Strides as a strong anchor point***

These statements reinforce Strides' credentials in the injectables space.

The first drug as part of this transaction is expected to be launched by 2H2010. Under the arrangement, Strides will likely receive upfront licensing fee, milestone payments as well as share of revenues. The company has not shared the financial details of this transaction but we believe these payments could be fairly substantial going by the significant payments received by Aurobindo Pharma as part of its deal with Pfizer for primarily oral formulations across the US, EU as well as multiple emerging markets ($110m for 60-70 products partnered out to Pfizer).

Given that Pfizer intends to be among the top 5 injectables players globally over the next five years and has the capability to meet this aspiration, this deal may lead to significant recurring revenues for Strides (apart from the upfront payments) going forward as it benefits from the higher market share garnered by Pfizer across multiple partnered products.

❑ GSK partnership for emerging markets

Prior to the deal with Pfizer, Strides had also entered into a similar deal with GSK Plc in 2008, wherein Onco Therapies Private Limited will first supply 10 injectable products (primarily oncology) meant for 95 countries across the world. GSK will register the drugs in these countries as will be responsible for their distribution and commercialization. The first drugs from this partnership are likely to be commercialized in 2010. This partnership may be extended going forward.

❑ Significant capacity expansion on the anvil; to accelerate growth

Currently, Strides operates six injectable manufacturing plants across the globe (Bangalore and Poland) and has one of the largest freeze drying (lyophilization) capacities in the world.

Exhibit 6: Strides – large injectable capacities

Facility	Location	Regulatory Status – USFDA and MHRA approval
SPD - I	Bangalore	Approved by USFDA and MHRA
SPD - II	Bangalore	MHRA approved; USFDA approvable
Beta Lactams facility	Bangalore	Approved by USFDA and MHRA
Cephalosporin facility	Bangalore	Approved by USFDA and MHRA
Sterile and controlled substance facility	Poland	EU approved, USFDA approvable
Oncology facility	Bangalore	MHRA approved; USFDA approvable

Source: Company, IDFC-SSKI Research

Three of these sterile facilities have been approved by the USFDA and remaining three are awaiting approval. The approved facilities include two facilities for the manufacture of cephalosporins and betalactams while one sterile facility in Bangalore with lyophilization capabilities. The current USFDA approved facilities are running to capacity – thereby constraining Strides' ability to ramp up its US injectable sales.

USFDA approval for SPD-II will lead to ~10x expansion in overall injectable liquids capacity, 4x increase in lyophilization capacity and enable oncology injectable sales for US market. Additionally, the Polish plant has undertaken a significant expansion by adding Lyophilization, pre-filled syringes as well as liquid vials lines to the existing ampoules manufacturing lines. Strides primarily aims to sell controlled substances from this plant to cater to the demand in EU markets. Part of this plant has been dedicated to a global pharma major for select products.

Exhibit 7: Significant capacity expansion for liquid injectables expected to come on stream by end-2010

	Existing capacity (m doses)	Expanded capacity (m doses)
Lyophilization (non-oncology products)	10	50
Lyophilization (oncology)	0	7
Liquid vials	11	103
Liquid vials (oncology)	0	16
Pre-filled syringes	9	29

Source: Company

Strides expects these inspections to be done by 1H2010, leading to significant expansion in capacity to service the key US market going forward.

❑ Steriles expected to be the key growth driver for the business

Given a timely approval, Strides expects its US sales to grow to more than $40m for CY10 as compared to ~$15m in CY09. Additionally, we expect Strides to book substantial licensing income during CY10 as part of its partnering deal with Pfizer. Further, non-US sales will also grow rapidly on the back of commissioning of the new injectable capacities. Overall, Strides expects steriles segment revenue (including licensing income) to more than double (CY09E estimates sales of $86m) in CY10.

With a large chunk of new injectable ANDA approvals expected Q4CY10 onwards, US growth will likely accelerate in CY11 as Strides expects ~30 new product approvals/ launches over 2010-11. Any delay in USFDA approval for SPD-II remains a key risk to 2010 earnings growth in view of the capacity constraint in existing USFDA-approved facilities.

❑ Recent Orchid-Hospira transaction indicative of value of sterile assets

To put it in context of the value of Strides' steriles IP and manufacturing capacities, Hospira recently paid $400m (~5.5x revenues) to buy out Orchid Pharma's injectable business (primarily cephalosporin and betalactams) including the manufacturing plant and related IP. We estimate Orchid had 37 ANDA filings for these products including orals and injectables.

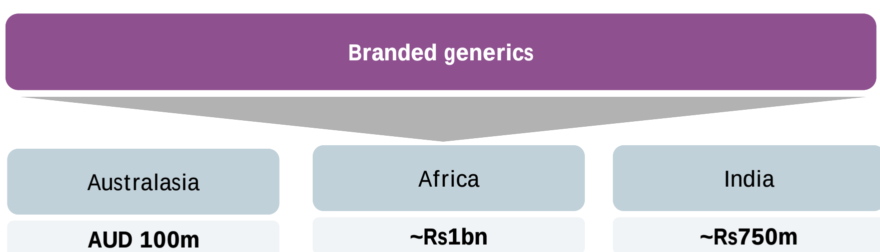
Strides believes that its ANDA filings/ approvals include almost all the injectable products that formed part of this transaction including the much-vaunted Tazo Pip. Further, these cephalosporin and betalactams filings are only one component of Strides' overall ANDA filings portfolio. Incidentally, Strides has also started selling Tazo Pip in EU markets and has also filed the ANDA for US market.

OTHER BUSINESSES: PLAYING SECOND FIDDLE FOR NOW

❑ Branded generics

Strides' branded generics business spans Australasia, Africa and India with Australasia being the key market. We estimate this business to have sales of ~Rs6.5bn per annum with 10-11% EBITDA margins.

Exhibit 8: Branded generics (geography-wise)



Source: Company, IDFC-SSKI Research

Given that Strides is not vertically integrated, it leads to subdued profitability for the company compared to other Indian peers. Barring the new division launched recently in India, branded generics business does not quite leverage Strides' core competency of manufacturing complex injectable products.

- Australasia – Strides is present in this geography through a 57% stake in Ascent Pharmahealth with sales of >AUD 100m. Australasia region is the key branded market for Strides with presence in Australia and Singapore and five other emerging South East Asian markets including a manufacturing facility in Singapore. Ascent has 60 generic medicines registered in Australia and another ~400 prescription and OTC products registered across multiple South East Asian countries. Ascent is one of the top five generics companies in Australia. Strides believes that its future pipeline under registration and development includes all major product launches across the region through 2014.
- Africa – Currently, footprint spans West Africa, French Africa and Other Africa with 2009E sales of ~Rs1bn. While Strides has direct presence in some markets, it participates only in tender business in some others. Strides has 300+ registrations and the portfolio includes a mix of generics as well as branded products. The company has three dedicated manufacturing sites including one in Lagos, Nigeria.
- India – This is a relatively new business and was launched through the Rs1bn acquisition of Grandix two years ago. Grandix is currently generating revenues of ~Rs750m with a 400-people strong sales team and is currently focused on Southern India. Additionally, Strides has recently launched a specialty division catering to hospitals to leverage its strong injectables portfolio.

❑ Pharma business

This business largely comprises Strides' oral products business across AIDS, TB and Malarial therapies. Strides has contractual agreements with global aid and charitable organizations like UNICEF, PEPFAR, Clinton Foundation as well as a JV with Sandoz for TB products which provides some growth visibility. On the manufacturing front, this business division has soft gel capacity based in Bangalore and a semi-solids facility in Milan, Italy. We estimate this business to have revenues of Rs4bn in with ~10% EBITDA margins (profitability impacted by lack of vertical integration).

While Strides' growth agenda for this business involves developing products in niche segments like Vitamin Analogues, Immunosuppressants, Hormones, etc and licensing products to large global players, we believe it is not the focus area in terms of investments for future growth.

❑ Expect partial/ full divestment of stakes in these entities

The restructuring exercise to align the business across three distinct groups, we believe, paves the way for Strides to enhance its focus on the specialty business and unlock value in the pharma as well as branded formulations business. As has been speculated in the media for a while now, we anticipate partial/ full divestment of stake in one or more of these divisions over the next few quarters/ years. This will also enable Strides to reduce the gearing on its balance sheet.

HISTORICAL FINANCIALS: AN AGGRESSIVE INVESTMENTS STRATEGY

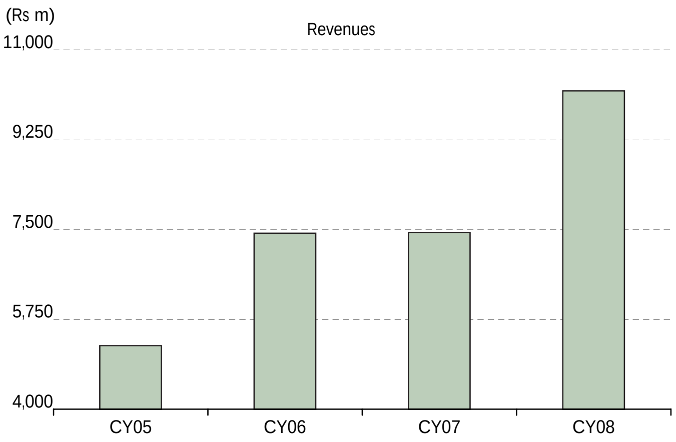
Over the last few years, Strides has been aggressively investing in building sterile manufacturing capacities while expending resources in developing a comprehensive steriles ANDA portfolio. As is endemic to such aggressive growth strategies involving significant upfront investments, Strides has been saddled with high debt and relatively limited operating profits as revenues have yet begun to scale up.

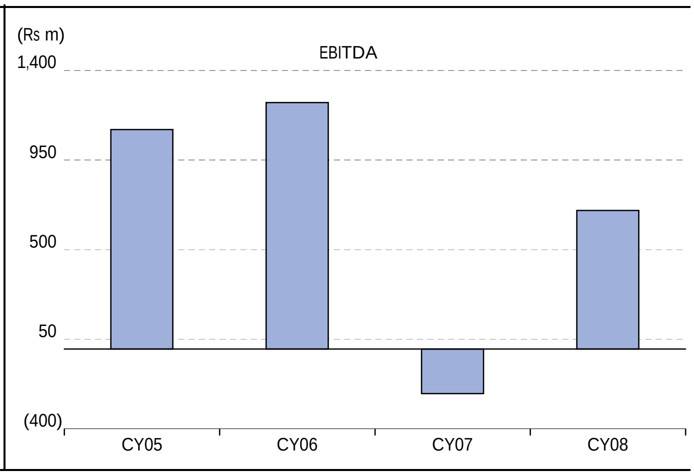
❑ Revenues have shown 25% CAGR over CY05-08; EBITDA has not kept pace

Strides has registered 25% revenue CAGR over CY05-08, though operating profits have not quite kept pace. A sharp variances in raw material, personnel and other expenses (as % of sales) over the last four years has imparted volatility to operating margins – and thereby cash flows. Strides' raw material and other expenses (as % of sales) have varied by 1200bp over CY05-08 – leading to marked fluctuations in margins.

2008 annual results were impacted by a slew of significant non-recurring items including Rs2.5n gain on sale of assets and net forex gains of Rs654mn along with Rs1.6bn impairment charge on investments.

Exhibit 9: Operating profits not keeping pace with revenue growth





Source: Company, IDFC-SSKI Research

Exhibit 10: Summary 9MCY09 financial performance

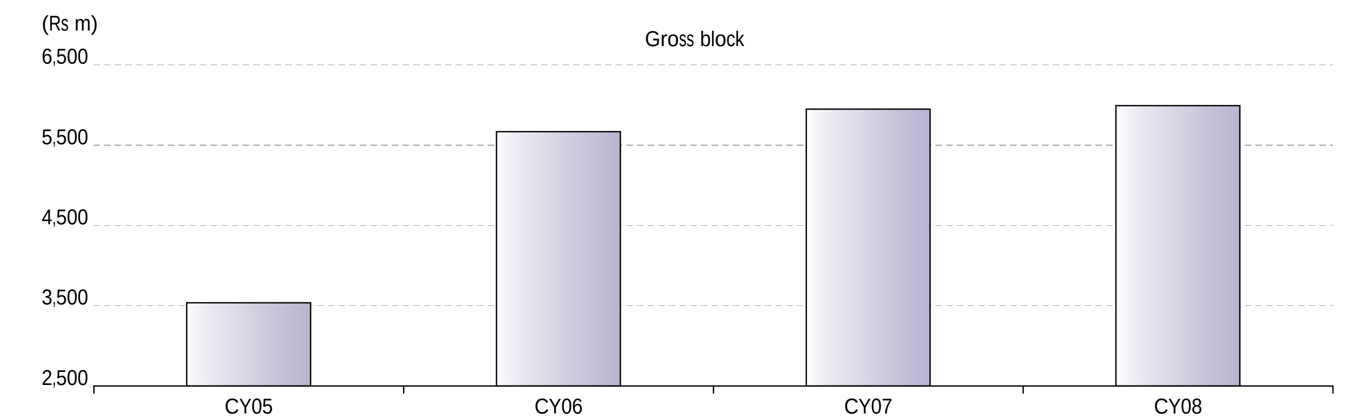
(Rs m)	2QCY08	3QCY08	4QCY08	1QCY09	2QCY09	3QCY09
Net sales	2,554	2,721	2,859	2,843	3,098	3,171
Other operating Income	-	42	-	74	12	20
Other income	138	1,706	1,176	109	462	108
Total income	2,691	4,469	4,035	3,025	3,572	3,299
PBIDT	(219)	1,259	523	405	807	500
Interest	99	148	448	194	181	208
PBDT	(318)	1,111	75	211	626	292
Depreciation	108	75	114	101	116	120
Tax	51	6	8	8	67	(49)
Reported PAT	(484)	1,030	(47)	102	443	221
Adjusted PAT for extra-ordinary items	225	1,678	(11)	122	17	124

Source: Company

❑ Gross block has grown 4x over CY04-08

Strides' aggressive growth strategy – involving significant upfront investments – has led to ~4x increase in its gross block in the last four years. However, with operating cash flows lagging the aggressive investments, the company has seen a steep rise in its debt over the period.

Exhibit 11: Gross block bloats 4x in four years

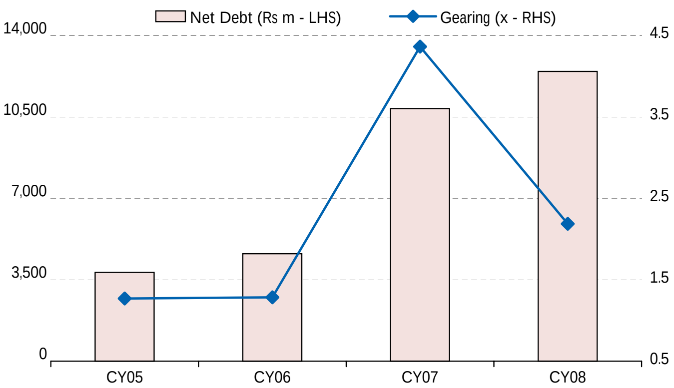


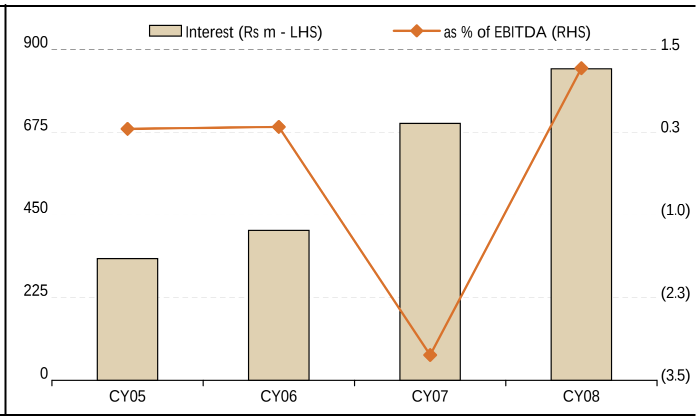
Source: IDFC-SSKI Research, Company

❑ Aggressive upfront investments have strained the balance sheet

Strides' persistent focus on investment-led growth without adequate internal cash flow generation and equity dilution has resulted consolidated debt ballooning by ~3x over CY05-08 to Rs12.5bn (including Rs2bn of working capital debt) with FCCBs accounting for Rs7.2bn of this. Increase in debt has not just resulted in a steep decline in Strides' interest coverage ratio from ~2.6x in CY05 to ~0.35x in CY08 but also eroded its profitability. Interest costs accounted for a significant 80% of EBITDA generated over CY05-08.

Exhibit 12: Interest cost accounted for ~80% of EBITDA over CY05-08





Source: Company, IDFC-SSKI Research

On the positive side, majority of the capex is behind and with steady revenue expected from supply agreements CY11 onwards as also hefty licensing incomes, debt/ interest costs would likely decline steadily in the coming years.

❑ Redemption of 2010 April FCCB bonds implies cash outflow in the near term

Exhibit 13: Two outstanding FCCB issues as of date

Bonds issued	Value	Date of conversion	Outstanding amount
0.5% FCCB	US$40m	Apr-10	US$34m
Zero-coupon FCCB	US$100m	Jul-12	US$80m

Source: IDFC-SSKI Research

Around $34m worth of 0.5% FCCBs (conversion price Rs358.7) are due for redemption in April 2010 and will entail cash outgo of ~Rs2.2bn ($47m). Aided by the licensing income inflow expected in the near term, we understand Strides is adequately prepared to manage the cash outflow. This event will provide enough breathing space to the management to repair the balance sheet as the next major potential cash outflow will happen only in July 2012 if the 2012 FCCB issue is not converted by then

❑ Equity structure

Presently, Strides has 40.2mn shares. During May 2009, the company has issued 6.2mn preferential warrants to the promoter group convertible into shares @Rs91.15/ warrant. Conversion of the warrants will expand the capital base to 46.4mn shares and increase the promoter stake to 36% from 26% currently. If the pending $80mn 2012 FCCB (conversion price of Rs462/share) gets fully converted, the fully diluted equity will be 53.5mn shares.

Income statement

Year to Dec 31 (Rs m)	CY05	CY06	CY07	CY08
Net sales	**5,237**	**7,430**	**7,443**	**10,203**
% growth	-	*41.9*	*0.2*	*37.1*
Operating expenses	4,135	6,192	7,667	9,507
EBITDA	1,103	1,238	(224)	696
% growth	-	*12.3*	*(118.1)*	*(410.5)*
Other income	56	172	1,254	3,574
Net interest	(331)	(408)	(699)	(847)
Depreciation	236	336	377	401
Pre-tax profit	592	666	(346)	1,149
Deferred Tax	(18)	61	(67)	(24)
Current Tax	52	112	238	131
Profit after tax	558	492	(516)	1,041
Minorities	-74	-90	15	39
Non-recurring items	2	-	0	-
Net profit after non-recurring items	486	402	(501)	1,080
% growth	-	*(17.1)*	*(224.5)*	*(315.4)*

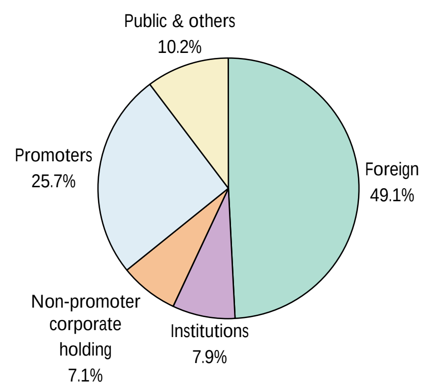
Key ratios

Year to Dec 31	CY05	CY06	CY07	CY08
EBITDA margin (%)	21.1	16.7	(3.0)	6.8
EBIT margin (%)	16.6	12.1	(8.1)	2.9
PAT margin (%)	9.2	5.4	(6.7)	10.6
RoE (%)	28.1	10.4	(13.9)	24.3
RoCE (%)	21.1	9.6	(4.4)	1.6
Gearing (x)	1.3	1.3	4.4	2.2

Valuations

Year to Dec 31	CY05	CY06	CY07	CY08
Reported EPS (Rs)	13.9	11.5	(14.3)	27.0
PER (x)	21.2	25.5	n/a	10.9
Price/Book (x)	3.0	2.4	3.5	2.0
EV/Net sales (x)	2.8	2.1	2.9	2.6
EV/EBITDA (x)	13.1	12.5	(95.0)	37.4
EV/CE (x)	1.8	1.5	1.3	1.3

Shareholding pattern



As of December 2009

Balance sheet

As on Dec 31 (Rs m)	CY05	CY06	CY07	CY08
Paid-up capital	841	841	842	892
Reserves & surplus	2,263	2,939	1,924	3,262
Total shareholders' equity	3,441	4,299	2,929	5,956
Total current liabilities	1,103	1,771	3,720	3,599
Total Debt	4,370	5,519	12,774	13,020
Deferred tax liabilities	129	196	107	87
Other non-current liabilities	293	476	801	611
Total liabilities	5,894	7,962	17,402	17,317
Total equity & liabilities	**9,335**	**12,261**	**20,331**	**23,273**
Net fixed assets	3,837	5,816	7,428	6,385
Investments	0	15	19	3,464
Total current assets	4,216	4,735	7,353	7,475
Deferred tax assets	-	-	3	43
Other non-current assets	1,281	1,695	5,527	5,905
Working capital	3,114	2,964	3,633	3,876
Total assets	**9,335**	**12,261**	**20,331**	**23,273**

Cash flow statement

Year to Dec 31 (Rs m)	CY05	CY06	CY07	CY08
Pre-tax profit	592	666	(346)	1,149
Depreciation	236	336	377	401
Chg in Working capital	(2,559)	495	348	(1,591)
Total tax paid	(52)	(112)	(238)	(131)
Ext ord. Items & others	293	183	325	(190)
Operating cash Inflow	(1,489)	1,568	466	(363)
Capital expenditure	(5,354)	(2,729)	(5,821)	264
Free cash flow (a+b)	(6,843)	(1,162)	(5,355)	(99)
Chg in investments	(0)	(15)	(4)	(3,445)
Debt raised/(repaid)	4,370	1,149	7,255	246
Capital raised/(repaid)	841	-	1	50
Dividend (incl. tax)	(58)	(82)	(131)	(7)
Misc	2,246	454	(747)	1,906
Net chg in cash	556	345	1,018	(1,348)

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Explanation of Ratings:

1. Outperformer: More than 5% to Index
2. Neutral: Within 0-5% to Index
3. Underperformer: Less than 5% to Index

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