

Strides Shasun AR 2017 Analysis

About Company:

- Headquartered in Bangalore.
- A vertically integrated global pharmaceutical Company.
- Develops and manufactures a wide range of IP-led niche pharmaceutical products for regulated and emerging markets.
- Scaling over-the-counter (OTC) franchise across key regulated and emerging markets.
- Well-diversified consumer facing business in regulated and emerging markets.
- Vertically integrated manufacturing infrastructure with key regulatory approvals.
- Six FDF facilities in India, Europe and Africa (four USFDA approved).
- Three USFDA approved API facilities in India.
- Two dedicated R&D facilities in India with global filing capabilities.
- Capabilities in multiple delivery technologies and dosage formats.
- Portfolio across topicals, liquids, creams, ointments, soft gels, hard gels, sachets tablets and modified release formats.
- Experienced and proven management team with strategic oversight of a reconstituted Board.
- Strong compliance environment with impeccable regulatory track record.
- Technology-led control on operations, quality and data management.

Vision:

To be the leading Indian pharma multinational with a reputation for the highest quality and integrity.

Mission:

With a **differentiated B2C portfolio** focused on attaining leadership, we will provide an **unparalleled growth opportunity** for our people and **value creation opportunity for our stakeholders**.

Some Important Facts:



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FY17 Operational Highlights:

- The regulated market business continued to witness robust growth, as co increased market share of all key products, including Dutasteride, Ergocaliferol, Methoxsalen in North America.
- Co. commercialised Ranitidine, the first integrated product approval from Strides, which garnered a significant market share.
- Co. received six new product approvals during 2016-17.
- New product filing momentum picked up on the back of R&D investments which nearly doubled.
- In Australia, co has strengthened it's business with the launch of twenty new products during FY 2016-17.
- Co continued to expand it's product portfolio, including new products from Generic Partners.
- Strides expanded it's pharmacy coverage in Australia through the fast growing Pharmacy Alliance franchise, and consolidated it's position as a leading generics company.
- The emerging market business saw strong growth, driven by contributions from Kenya.
- The Africa Brands business delivered steady performance, despite a volatile operating environment.
- Co added more than 50 medical representatives in Africa taking total field force strength to more than 250.
- India Brands business remained subdued, owing to the impact of demonetisation and uncertainty around GST implementation.
- The Institutional Business sustained its market share in the donor funding programmes.
- Antiretroviral (ARV) business continues to witness healthy traction whereas the Malaria business was lower on account of reduced funding.
- Key to achieve the guidance is to get the product approvals. Unfortunately, co did not receive any of the key product approvals, which were factored in co's profitability. Despite the scenario, co achieved 95% of guidance.
- Strategy is to build an integrated, customer-facing, B2C business, with a diversified portfolio and the highest standards of quality and compliance integrity in the industry.
- Strides 2.0 is a company that is Direct. Diversified. Driven.
- ***Snapshot of key highlights of 2016-17 –***

Positives

- o Invested for the future (capex of US\$ 58 million towards compliance and capacity enhancement);
- o Strengthened the balance sheet; comfortably placed on capital structure with debt to EBITDA < 3x post Biotech carve out;
- o Completed Mylan settlement with successful closure of regulatory Escrow arrests uncertainly, received US\$ 28.33 million inflows;
- o Completed first full year of Arrow integration; strong financial controls in place, on the way to execute the long-term strategy.

Negatives:

- o Delay in product approvals;

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- Significant PBS impacts dented Arrow performance;
- Challenging year in terms of increased investments in R&D and capex and working capital needs at the same time;
- Linearity in R&D filings will need few more quarters;
- Synergy benefits taking more time.

Top Priorities:

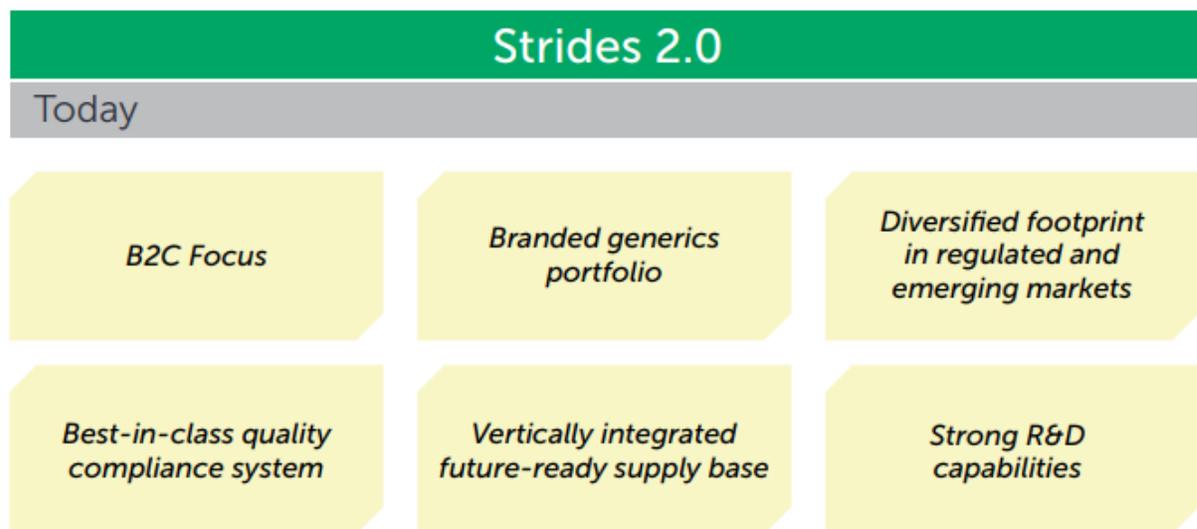
- A close watch on Australian investments, overall profitability and EPS accretion, tight working capital management, GST implementation, integrated R&D filings and complete all corporate actions in time.

Strides Shasun 2.0 (*direct, diversified, driven company.*)

- Strides Shasun 2.0 will make company well-diversified, fully integrated, consumer-facing formulations player with focus towards regulated markets.
- During the year, management reconfigured co's business priorities in line with the broad trajectory of the global pharmaceutical industry. They have now formulated a direct market approach to further strengthen co's core business and shape Strides 2.0.
- Management announced their intent to demerge co's Commodity API business to Solara Active Pharma Sciences Limited (Solara). The human API business of SeQuent Scientific Limited (a promoter owned listed company) is also proposed to be carved out and merged into Solara. The combined entity, to be listed in the BSE and NSE, will be one of India's largest API companies.
- Solara will be among the leading standalone listed API companies in India.
- Given the B2C strategy, co has capped equity infusion in bio-generics business for a significant minority stake.
- At a later stage, co will unlock significant value, when commercial revenue generation starts.
- Focus is to build a vertically integrated, consumer focused global formulations company.
- Focus is on a fully integrated consumer facing business, which is IP led.
- It will be backed by a robust portfolio with a focus on aggressive market expansion, supported by a strong balance sheet.
- Business includes a leading position in Australia under Arrow, a growing US front-end business, backed by a strong IP-led portfolio.
- On the other hand, emerging markets business will include our branded business in Africa, India and Southeast Asia.
- Co has a fully compliant and globally diversified manufacturing footprint.
- A robust pipeline of products to benefit from faster approvals under the new GDUFA guidelines.
- Co has developed a portfolio of niche products with a high-entry barrier.
- Future growth will be driven by new products and market share gain of our key products.
- Under Strides 2.0 strategy, co exited from the low-margin generics business in Africa.
- Focused on a more dependable branded generics business in attractive therapeutic segments.
- Brands are now promoted by a powerful over 1,000-member sales force in Africa and India to medical practitioners.

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- Strides Shasun 2.0 is direct, driven and diversified will continue to create new growth frontiers.
- Focus is to execute the Strides 2.0 strategy by –
 - o Stepping up US new product filing to 15-20 per year.
 - o Expanding portfolio and goto-market footprint in Australia Sales force productivity in Emerging Markets.
 - o Highest standards of quality and compliance integrity.
 - o Competitiveness driven by best in-class efficiency.
 - o Co has the building blocks in place, a winning team, a shared vision and the passion to excel.
 - o ***Strides 2.0, is a direct, diversified, driven company.***



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Shaping Strides 2.0

Organic and inorganic strategies enabled us to attain critical mass



2014-15

- Merger with Shasun for access to pipeline and supply chain security
- Set up R&D base from scratch (previous R&D set up was part of divestments)

US\$ **190** Mn

Revenue (FY2014-15)

US\$ **425** Mn

Market Cap (March 2015)



2015-16

- Acquisition of Universal Corporation in Africa to rewire 'In Africa For Africa Strategy'
- Brand acquisitions in the US and emerging markets to strengthen product offering
- Re-entered Australia through Arrow. Bolt on acquisitions of Generic Partners, Pharmacy Alliance

US\$ **440** Mn

Revenue (FY2015-16)

US\$ **1.5** Bn

Market Cap (March 2016)



2016-17

- JV with Vivimed for its US FDA formulations facility, provides access to pipeline and de-risked manufacturing
- Proposed demerger of B2B oriented commodity API business*
- Acquisition of USFDA approved multi product API facility from Perrigo for integrated products
- Exit from CRAMS, Sale of Africa generics manufacturing business and capping investment in Stelis Biopharma

US\$ **524** Mn

Revenue (FY2016-17)

US\$ **1.5** Bn

Market Cap (March 2017)

* Subject to requisite approvals

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Key Highlights From Founder Chairman's Letter:

- After 27 years as CEO he has moved on to a more strategic role as the Chairman of the Board.
- Passed on the baton to Shashank Sinha, who has joined the Group a year ago.
- Reconstituted Board to guide the management to take the business to greater heights.
- Management has realigned business priorities in line with the broad trajectory of the global pharmaceutical industry.
- Price-based competition does not have significant impact on business considering co's business is diversified with presence in Australia, the US, Europe, Africa and India.

Key Highlights From Managing Director's Letter:

- Co initiated the technology transfer of key products to its WHO approved facility of Universal Corporation in Kenya; and management hope to commence supplies by the second half of FY18.
- The API portfolio was focused on driving volume led pricing discipline, which enabled it to deliver superior margins.
- Management scaled up new product filing for high-entry barrier markets such as Japan and Korea.
- R&D investments are fully deployed to build the future product pipeline.
- Co made nine new product filings during the year.
- Formulation and the API R&D teams worked on a joint development platform to build a portfolio of integrated products.
- Management expects new product filing momentum to double as the pipeline is healthy and approval timelines have reduced.
- During the year company set up a consumer healthcare vertical.
- Subodh Marwah joined as Group President – Consumer Health Care.
- Rahul Maitra joined our leadership team as CHRO (Chief Human Resources Officer).

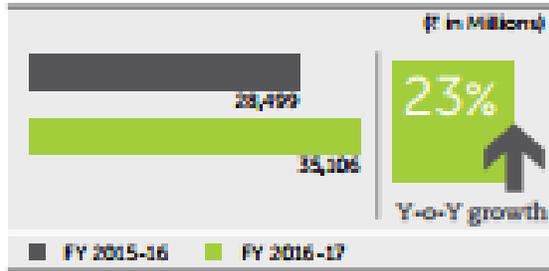
Key Highlights From CFO's Letter:

- FY17 was characterised by Volatility, Uncertainty, Complexity and Ambiguity.
- There were many challenges, both internal and external.
- Management has executed 'multiple actions in multiple directions' since there were many moving parts in the Company.
- The external challenges were characterised by wild forex movements, tough pricing environment, demonetisation, tepid growth in emerging markets, slow regulatory approvals, GST implementation, PBS reforms in Australia, low investor confidence in the healthcare sector, the US elections and the overall credit squeeze.
- The internal challenges comprised formulating appropriate strategies to improve business profitability, second round of restructuring to position the Company from B2B to B2C, increase in R&D investments to accelerate future growth, build capacities, achieve synergies for past acquisitions, handling US FDA inspections, meeting the ever-increasing demand of compliance; and above all setting up a right process for handling diverse businesses with different drivers.

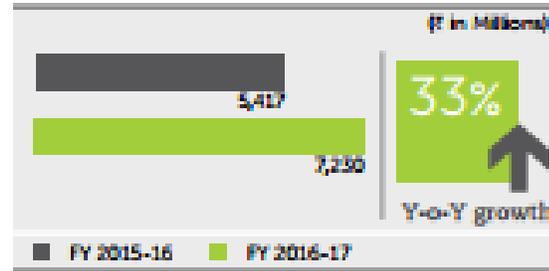
Financials:

Consistent performance

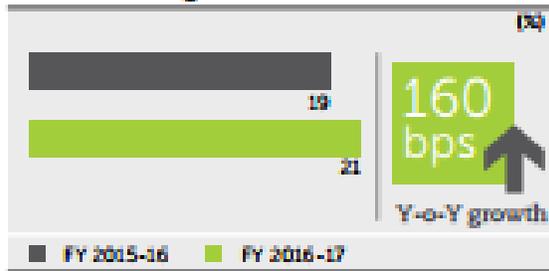
Pharma Revenue



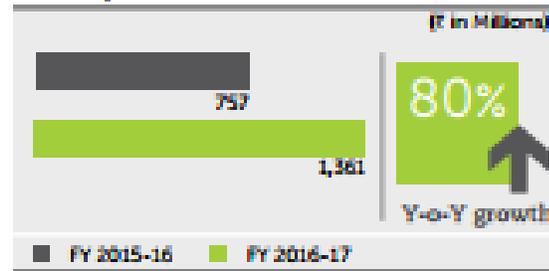
Pharma EBIDTA



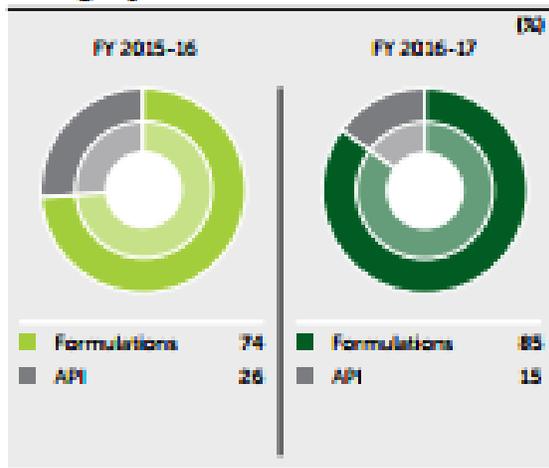
EBIDTA Margins



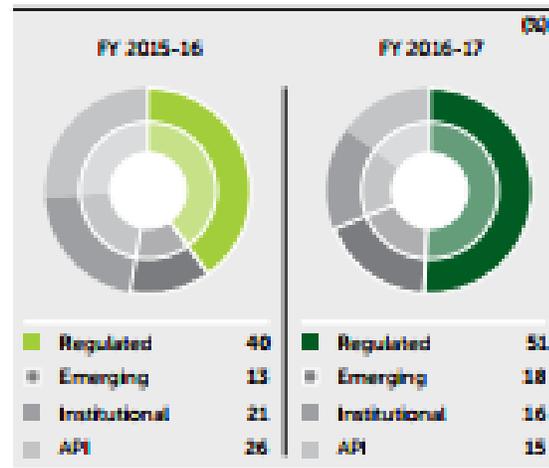
R&D Spend



Category-wise Revenue



Business-wise Revenue



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What are the growth drivers?

- Quality Compliance.
- Cost Focus.
- R&D Execution.
- Proven Management.
- Team Winning Culture.

Market wise strategies and growth drivers:

- Diversified B2C business model with front-end presence across regulated and emerging markets.

Regulated markets:

- Front-end presence across Australia, USA and The United Kingdom.
- Extensive product portfolio for Rx and OTC across various dosage formats.
- Five USFDA approved facilities in India, Europe, upcoming regulated market facility in Singapore. Expected to come on-stream in late 2017.
- Capacity of 15-20 ANDA filings per annum.

Emerging markets:

- Focus on front-end markets of Africa and India with a portfolio of branded generics.
- 'In Africa for Africa' strategy with the acquired facility of Universal Corporation, Kenya.
- 1,000+ sales force promoting brands to medical practitioners.
- Catering to donor-funded programmes using local facilities.

R&D Capabilities and Compliance:

- Modelled on Full Time Equivalence (FTE) structure for improved efficiency and increased scientific collaboration.
- Focus on difficult to-develop and differentiated products.
- Capable of developing and filing products for all regulated markets.
- R&D investments commitment of US\$ 30 million per year.
- Four of the last five USFDA audits cleared with Zero 483s.
- Structured approach of product development and lifecycle management embedded with Quality by Design.

Geographically strategies:

United States



Focus on niche segments and a differentiated portfolio

- Concentrate on niche, low competition, high-technology barrier products built around modified release, soft gel capsules, topicals and integrated products
- Emphasise on the OTC franchise
- Target of 15-20 filings every year benefiting from new GDUFA regulations

Australia



Reaching a leadership position in generics and OTC

- Secure market leadership in Australia in three years
- Expanding our portfolio and go-to-market footprint
- Enhance pharmacy coverage as first-line generics with high loyalty across
- Site transfer product portfolio (in-house) will expand margins

European Union



Driving momentum on the UK front-end and partnership in EU

- Improve product range through global regulated market portfolio
- Increase coverage by expanding front-end presence in the UK
- Carry own IP generics to rest of Europe with strategic partnerships

Africa



'In Africa for Africa' theme with focus on branded generics

- Develop as a Sub-Saharan Africa branded generic player with leadership position in key markets and therapies
- Focus on lifestyle chronic therapies, driven by brands
- Enhance sales force productivity

India



Gaining traction with focus on select therapies

- Focused attention on high-growth areas of Central Nervous System (CNS), diabetes, cardiovascular, women's health and pain management
- Develop a portfolio of strong brands
- Foray into high-growth OTC segment, including Rx to OTC switch
- Enhance sales force productivity

Institutional Business



Focus on backward integration

- Develop next generation products as per donor agency guidelines driven by enhanced R&D expertise
- Leverage strong visibility with innovator organisation to be amongst the first wave of launches in select emerging markets

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Regulated market strategy (US + UK + AUSTRALIA)

Strides have a strong product portfolio in the regulated markets of North America, the UK and Australia.

US:

- Strides have 38 products approved for commercialisation in the US.
- Some of the key products are vancomycin, ergocalciferol, benzonatate, calcitriol, ibuprofen, ranitidine, methoxsalen and dutasteride.
- Co has two Para IV ANDAs with tentative approvals for the United States - roflumilast tablets and fingolimod capsules.
- Management's primary focus is to capitalise on co's existing product portfolio and pipeline for North America and Australia, for increased crossselling opportunities.
- In the United States, co's strategy will be to focus on growing as a niche player with a portfolio of small off-patent products.
- From FY18 onwards, management aims to target approximately 15-20 ANDA filings annually to drive growth and help co to gain market share in the limited competition products.

UK:

- Co has a diversified product portfolio in generics and OTC segments in the UK, spanning wide ranging therapies.
- Strides has filed the first modified release product under article 8.3 in Europe, which is Ibuprofen 300 mg Prolonged Release Tablets.
- Strides will continue to adapt to the regulated markets in Europe, including the United Kingdom.

Australia:

- Co enjoys a strong portfolio of Rx and OTC products.
- Strides also own Chemists' Own OTC brands, which include a portfolio of cough, cold and flu, analgesics, sun care, smoking cessation, digestive health, anti-infective and allergy medicines.
- Co will concentrate on adding new products to its current portfolio, including in-licensing products, which will be going off patents in the next few years.
- In the OTC segment, co intends to capitalise on Nuprin® brand, Jointflex and Pediacare globally.

Emerging market strategy:

- Emerging markets strategy is focused on building a robust branded generics portfolio for the treatment of chronic therapies - including CNS, women's health, cardiovascular, probiotics, diabetes and dermatology.
- In the domestic market, Strides has established brands like Renerate®, Raricap® and Nuprin® in vitamin supplements, oral haematinics segments and pain management, respectively.
- In Africa, co has over 750 products registered. With strong front-end presence in Africa, co effectively meet local market preferences and drive sales growth and margins.

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- Going forward, management will expand Strides' product range in Africa with a pipeline of approximately 500 product registrations.
- Co will strengthen its presence across Africa's market by adding more feet-on-street.
- In India, co designs go beyond developing a portfolio of established brands in high-growth, niche therapeutic categories.
- Co has access to in-house API capabilities, which can be leverage by filing additional ANDAs to develop integrated portfolio.
- The integrated development approach ensures distinct advantages for the organisation.
- It helps to control quality attributes of key input materials and cost across product lifecycle; apart from de-risking supply chain challenges.
- Co started developing products that are backward integrated for a significant part of its generic formulations business.
- This strategy will improve its ability to maintain quality control, mitigate demand supply fluctuations in generics markets, and provide consistency and reliability of supply in an increasingly regulated global environment.
- Institutional business will be vertically integrated the manufacture of anti-retroviral and anti-malarial products.
- Management believes these products will improve ability to bid for institutional contracts and increase the scale of operations.

Solara Active Pharma Sciences Limited (Solara):

- During FY17, management announced their intent to de-merge Strides Commodity API business into Solara Active Pharma Sciences Limited (Solara).
- The human API business of SeQuent Scientific Limited (a promoter group listed company) is also proposed to be carved out into Solara, thereby providing critical size to this business.
- Solara will emerge as one of the largest standalone API companies in India.
- With robust manufacturing facilities and a strong compliance culture, the business is suitably poised to grow sustainably.
- Solara will have a strong portfolio of DMF filings and will be complemented by five manufacturing sites (including three USFDA approved facilities) having key global regulatory approvals.
- In terms of the proposed scheme of arrangement, every shareholder of Strides Shasun will get 1 equity share of Solara for every 6 shares held by them in Strides Shasun.
- Solara has 5 manufacturing sites.

Growth drivers of Solara:

- Expanding size and scope.
- Diversified production units to mitigate regulatory risks
- Leverage on experience of parent companies - Strides and SeQuent
- Stay ahead of the curve on GMP and EHS requirements
- Integrate automation levels ahead of industry

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- Move up the value chain with focus on R&D
- Strengthen presence in high-entry barrier markets.
- Foray into advanced next generation APIs.
- Work on supply chain security with innovator and generic companies and evaluate profit sharing alternatives.

Diversified Portfolio:

- Management has steadily invested in a wide range of innovations to make Strides' portfolio of products diverse and differentiated in a competitive market scenario.
- Product innovation and reducing time-to-market are key elements of Strides R&D-led growth strategy.
- Strides is also leveraging combined global products portfolio and strengthening distribution network in markets.

Focus on product development

- Co. emphasise on legacy products, which enjoy limited competition and are growing presence in those product areas, where Strides is currently present.
- These are soft gel capsules, hard gel capsules, topicals and so on.
- Co is more focused on novel delivery systems for solid orals (modified release tablets and capsules) for both regulated and emerging markets.