



## **Investor Presentation**

September 2011

# inspiring synergies





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Local market value ('LMV") is provided as a reference for assessing the overall market value for a particular type of pharmaceutical product. It should not be considered as an indicator of Strides' sales of any its pharmaceutical products or the expected performance of such products in the future. Extrapolation of performance for a particular product from LMVs for such types of products, is an inappropriate use of LMV data. There can be no assurance that our approved pharmaceutical products will be successfully commercialized, or that our current filings will be approved



## Introduction

### **Company overview**



#### Overview

- A leading Indian Pharmaceutical company operating in two major segments: Specialties and Pharma
- Offers wide range of products covering Orals, Semi Solids and Specialty injectables including Beta-lactams, Cephalosporins, Oncolytics and Penems Has one of the largest Lyophilzation (freeze drying) capacities in the world Amongst the leading manufacturers of Soft Gelatin capsules in the world Partnerships with leading global players like Pfizer, GlaxoSmithKline, Aspen, Novartis, Sandoz, and Teva

#### Geographical presence: 14 manufacturing plants + marketing operations in 75 countries

Marketing presence

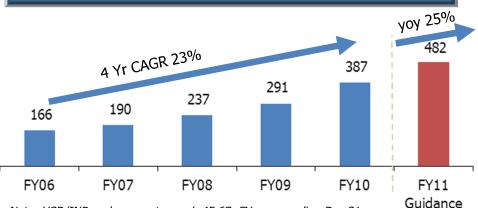
#### Plant locations

- 1. Campos, Brazil
- 2. Lagos, Nigeria
- 3. Bangalore & Mumbai, India 4. Milan, Italy
- 5. Warsaw, Poland
- 6. Jurong, Singapore

| 2009   | Revenue by geography <sup>(1)</sup> | 2010   | % Split | %Growth     |
|--------|-------------------------------------|--------|---------|-------------|
| US\$mn |                                     | US\$mn |         |             |
|        | Established Markets                 | 7      |         |             |
| 62     | Australia                           | 97     | 26%     | 56%         |
| 29     | North America                       | 86     | 23%     | 200%        |
| 30     | Europe                              | 41     | 11%     | 37%         |
| 8      | South Africa                        | 8      | 2%      | -1%         |
| 129    | Sub-Total                           | 232    | 62%     | <b>80</b> % |
| 157    | Emerging Markets                    | 139    | 38%     | -11%        |

Note: USD/INR exchange rate used: 45.67

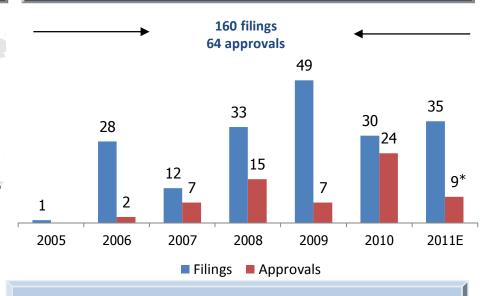
Note: (1) Does not include 'other income' of US\$ 5 mn and US\$ 15mn respectively



**Revenue growth (US\$mn)** 

Note: USD/INR exchange rate used: 45.67; FY: year ending Dec 31

#### Filings & approvals track record (ANDA)



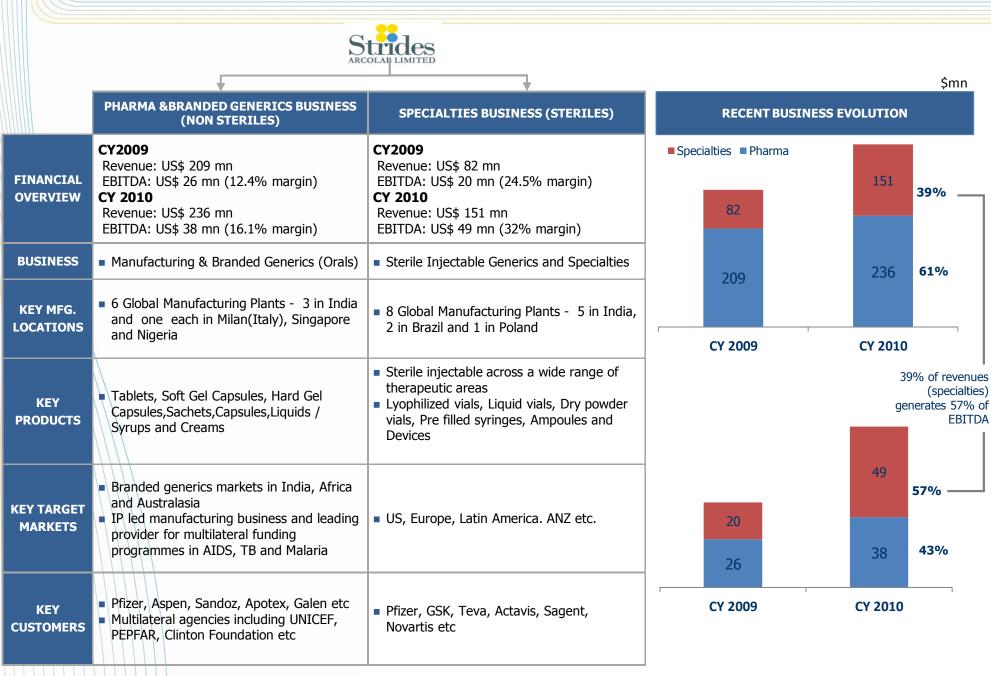
Amongst highest steriles approvals in the industry in 2010

\* Actual YTD



### **Strides Arcolab – Business Overview**





### **Strides – Key differentiators**



- Integrated capabilities spanning entire product development cycle
- Full services provider from identifying business opportunities to product approval and commercialization
- 2 Focus on R&D resulting in industry leading formulation expertise
- Proven R&D capabilities for developed markets
- Employs around 350 scientists in its R&D department, delivering average 35 ANDAs annually

- <u>Diversified portfolio across Specialties and</u> <u>Pharma offers stability</u>
- Offers wide range of products covering Orals, Semi Solids and Specialty injectables including Beta-lactams, Cephalosporins, Oncolytics and Penems
- Broad product portfolio is critical for getting GPO contracts in the US (Strides has a contract for sterile injectables with Premier)

Partnership with Big Pharma

- Partnerships with pharmaceutical majors such as Pfizer, GSK, Novartis, Teva & Aspen in US, Europe, Australia, LATAM, and South Africa
- Recent partnerships with Pfizer and GSK validates Strides' niche capabilities in sterile injectables and pharmaceuticals portfolio



- 5 Solid track record of regulatory compliance
- Successful inspections by USFDA/EMEA/PIC over the last few years.
- Continue to maintain strong track record in all Regulatory inspections.

#### Targeting products with significant demand

- Increasingly targets products that are (i) in short supply (ii) near term patent expiries (iii) difficult to manufacture segments
- Moving towards larger sized molecules

#### Solid track record of filings and approvals

- 160 ANDA filings (122 in steriles) and 64
   Approvals (41 in steriles) till date
- Branded generics product registrations:
   300+ in Africa, 60+ in Australia, and 400+ in eight South East Asian markets

- 5 <u>Significant investments completed in</u> <u>manufacturing facilities</u>
  - Significant investments completed in specialties space
  - Recently FDA approved facilities will accelerate the developed markets strategy





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### The core business going forward......

### **Steriles - Snapshot**

#### **Key strengths**

One of the most competitive steriles franchise globally with 8 manufacturing facilities

One of the largest lyophilization (freeze drying) capacities in the world

Full services player with a well diversified portfolio

Track record of filing average 35 ANDAs annually in the last three years

Significant investment in manufacturing facilities completed

Long term customer contracts and joint ventures to provide stable revenue stream

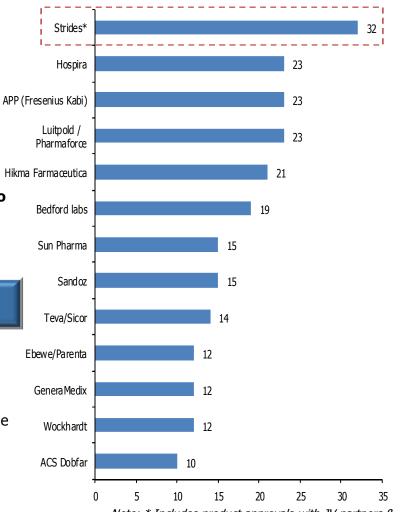
#### Product categories -Wide range

- High Potency Drugs (Oncology, Peptides and Controlled Substances)
- Antibiotics
- Penems & Penicillins
- Cephalosporins
- Suspension injections
- Oncology
- Ophthalmics and Peptides to be new domains

#### Packaging formats – All major types

- Vials Liquid & Dry Powder
- Pre filled syringes (PFS)
- Ampoules
- Market leading ability to package in lyophilized form
- Focus on pre filled syringes and lyophilized formats

### FDA injectables ANDA approvals by company 2008-2010



Note: \* Includes product approvals with JV partners & ANDAs sold to Pfizer in Dec 2010 Source: Approval data sourced from US FDA



### **Market Opportunity**

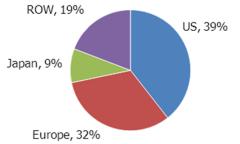
#### **Key industry trends**

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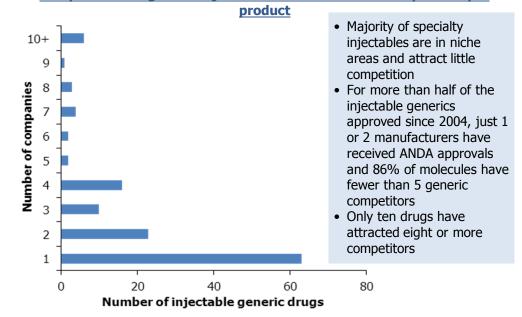
- Convergence of branded pharma and generics
  - Increasing investments by innovators in generics
- Injectables is the key growth area
- Oncology and generic biologics (biosimilars) hold significant potential
- Injectable oncology segment patents to expire by 2015, current market estimated @ USD 8.3 billion (*Source: IMS*)
- Regulatory pathways for biosimilars in developed markets being implemented
- Limited pricing pressure in generic injectables
- Limited injectable manufacturing capacities globally
- Major Injectable Manufacturers currently facing regulatory and compliance challenges with FDA

- Injectable market
- Overall injectable market @ US\$ 200bn for the year 2009

#### Break up by region (US\$mn) - 2009



Source: IMS Health as on 10 Aug 2010



Competition for generic injectables in the US – Few competitors per

Source: ESPICOM report titled "'Injectable Generic Drugs: Prospects & Opportunities to 2014"

Scarcity value in the injectables space leading to consolidation

| Year | Acquiror  | Target           | Deal size    |
|------|-----------|------------------|--------------|
| 2010 | Mylan     | Bioniche (USA)   | c.US\$ 550mn |
| 2010 | Recipharm | Madaus (Germany) | n.a.         |
| 2009 | Hospira   | Orchid (India)   | c.US\$ 400mn |
| 2009 | Novartis  | Ebewe (Austria)  | c.US\$ 1.2bn |
|      |           |                  |              |

Source: Deal announcements

### **Drug Shortages in US** 178 drug Shortage in US in 2010, majority of products are injectables

#### Shortages of drugs in US

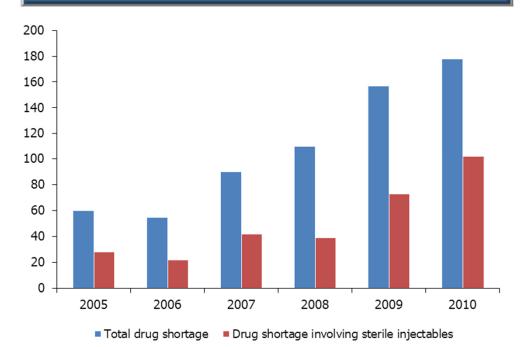
- 2010 102 (57%) drugs out of list of 178 drugs were steriles
- 2009 73 (46%) drugs out of list of 157 drugs were steriles
- 2008 39 (35%) drugs out of list of 110 drugs were steriles

#### Why shortages ?

- Process complexity & relatively long manufacturing lead time
- A limited number of companies are able to make sterile injectable products

### Strides' preparedness to meet steriles drug shortages in US

- Strides pipeline includes drugs which are part of FDA shortage list
- Strides launched Vancomycin through JV partner and later through Pfizer helped mitigating drug shortage situation



Data is from the Drug Shortage Program, Center for Drug Evaluation and Research, FDA and does not include shortages of vaccines, immune globulin products, or other biologic products that are managed by FDA's Center for Biologics Evaluation and Research

Source: The New England Journal of Medicine and Drug Shortage Summit Held in Nov'2010 organized by American Society of Health-System Pharmacists (ASHP)

### Total number of drug shortages and shortages involving sterile injectables drugs in United States, 2005-2010



### Strategy focusing on capturing higher value business and sustainable growth



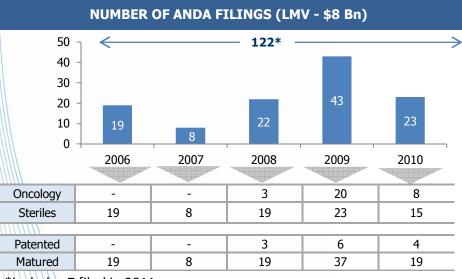
|   |                                | Phase-I<br>05-200 |             |                    |                        | hase-II<br>08-201              |                           |                                    | Current Phase<br>[2011-2015]  |
|---|--------------------------------|-------------------|-------------|--------------------|------------------------|--------------------------------|---------------------------|------------------------------------|---|
|   | Segment                        | Nos of<br>Filings | LMV<br>\$bn | Avg<br>LMV<br>\$mn | Segment                | Nos of<br>Filings              | LMV<br>\$bn               | Avg.<br>LMV<br>\$mn                | High value creation domains<br>Biosimilars  |
| PRODUCT<br>FILINGS  | Steriles                       | 27                | 0.7         | 26                 | Steriles               | 53                             | 3.3                       | 62                                 | <ul> <li>Devices and delivery systems</li> <li>Para IV &amp; 505b(2)</li> </ul>   |
|   | Oncology                       | -                 | -           | -                  | Oncology               | 33                             | 4.0                       | 121                                | To emerge as a first wave player  |
|   | Pens & Penems                  | -                 | -           | -                  | Pens & Penems          | 9 0.7                          | 0.7 78                    | for most products going off-patent |   |
|   | Total                          | 27                | 0.7         |                    | Total                  | 95                             | 8.0                       |                                    |   |
|   |                                |                   |             |                    |                        |                                |                           |                                    |   |
| Microsyle       Solution       121       Microsyle       Microsyle       121       Microsyle       121       Microsyle       121       Microsyle       121       Microsyle       121       for most products going off-particity         Pens & Penems       - </th <th>growth: Integrated Biosimilar,</th> | growth: Integrated Biosimilar, |                   |             |                    |                        |                                |                           |                                    |   |
| STRATEGY<br>11  | opportunisti<br>distribution   | c pro             | oducts      | with               | and Oncolog Partnering | y produc<br>with I<br>ex, Teva | cts<br>Big Ph<br>etc witl | arma's                             | <ul> <li>Strengthening partnership for<br/>new products/partners &amp; new<br/>Geographies</li> <li>Building front ending business<br/>in select geographies of USA,<br/>UK, Canada, Asia, Turkey,<br/>Indonesia, India, Nordic and<br/>Brazil</li> <li>Continuing Licensing<br/>opportunities in selected<br/>domains</li> </ul> |

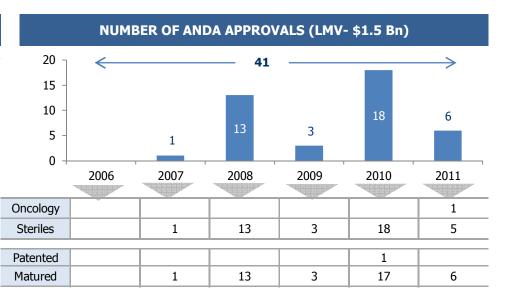
### **Agila Value Chain synergies for next level growth**



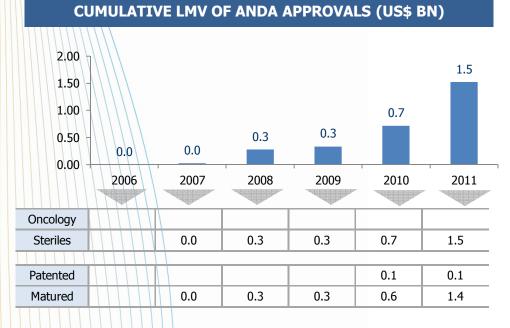
| Biologics            | <ul> <li>Expected Market to reach \$225 Bn by 2015</li> <li>Acquired 70% controlling stake in Inbiopro-a biotechnology focused company</li> <li>Immediate access to a pipeline of 8 products (including 5 MAB's), estimated to have global sales of US\$ 28 billion; commercialization expected to begin in 2013 in emerging markets</li> </ul> |
|----------------------|---|
| Front Ending         | Building frontend Sales and Marketing capabilities to capture market share in the<br>selected geographies of USA, Canada, Brazil, Nordic, South-East Asia, India, Turkey<br>and Indonesia   |
| Value Generics       | Creating portfolio of fewer but valuable products in R&D and to achieve capabilities<br>with first-to-file, Para-IV, delivery systems and devices   |
| Oncology             | <ul> <li>State-of-art manufacturing facility at Bangalore approved by all key Regulated agencies including USFDA with one of the broadest portfolio of Oncology products in the industry covering all major formats</li> <li>Global partnership with Big Pharma for established and emerging market</li> </ul>                                  |
| Penems               | <ul> <li>Top 3 Penems covering 90% of the Global Market in pipeline, 2 ANDA'a already filed awaiting approval</li> <li>Brazil Penem facility approved by major regulatory agencies like MHRA, ANVISA etc</li> <li>USFDA inspection in H2'11</li> </ul>  |
| Steriles Injectables | <ul> <li>Wide portfolio of injectable products including Cephalosporins, Beta-Lactum and<br/>Niche Steriles</li> <li>Marketing tie ups with Big Pharma for key geographies</li> </ul>   |

#### Increasing focus on high value products





\*includes 7 filed in 2011



#### Number of filings & Approvals in other Established and Emerging markets

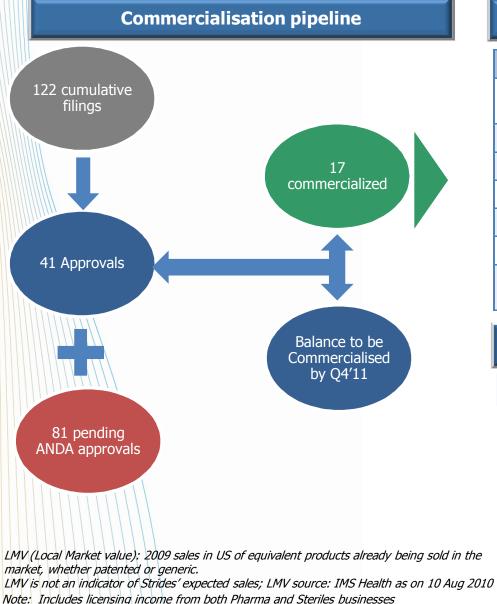
|               | Filings  |          | Appr     | ovals    |
|---------------|----------|----------|----------|----------|
|               | Steriles | Oncology | Steriles | Oncology |
| Europe        | 27       | 21       | 8        | 2        |
| Australia     | 18       | 8        | 14       | -        |
| South Africa  | 66       | 5        | 25       | -        |
| Canada        | 20       | -        | 19       | -        |
| New Zealand   | 1        | 2        | 1        | -        |
| Africa        | 145      | 4        | 119      | -        |
| Latin America | 181      | 2        | 151      | -        |
| ROW           | 211      | 85       | 109      | 11       |
| Total         | 669      | 127      | 446      | 13       |

13 Note: LMV (Local Market value): 2009 sales in US\$ of equivalent products already being sold in the market, whether patented or generic. LMV is not an indicator of Strides' expected sales;



### **Recent successes in line with new strategy**

#### Bulk of ANDA approvals yet to be commercialized



USD/INR exchange rate used: 45.67

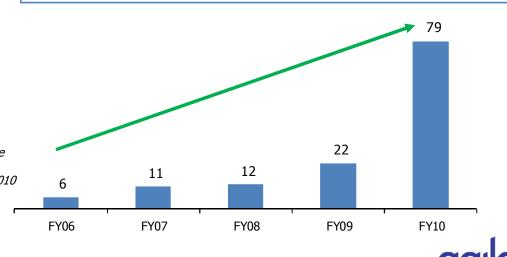
\*MAT IMS Sept'10

#### **Major Commercialized products**

|                                   | Vancomycin | Rifampicin | Azithromycin |
|-----------------------------------|------------|------------|--------------|
| Addressable market<br>value (LMV) | \$157 mn   | \$8 mn     | \$28 mn      |
| Partner                           | Pfizer     | Pfizer     | Sagent       |
| No. of Players                    | 7          | 3          | 6            |
| Filing year                       | 2006       | 2006       | 2007         |
| Approval date                     | Dec 2008   | May 2008   | Mar 2009     |
| Commercialized date               | Feb 2009   | June 2008  | April 2009   |
| Market share*                     | 11%        | 59%        | 18%          |

#### Licensing income (US\$mn)

#### **Received \$100mn licensing fee in year 2010**





### Global partnerships an endorsement of Strides' strong capabilities

#### **PFIZER**

#### Jan 2010: Collaboration on Generic Products

Pfizer to commercialize 40 off patent products (to be licensed / supplied by Strides) – primarily injectable cancer medicines to healthcare providers and patients in the United States

#### May 2010: Partnership strengthened

- Oncology products extended to EU, Australia, Korea, Japan and Canada
- Additional niche sterile injectable products included for the US market
- Collaboration now extends to a total of 45 products addressing countries across the globe

#### Dec 2010: Sold 22 ANDAs (16 approved)

Entered into long term agreement for manufacture and supply of these products

#### Why Strides?

- Strides is a powerhouse in the steriles injectable area
- ✓ Pfizer looked at more than 100 companies before settling on the deal with Strides
- $\checkmark$  This collaboration is new and exciting, and we are encouraged about the potential of this relationship
- ✓ We view this as a beginning of a partnership and look at Strides as a strong anchor point

Comments by: David Simmons – President & General Manager, Established Products Business Unit – Pfizer

#### **GSK**

- Deal is transformational for GSK (Source: GSK Press Release)
- GSK shares profits and pays licensing fees
- Arrangement for 95 countries worldwide
- First 10 products from Strides

### 🔜 Teva Novartis 🔜 Aspen **Apotex** Martindale **Sagent ICN**

**Other Global Partners** 

Sandoz

Actavis

#### Why Strides?

"This collaboration gives us access to a renewable, high quality and competitively priced source of branded pharmaceuticals in high demand therapeutic areas, Aspen, through its own pipeline and that of its join venture with Strides has a product portfolio of over 450 molecules and 1200 products which complements our own product portfolio and will enable us to deliver more medicines of value to more patients in these countries"

*Comments by:* Andrew Witty – CEO of GSK

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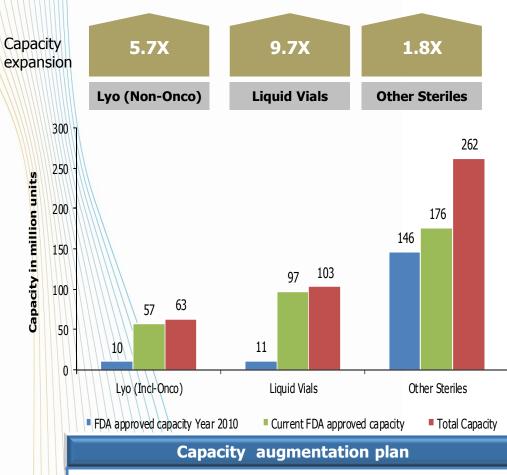
### **Biosimilars-Unfolding Opportunities**

| Market Overview                   | <ul> <li>Biologics* market expected to grow at a CAGR of 8%-10% during 2010 to 2025, against 4%-6% for total pharmaceutical market</li> <li>Biologics worth \$ 59 Billion to lose patent protection by 2015</li> <li>Biologics market expected to touch \$227 billion by 2015 against \$126 billion in 2009</li> <li>Biosimilars# market expected to touch \$13 billion by 2015</li> <li>6 Biosimilars already approved and commercialized in EU</li> </ul>   |
|-----------------------------------|---|
| Agila Foray into<br>Biosim Domain | Acquired 70% controlling stake in Inbiopro-a biotechnology focused company  |
| Competitive<br>Advantage          | <ul> <li>Immediate access to a pipeline of 8 products, estimated to have global sales of US\$ 28 billion, with commercialization expected to begin in 2013</li> <li>The products include 5 monoclonal antibodies which have use in cancer treatment further strengthening Strides' oncology products basket</li> <li>Facilities access to high expression mammalian and microbial platform-based capabilities</li> <li>High yielding cell lines in-licensed and improved upon</li> <li>Definite advantage in the biologics industry, which is characterized by specialized expertise in recombinant DNA technology and manufacturing process development with stringent and well defined regulatory guidelines , resulting in long gestation periods for product development</li> </ul> |



### **Significant FDA Approved capacities**

Capex towards 261m additional sterile units capacity completed and approved



✓ Executed agreement with Malaysian Bio-Xcell for establishment of customized facility to manufacture Biopharmaceuticals and sterile Injectables in the Bio-XCell ecosystem in Johor, Malaysia.

✓ Facility will be built by Bio-XCell to the design requirements of Strides and will be leased out to Strides on a long-term basis with lease rentals applicable from the date of commercialization.

| USFDA                           | Inspection Sta | otus            |
|---------------------------------|----------------|-----------------|
| Plant                           | Year           | Approval Status |
| Sterile Product<br>Division -I  | 2007, 2009     | Approved        |
| Penicillin                      | 2008           | Approved        |
| Cephalosporin                   | 2009           | Approved        |
| Sterile Product<br>Division -II | 2011           | Approved        |
| Oncology                        | 2011           | Approved        |
| Penems                          | Inspectio      | n by H2'2011    |

Well positioned in the industry where regulatory challenges are high

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# Benefits of operating leverage as new capacity supports roll out of new approvals

|                              |            | Ex                 | cisting faciliti   | es                  | New facilities     |                        |                    |                                     |
|------------------------------|------------|--------------------|--------------------|---------------------|--------------------|------------------------|--------------------|-------------------------------------|
| Manufacturing site pa        | articulars | Steriles           | Penicillins        | Cephalo-<br>sporins | Steriles           | Penicillins&<br>Penems | Oncology           | Poland                              |
| Location                     |            | Bangalore<br>India | Bangalore<br>India | Bangalore<br>India  | Bangalore<br>India | Campos<br>Brazil       | Bangalore<br>India | Warsaw<br>Poland                    |
| USFDA                        | Plant      | <b>~</b>           | <b>~</b>           | <b>~</b>            | <b>~</b>           | Awaited                | ~                  | Primary focus<br>on European<br>Mkt |
| approval<br>status           | Products   | ✓                  | Awaited            | Awaited             | ✓                  | Awaited                | ✓                  | EU approved<br>Plant                |
| Total capacity (mn<br>units) |            | 64                 | 33                 | 44                  | 140                | 66                     | 25                 | 56                                  |
| Filings (US)                 | Nos        | 55                 | 8                  | 5                   | 19                 | 2                      | 32                 | 1                                   |
| Approvals (US)               | Nos        | 39                 | Nil                | Nil                 | 1+39               | Nil                    | 1                  | Nil                                 |

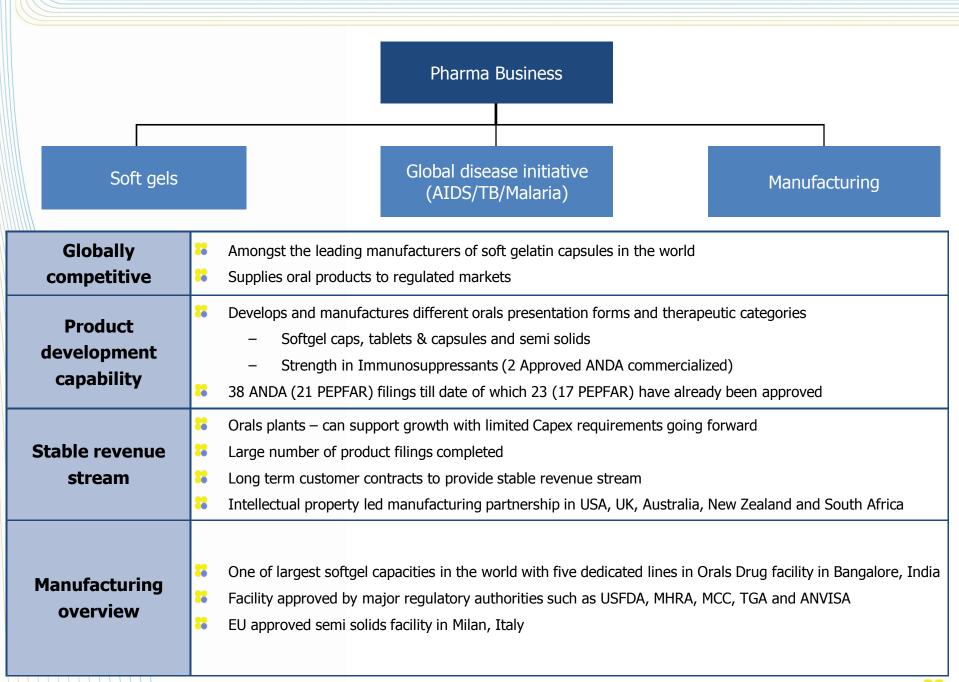
All FDA approved products can be moved from one FDA approved plant to another within 30-120 days



## **Pharma & Brand Business**

### Pharma business – A Snapshot







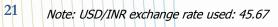
### **Branded generics business -snapshot** Regional Sales exceeding US\$165 million



Sti

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|               | Australasia   | Africa   | India  |
|---------------|---|--|--|
| Description   | Operating as Ascent Pharmahealth, a leading pharmaceutical, generic and consumer health company   | Leading player manufacturing and<br>marketing volume driven generics<br>and margins driven branded<br>products   | Emerging as a niche player in branded pharmaceutical products  |
| Manufacturing | Dedicated facility in Jurong, Singapore   | <ul> <li>3 dedicated facilities: 1 in Lagos,</li> <li>Nigeria and 2 in India</li> </ul>  | Orals plant in Bangalore also used<br>for manufacturing branded generics                               |
| Footprint     | <ul> <li>Australia (5<sup>th</sup> largest) &amp; Singapore</li> <li>(Largest) with growing operations in 5</li> <li>other Emerging South-East Asian markets</li> </ul>   | West Africa, French Africa & other parts of Africa   | Grandix has presence in 5 states in<br>South India   |
| Products      | Ethically promoted generic<br>pharmaceuticals, OTC and skincare<br>(prescription and consumer) products<br>with some well established consumer<br>brands such as Avene (Skincare), Hairy<br>Lemon (OTC) and Estelle (Prescription<br>medicine) and Dermorganics (Organic<br>Skincare) | <ul> <li>Branded generics, Commodity generics and OTC products marketed through own sales team in partnership with local distributors</li> <li>French Africa business is front ended comprising ethically promoted and OTC products</li> </ul> | Grandix covers therapeutic areas of diabetes, cardiovascular diseases, neurology and female healthcare |
| Sales         | S\$128mn  | S\$30mn  | S\$10mn  |
| Ownership     | <ul><li>94% Stake</li><li>Recently Privatized</li></ul>   | 100% stake   | 3 100% stake   |





### **Key Steps Towards Building Global Business**



#### 2009

#### • Merger of Subsidiaries –

(Grandix Pharmaceuticals, Grandix Laboratories, Quantum Remedies and Global Remedies were merged with Strides)

 Spin off of specialties and R&D businesses to Strides Specialties Private Limited, a wholly owned subsidiary 2010

#### • Building Specialties Organization

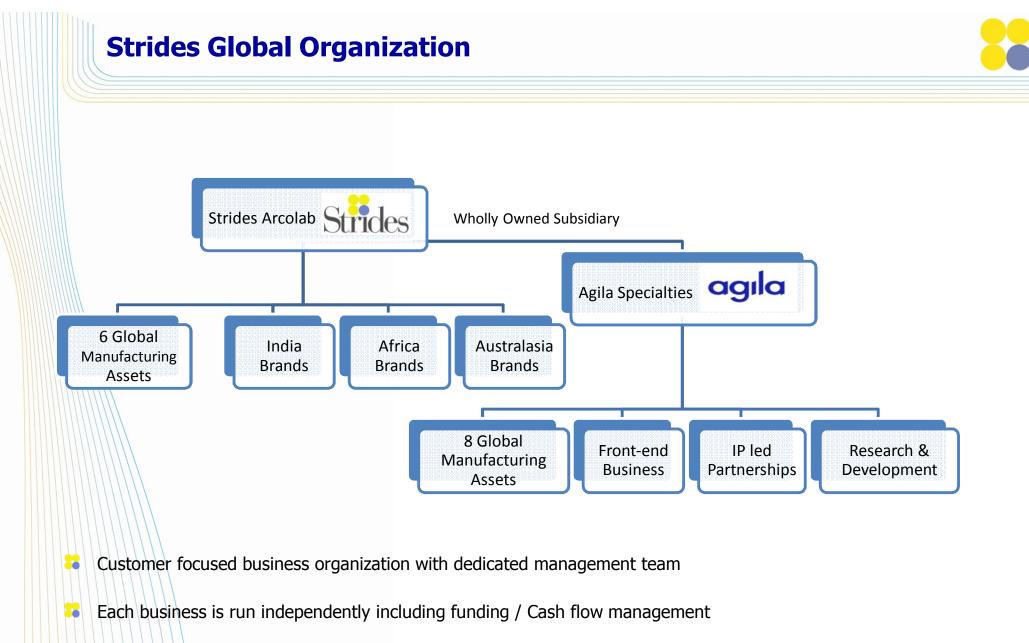
- Branding of specialty business as "Agila"
- Acquired Penems and Pencilian Plant in Brazil
- Acquired Aspen's Interest in Oncology JV
- Acquired Inbiopro , a biosimilar Portfolio

2011

- Privatization of Ascent
   Pharma, Australia , stake
   hiked from 60% to 94%
- Realignment of Investments to create global Phamra and Specialty Organization

Balance Sheet Size increased from USD 505 Mn to USD 976 Mn



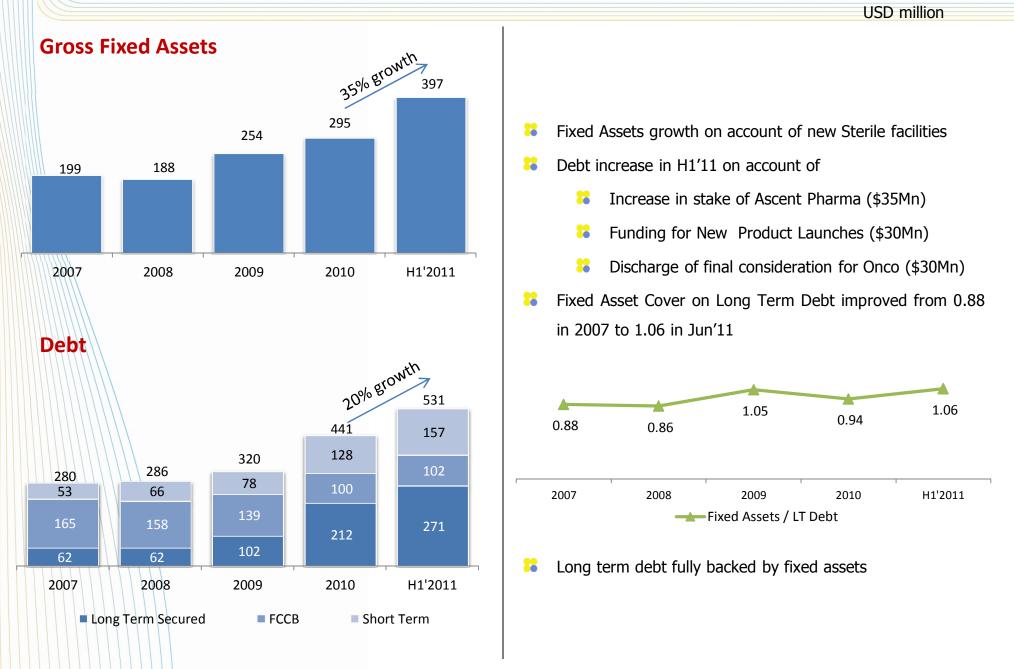


Implemented Shared Services Organization to achieve "Process Excellence" in transaction processing



### **Debt prudently employed to support Global Organization**

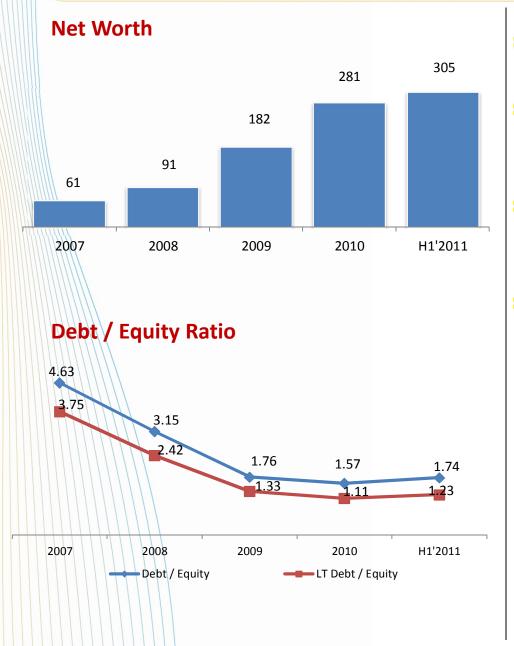






### Declining D/E while meeting demands of building Global Organization

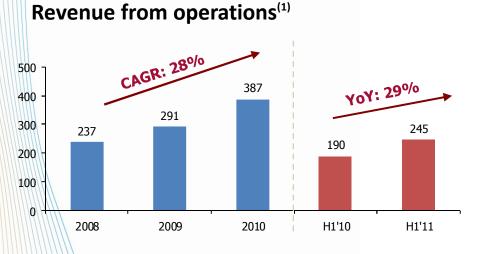
#### **USD** million



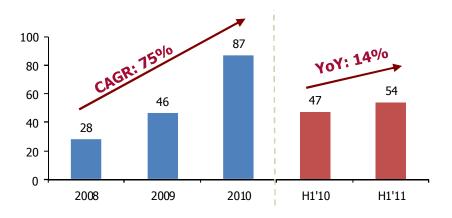
- Debt/Equity reduced from 4.63 in2007 to 1.74 in Jun'11
- Equity Infusion through QIP and Promoter's Capital in2010, to improve Debt/Equity
- Current Debt/Equity, a favorable capital structure for a high growth business
- Growth on Short Term Debt on account of enhanced working capital requirements to support high growth



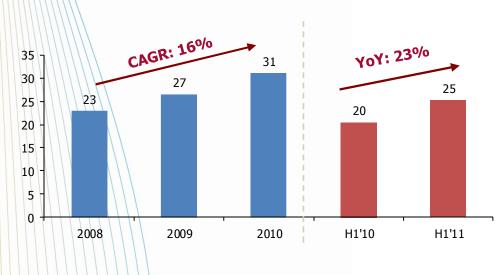
### **Key Performance Indicators**



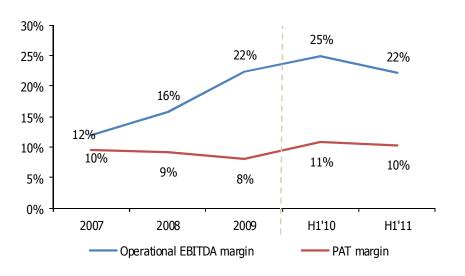
#### **Operational EBITDA**<sup>(1)</sup>



### Profit after tax



### Margins trend



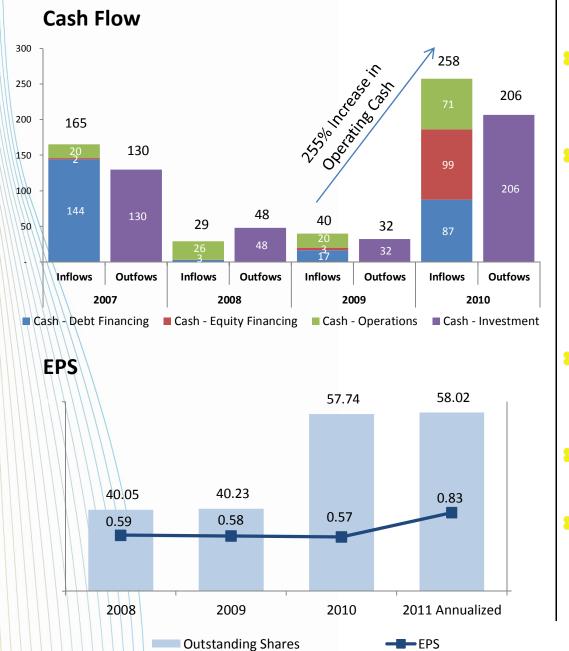
Note: (1) Excludes profit on sale of investment (c.US\$ 55mn in 2008) and exchange fluctuation gain on sale of investment (c.US\$ 10mn in 2008) All income statement items, USD/INR exchange rate used:45.59





### **Key Performance Indicators**

USD million



EPS

- 88 Significant Contribution of Cash from Operations in 2010
- 88 2010 Outflows for Investments include
  - 55 Oncology - \$87Mn
  - Brazil \$68Mn **55**
  - Inbiopro \$7Mn 88
  - Capex \$42Mn
- Stable EPS for last 3 years, inspite of EPS for 88 2010 and 2011 on a larger base of equity shares
- 88 2011 Annualized EPS at \$0.83
- EPS Accretion through acquisition of Minority 88 Interest of Ascent Pharma in Q2'11

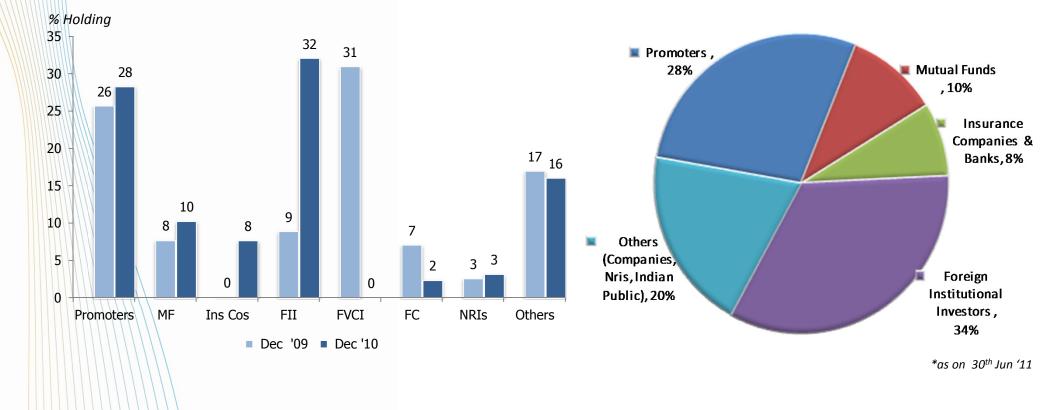


### **Market View**



#### Strong Institutional support for the stock

Shareholding Pattern



- Successfully placed \$100Mn QIP in 2010
- Increase in Outstanding Shares from 40Mn in Dec'09 to 58Mn in Dec'10



## **Key Takeaways**

| 1. | Focus on high margin specialties business  |  |
|----|--|--|
| 2. | Large number of ANDA filings – 160 (122 in Steriles and 38 in Pharma)              |  |
| 3. | Significant ramp-up in Capacities - recently approved by FDA                       |  |
| 4. | Bulk of the approved Sterile products in process of commercialization              |  |
| 5. | Foray into new domains of Ophthalmics, Biosims and Peptides to open up new avenues |  |
| 6. | Significant investment in organic and inorganic expansion completed                |  |
| 7. | Global partnerships with the likes of Pfizer, GSK and Aspen etc.                   |  |
| 8. | Pool of around 350 scientists to drive R&D growth                                  |  |



## **Thank You**

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