



September 14, 2020

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai – 400 001

The National Stock Exchange of India Limited
Exchange Plaza , Bandra-Kurla Complex
Bandra (E) Mumbai - 400 051

Scrip code: 532531

Scrip code: STAR

Dear Sirs,

Sub: Press Release

Please find attached press release issued by the Company titled:

“Strides unveils SteriScience as its dedicated arm for sterile injectables”

Thanks and Regards,
For **Strides Pharma Science Limited**

A handwritten signature in blue ink that reads 'Manjula R.'.

Manjula Ramamurthy
Company Secretary



Strides Pharma Science Limited

CIN: L24230MH1990PLC057062

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Strides unveils SteriScience as its dedicated arm for sterile injectables

- *Strides to invest ₹1,350 million over the next 24 months*
- *Strides to have ~54% ownership in the SteriScience injectable platform*

Bengaluru, September 14 2020 - Strides Pharma Science Limited ('Strides' or 'Company'), a global pharmaceutical company announced today that it is investing in SteriScience Pharma Private Limited ('SteriScience') to make it the Company's dedicated arm for global sterile injectables business. SteriScience has started the development activity for 20+ quick to launch products and expects the first Abbreviated New Drug Application ('ANDA') filing to be achieved within FY21. Furthermore, SteriScience has entered into a Joint Venture ('JV') with Brooks Laboratories Limited ('Brooks') for building a robust carbapenem business with integrated manufacturing capabilities. The transaction with Brooks is subject to approval from the shareholders of Brooks.

Background

As Agila Specialties ('Agila'), Strides operated a sizeable sterile injectable business with nine global manufacturing plants and established capabilities for carbapenems, beta-lactams and oncology. Agila enjoyed a formidable position in the marketplace with significant domain expertise and over 200+ filings in the US with 180+ filings in other regulated markets. At the right strategic opportunity, the business was sold to Mylan Inc. ('Mylan') for an enterprise value of \$1.6 billion with ₹605 per share distributed as a special dividend to Strides shareholders, a corporate record for India.

On September 20, 2019, Strides announced that it would re-enter into sterile injectables business post the completion of the Company's non-compete period with Mylan. The non-compete period ended in December 2019. Given the unexpected developments due to Ranitidine product withdrawal from the US markets and COVID-19 outbreak, the Company had put on hold all the new investments. However, the Company retained the option to participate in the injectable platform SteriScience in partnership with the family office of the promoters until December 2020 with a ~54% economic interest.

The investment in SteriScience will allow Strides to leverage its rich expertise and experience in the high-value injectables business. SteriScience is designed for a global foray in sterile injectables leveraging the group's rich experience in the domain. It will be a lighter, faster, and yet more valuable platform with a robust B2C strategy that bodes well with the industry opportunity.

Structure and Investments

Strides and the family office of promoters will partner to infuse capital into SteriScience. The partners will also transfer their current sterile injectable related assets and Intellectual Property (IP) to the platform at cost. The business will require a total investment of ₹4,000 million (₹2,500 million equity and ₹1,500 million debt) until it achieves an operational break-even in the next 24 months. The partners will invest this amount in proportion to their ownership (Strides will contribute ₹1,350 million for a ~54% ownership, while the family office of the promoters will make the remaining investments). The investments are envisaged for the following:

a. Development of the Portfolio

SteriScience has already commenced the development of a compelling portfolio driven by a three-pronged strategy viz. acquired IP with significant cross-market opportunity, in-house development of products and by strategic partnerships with high-quality R&D organizations to in-license late-stage products with a focus on specialty injectables. The Company expects to develop 20+ quick-to-market products and will file its first ANDA within FY21.

b. Joint Venture with Brooks for Carbapenems

SteriScience has entered into a JV with Brooks to carry out manufacturing, marketing and distribution of carbapenems for the global markets. Carbapenems are a class of highly effective antibiotic agents commonly used for the treatment

of severe or high-risk bacterial infections. It is a \$2 billion+ global opportunity with limited players having dedicated capabilities to manufacture these products. As part of the transaction with Brooks, SteriScience will have a majority economic interest to commercialize four products in the global markets along with the integrated infrastructure to manufacture both drug substance and drug product internally. The broad terms of the JV transaction between SteriScience and Brooks are:

- i. SteriScience and Brooks will set up a front-end entity to market carbapenem products in the global markets, including the US, Europe, Canada, and Australia. This front-end entity will also own the IP/ANDAs/dossiers of all the carbapenem products across markets. The economic interest for SteriScience will be ~56%.
- ii. SteriScience will invest ₹100 million in the front-end entity for the regulatory filings. The EU Filing for the first product was completed in August 2020.
- iii. Subject to the approval from Brooks' shareholders, Brooks shall transfer its EU approved manufacturing facility at Vadodara, India to a Joint Venture Company on a debt-free basis. SteriScience will have ~27% economic interest in this Joint Venture Company and will invest up to ₹400 million over 12-15 months period in this facility to create additional capabilities including the manufacturing of all carbapenem APIs and also to commission a dedicated lyophilization line for Ertapenem.
- iv. This manufacturing facility will be an exclusive partner to the front-end entity for the international markets.

About Strides

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is a global pharmaceutical company headquartered in Bengaluru, India. The Company mainly operates in the regulated markets and has an "in Africa for Africa" strategy along with an institutional business to service donor-funded markets. The Company's global manufacturing sites are located in India (Chennai, Puducherry and two locations in Bengaluru), Singapore, Italy (Milan), Kenya (Nairobi) and the United States (Florida). The Company focusses on "difficult to manufacture" products that are sold in over 100 countries. Additional information is available at the Company's website at www.strides.com

For further information, please contact:

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STERISCIENCE

RECREATING VALUE IN STERILE INJECTABLES



As Agila Specialties(Agila), our group operated **9 global sterile manufacturing plants** with established capabilities for **penems, beta lactams and oncology products** across formats including **pre-filled syringes, vials, ampoules, lyophilized injections, suspension injections and mini-bags**



Agila had a **formidable position for itself in the marketplace** with **significant domain expertise** in product development for Liposomal, nanoparticle , emulsions, peptides, colloidal formulations. The Company had over **200+ filings** in the US with **180+ filings** in other regulated markets and a **~85% success rate in development**



Agila had a **strong 15-year track record of 65 USFDA inspections** with **organization wide culture** of compliance. The Business was run by **Standalone management team** comprising **highly experienced employees**

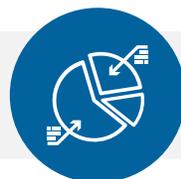


In 2012-13, significant global shortages in injectable capacities emerged and this resulted into a strategic opportunity for Agila with Mylan. The group exited **Agila creating \$1.6b value** , one of the **largest transactions in Pharma from India** and distributed **Special dividend of ₹605 per share to Strides shareholders, a corporate record in India**



CONTINUED MARKET GROWTH

- Global Injectable Opportunity of >**\$400b** of which generics is **\$70b**
- Market growing at a CAGR of **13%** versus **7-8%** for Oral solids
- Market operated **by 8-10 players** which account for 70% of the revenues



REMAINS A SPECIALISED PLAY

- **No major player has emerged since** the exit of Agila
- Limited players have **built a portfolio of 20+ products in last six years**
- **70% of the market** by value has **4-5 players** compared to **6-7 generics** in the oral solids



SUPPLY SHORTAGES

- **60% of the drug shortages** in the FDA list are of injectables
- Various incumbents have issues with **the capacities or regulatory concerns** around the manufacturing sites
- Owing to issues around **API sourcing**, several products have inconsistent/disrupted supplies



OPPORTUNITIES TO CREATE A NEW NICHE

Phase 1 –

- Opportunity to develop products that are continuously in shortage
- Leverage group's capabilities in freeze dried technology to fast-track development of a niche generics portfolio
- Focus on high value carbapenems which have a supply scarcity in the industry (JV with Brooks)

Phase 2-

- Significant opportunity to develop, acquire or in-license products with proprietary technologies useful in removing adverse excipients for safer injections, developing easier to administer dosage formats, cold chain management, and increased efficiencies in hospital workflow



Rich Domain Experience

- **100+ years of domain experience** with leadership having proven track record in Agila
- Group centralised **quality , risk management , compliance and regulatory framework**



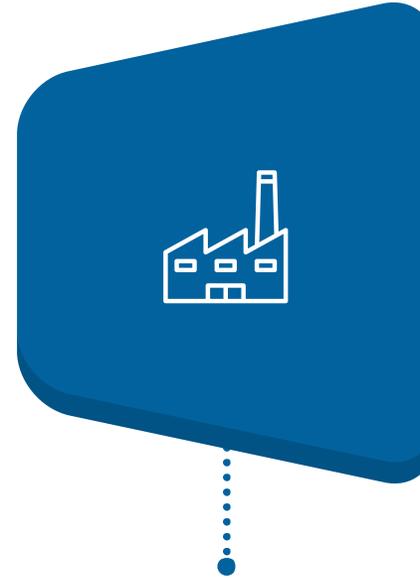
Compelling Portfolio

- **Acquired IP** with significant cross-market opportunity;
- **In-house development** of products;
- **Strategic partnerships** with **high-quality R&D** organizations to in-license late-stage products



High Pace Development

- 20+ **“Quick-to-market”** products
- **Complements our strategic focus** - limited competition or **specialized domain play** – lyophilization or **manufacturing scarcity**-Penems
- **First set of filings** within FY21



Adapted manufacturing

- Access to **Stelis manufacturing facility** which has **highly automated capabilities** for fill-finish in PFS, Cartridges, Vials and Lyophilization in vials with automatic loading/unloading systems and capping machine
- Dedicated **facility for Carbapenems** with upcoming integrated API capabilities (JV with Brooks)



Front End Focus

- **Front-end presence** in the markets of US, UK, Germany, Australia, and Canada
- Developing **sales and marketing presence** in key other regulated markets through own network



- SteriScience has entered into a JV with Brooks to build a global Carbapenem business
- Carbapenems are a class of highly effective antibiotic agents commonly used for the treatment of severe or high-risk bacterial infections.
- \$2 billion+ global opportunity with limited players having dedicated capabilities to manufacture these products



Marketing Partnership
with Sterisience
owning the majority

- SteriScience and Brooks will set up a **front-end entity** to market carbapenem products in the global markets, including the US, Europe, Canada, and Australia.
- This Entity will also own the **IP/ANDAs/Dossiers** of all the carbapenem products across markets.
- The **economic interest for SteriScience will be ~56%** and it shall infuse **₹100 million for the regulatory filings**.
- The **EU Filing for the first product** has been completed in August 2020.



Exclusive manufacturing
arrangement for the
marketing joint venture

- Subject to the approval from Brooks' shareholders, Brooks shall transfer its EU approved manufacturing facility at Vadodara, India to a **Joint Venture Company on a debt free basis**.
- SteriScience will have **~27% economic interest in this JV** and shall invest up to **₹400 million** over a **12-15 months** period in this facility to create additional capabilities including the manufacturing of all carbapenem APIs and also to **commission a dedicated lyophilization line for Ertapenem**.
- This manufacturing facility will be an **exclusive partner to the front-end entity for the international markets**.



Acquired Products/ Intellectual Property

- **25+ IPs** approved for the Canadian market and entitled to be extended **globally**. These products can be commercialized in Canada through a site transfer variation
- **Incremental R&D work & submission batches** for filing some of these products in other markets including US based on market opportunity initiated in **CY20**; Filings will be beginning from **Q1CY21**
- **Partnership with Brooks in the dedicated EU GMP** approved Penem facility to access a specialized portfolio of Penems



Co-developed / In- licensed Products

- Partnered with a **third-party CDO** to in-license **late stage developments** with a **direct technology transfer to Stelis facility in Bangalore**
- **Tech transfers** will be initiated by **Q4CY20** and filings will be beginning from **Q2CY21**
- **Commercialization** of this set of products in the US is likely to begin from **Q2CY22**
- **On-going discussions to acquire POCs for two specialty generic products providing a head-start to our specialized portfolio**



New Product development

- R&D at group's facility in Bangalore for **20 + new products** initiated in **CY20** with exhibit batches initiating from Q1CY21 and filings beginning **Q3CY21**
- **In-house portfolio designed** to meet strategy of differentiated and niche developments meeting **our targeted financial thresholds**



- Front-end presence in the markets of **US, UK, Germany, Australia, and Canada**
- Building partnerships in **key European Union Countries** to roll-out products
- Developing **sales and marketing presence** in key other regulated markets through own network

- Strides on September 20, 2019, announced that it would **re-enter into sterile injectables business** post the completion of the Company's non-compete period with Mylan, which ended in **December 2019**.
- Given the unexpected developments due to **Ranitidine product withdrawal** from the US markets and **Covid-19 outbreak**, the Company had **put on hold** all the new investments. Meanwhile, the family office of the promoters of Strides **continued to stay invested** in injectables and Strides retained an **option until December 2020** to participate in the injectable business
- **Strides** and the **family office of the promoters** will now infuse capital into SteriScience. The partners will also transfer their **current sterile injectable related assets** and **Intellectual Property (IP)** to the platform at cost.
- The business will require a total investment of **₹4,000 million** of which **₹2,500 million** will be equity and **₹1,500 million** will be debt.
- Over the **next 24 months**, the partners, in the proportion of their ownership, will contribute the following:
 - Strides to infuse **₹1,350 million** for a **~54%** ownership and
 - Family office of promoters will infuse **₹1,150 million** for the remaining **~46%** ownership
- This capital will be sufficient for Sterisience to **achieve an operational break-even (EBITDA)** in the **next 24 months**
- The necessary **Joint Venture agreements** to be executed in **Q3FY21**

Steriscience in a nutshell:

- ➔ Leveraging our rich **domain experience**.
- ➔ **High Pace development** of the portfolio.
- ➔ **Fewer products** but with **global orientation**.
- ➔ **Lighter infrastructure**. **Phased investments**.
- ➔ **B2C led regulated market** strategy.
- ➔ **~54% economic interest** for Strides.