

# recreating value in specialties

STERISCIENCE | A GLOBAL SPECIALTY PLATFORM IN THE MAKING



AUG 2023



## Introducing Steriscience: an emerging injectable platform from the team that delivered value with India's first truly global injectables company

1

Steriscience is an emerging sterile injectable company with a differentiated global strategy driven by strong capabilities across R&D and manufacturing and a significant focus on customer advocacy

2

The Company is focused on building a value-added portfolio of products that solves several challenges being faced by hospital personnel, improve hospital workflow, and ease of use

3

Steriscience leadership comprises the team that delivered several significant outcomes with Agila, India's first truly global specialty injectable platform (*the business was sold to Mylan Inc in 2012-13 for an enterprise value of USD 1.6b, one of the largest pharma transactions in India*)

4

Post completion of non-compete agreement with Mylan in 2020, the founders re-entered the space in 2021 with Steriscience as their version 2.0 in sterile injectables

5

In just over 2 years, Steriscience has completed significant work across R&D and manufacturing having completed 30+ product developments and acquired 4 manufacturing facilities - all US FDA/ EU GMP approved

# Presenting Steriscience: a differentiated sterile injectable platform in the making



## Rich Domain Experience

Led by promoters and technical team that has delivered several significant outcomes in India's first truly global injectable platform



## Global Presence

Building a leading global injectables business with a presence across regulated & emerging markets



## Differentiated Portfolio

Building a value-added portfolio offering of ready-to-use products that solves for challenges across stakeholders in hospitals



## Strong Capabilities

Strong capabilities across R&D and Manufacturing and go-to-market



## Robust Supply Chain

Significant focus on Supply chain with own manufacturing & backward integration within the group for key products



## Customer centricity

Becoming a reliable supplier across customers with the highest focus on supply commitment & product quality

## Our strategy is designed to address the underserved market segments globally



### STRONG & HIGH-PACED R&D FOR QUICK APPROVALS

- **Fast-track development** of products by **experienced in-house R&D** ensures quick facility inspections & approvals
- **R&D development completed for 30+ projects over 2 years** including critical ready-to-use pre-filled syringe programs; **15+ ANDA filings and 20+ global filings completed**



### DEDICATED MANUFACTURING FOR SUPPLY RESILIENCE

- Dedicated in-house manufacturing facilities for product **domains with limited suppliers** and **regular disruptions such as anti-infectives**
- **Supply security for key APIs within the group** with **vertical integration in Penems API** on-going to ensure cost leadership



### VALUE-ADDED READY-TO-USE PORTFOLIO FOR DIFFERENTIATED OFFERING

- Converting products into **ready-to-use (RTU) formats** to improve **efficiencies in hospital workflow**, safety of personnel, reduce wastages & dosing errors
- **Work initiated on next phase of differentiated portfolio - first-to-market RTU bag program** in collaboration with an international R&D expert



### DEVELOPING & MANUFACTURING COMPLEX PRODUCTS

- **Infrastructure to provide end-to-end services across drug development and manufacturing**
- **Developing/in-licensing complex products in partnership with high quality R&D organizations** - in-licensed assets in the RTU space including lyo to liquid switches and other complex products including suspensions

### The Steriscience Differentiators

- Ability to **identify and quickly develop a differentiated portfolio**
- Carefully defined, **adaptive manufacturing strategy** through state-of-the-art **global infrastructure**
- An all-encompassing **culture of quality integrated** into the fabric of the organization allowing us to **become a preferred partner**

# Global manufacturing infrastructure – four facilities with wide-ranging capabilities across formats

- **Four acquired/brownfield manufacturing sites** in India, and EU
  - **1 USFDA & EU Approved sterile injectable manufacturing facility** in Poland, Europe
  - **1 USFDA & EU Approved dedicated penems manufacturing facility** in India, Gujarat
  - **2 USFDA approved plants** in Bangalore, India – one for Sterile Products & the other one dedicated Penicillin facility
- Preferred access to **Industry’s most modern and highly automated manufacturing site** with integrated capabilities **through group network**

## NON-POTENT INJECTABLE FACILITY IN EUROPE

Particulars	Features
<b>Built-up Area</b>	14,000 sqm
<b>Dosage formats</b>	Ampoules, Lyophilized vials, Liquid vials, Pre-filled syringes
<b># employees</b>	155
<b>Key facility approvals</b>	USFDA, EUGMP, GIF
<b>Capacities</b>	Liquid Vials – 40mn Lyophilized Vials – 2mn Pre-filled Syringes – 3mn Ampoules – 37mn

## DEDICATED CARBAPENEM FACILITY IN INDIA

Particulars	Features
<b>Built-up Area</b>	100,000 sqm
<b>Dosage formats</b>	Lyophilized vials, Sterile Dry Powder vials
<b># employees</b>	70
<b>Key facility approvals</b>	USFDA, EU GMP, ANVISA, CDSCO
<b>Capacities</b>	Lyophilized Vials – 1.3mn Dry Powder Vials – 28mn

## FDA APPROVED PENICILLINS FACILITY IN INDIA

Particulars	Features
<b>Built-up Area</b>	3,900 sqm
<b>Dosage formats</b>	Sterile Dry powder vials
<b># employees</b>	300+
<b>Key facility approvals</b>	USFDA, EUGMP TGA, ANVISA
<b>Capacities</b>	Dry Powder Vials – 32mn

## FDA APPROVED STERILE PRODUCT SITE IN INDIA

Particulars	Features
<b>Built-up Area</b>	6,500 sqm
<b>Dosage formats</b>	Liquid - Aseptic and Terminal sterilized, Lyophilized vials, Pre-filled syringes
<b># employees</b>	300+
<b>Key facility approvals</b>	USFDA, EUGMP TGA, HC
<b>Capacities</b>	Liquid Vials – 16mn Lyophilized Vials – 1mn Pre-filled Syringes – 10mn

## Development capabilities across the novel dosage formats

DEMONSTRATED EXPERTISE IN CONVENTIONAL DOSAGE FORMATS WITH A FOCUS ON HIGHLY EFFICIENT MANUFACTURING PROCESSES

### CONVENTIONAL FORMATS



Liquid Vials



Lyophilized Vials



Ampoules

EXPERIENCE IN NICHE AND COMPLEX DOSAGE FORMATS THAT ARE PATIENT-FRIENDLY TO ADDRESS HOSPITAL NEEDS AND IMPROVE QUALITY OF MEDICATION OFFERED TO PATIENTS

### NOVEL FORMATS



Pre-Filled Syringes(PFS)



Bags, single & dual chamber bags



Cartridges



Pens  
(Disposable & Reusable)



## A global go-to-market strategy with high focus on “partner and customer centricity”



- **Portfolio driven GTM** strategy to achieve success across all market channels
- **Marketing authorizations acquired to expedite in-market presence in US and Canada –**
  - ❑ First set of antibiotics already launched in the US in 2022
  - ❑ 10+ new launches planned over the next 12 months
- **B2B partnerships for key emerging geographies** through strong regional partners
  - ❑ Capitalize on products developed and filed for regulated markets to leverage fast-track approvals
  - ❑ First set of filings completed for EU/ CA/ LATAM
- **Carbapenem portfolio already launched in key CIS markets, India, Mexico; finalizing partnerships in Africa and SEA**

Led by an experienced team with 100+ years of rich domain experience and proven track record



**Neeraj Sharma**  
25+ years  
CEO



**CK Sundhar**  
25+ years  
Manufacturing & Projects



**Biju Mathew**  
25+ years  
Quality & Tech Ops



**Dr. MS Vijaykanth**  
20+ years  
R&D



**Tarun Singh**  
15+ years  
Chief Financial Officer



**Joe Hendrickson**  
25+ years  
Strategy and Corp  
Development



**Murari M Mishra**  
15+ years  
CHRO



**Dhriti Sethi**  
8+ years  
Head, Global BD & Portfolio

*Leveraging Group infrastructure for Regulatory, Analytical, Clinical and IP services*



**Thank you**