Strides

September 26, 2024

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

Scrip Code: STAR

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

Stock Symbol: 532531

Dear Madam/ Sir,

Sub: Corporate Deck of OneSource

Please find enclosed an updated Corporate Deck of OneSource Specialty Pharma Limited (formerly Stelis Biopharma Limited), a Strides Group Company.

You are requested to take the same on records.

Thanks & Regards,
For Strides Pharma Science Limited,

MANJULA R
Digitally signed by MANJULA R
Date: 2024.09.26 16:26:22 +05'30'

Manjula Ramamurthy
Company Secretary
ICSI Membership No. A30515

Encl: As above

OneSource

Company Updates
September 2024

Disclaimer

OneSource Specialty Pharma Limited, formerly known as Stelis Biopharma Limited, is undergoing a significant transformation. As announced on September 23, 2023, OneSource will be acquiring and merging Strides' Oral Technologies (soft gelatin capsules) and SteriScience's Specialty Injectables businesses into its operations. This regulatory process is currently underway, and upon completion, OneSource will be listed on the stock exchange.

In the following mentions, "OneSource" refers to this integrated entity.

Except for the historical information contained herein, statements in this presentation and the subsequent discussions, which include words or phrases such as "will", "aim", "will likely result", "would", "believe", "may", "expect", "will continue", "anticipate", "estimate", "intend", "plan", "contemplate", “seek to", "future", "objective", "goal", "likely", "project", "should", "potential", "will pursue", and similar expressions of such expressions may constitute "forward-looking statements“. These forward-looking statements involve a number of risks, uncertainties, and other factors that could cause actual results to differ materially from those suggested by the forward-looking statements. These risks and uncertainties include, but are not limited to our ability to successfully implement our strategy, our growth and expansion plans, obtain regulatory approvals, our provisioning policies, technological changes, investment and business income, cash flow projections, our exposure to market risks as well as other risks. The Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date thereof.

Combination of 3 distinct entities and capabilities → OneSource

OneSource

Strides

Soft gelatin capsules division

(Demerged from Strides Pharma)

Stelis Biopharma

Biologics and drug-device combinations

steriscience

Complex injectables CDMO

(Demerged from Steriscience)

OneSource

(India's first multi modality CDMO)

Customer want

- **One stop shops** catering to wider outsourcing needs including development
- **Low complexity** in managing fewer 3rd parties (reduce cost, time, resources, …)
- **Better service level** from CDMO irrespective of size of business/ project

Opportunity for combined entity

- **Synergies** in cross-selling by leveraging customer bases with lower overheads
- **Operating leverage** from better capacity utilization & repurposing of mfg. sites
- **Broaden technology offering** to become 'one stop' shop for CDMO sponsors

OneSource is built on legacy of exemplary quality and compliance track record

1990

Incorporation of the Company as Strides Pharmaceuticals Private Limited

1995

Entered into collaboration with Pharmagel Italy to set up a plant for Soft Gelatin Capsules

New sterile manufacturing facility in Bangalore commenced production

1998

Successful commissioning and stabilization of Soft Gelatin Capsule plant at KRS Gardens, Bangalore

2007

First USFDA approval for Penicillin site

16 years of continuous FDA approved operation

2010

Rebranded Specialty (injectable) Division as Agila Specialties Private Limited

2014

Biotech business re-branded as "Stelis Biopharma"

Sold to Mylan

2020

Strides re-entered injectable business with SteriScience

2022

Drug Product (DP) manufacturing at Unit-2 of Stelis Biopharma got FDA approved

2023

Introduced OneSource, consolidating all the CDMO offerings from Strides group in one place

2024

Started operating as an independent entity within Strides group

Successful FDA approval of the generic injectable site

~30 years of experience in Soft gelatin and injectable operations

138 successful customer and regulatory audits in the group companies

OneSource is an end-to-end CDMO with one of the widest offerings

OneSource

Common CDMO archetypes

Biologics
- Drug Substance (DS) - Microbial
- DS - Mammalian
- Drug Product (DP) - Fill finish

Injectable fill finish
- Vials (Lyophilized, Aseptic, Terminally sterilized)
- Prefilled syringes
- Cartridges

Focused
- Drug device assembly
- Soft gelatin capsules
- Aseptic bag fill finish[1]
- Penicillin's fill finish

CDMOs (Non-exhaustive)

Samsung Biologics, Fujifilm Diosynth, Curia, WuXi Biologics, Boehringer Ingelheim BIOXCELLENCE, AGC Biologics, Thousand Oaks, MabPlex, Rentschler, Syngene, Piramal Pharma Solutions, Kemwell, chime, Rovi, Simtra, amri, Gland Pharma Limited, Recipharm, Pfizer CentreOne, Italfarmaco, Siegfried, aenova, Grand River Aseptic Manufacturing, Vetter, pci Pharma Services, aenova, Procaps, Softigel, InfoRLife SA, Recipharm

'One Stop' solution providers

OneSource

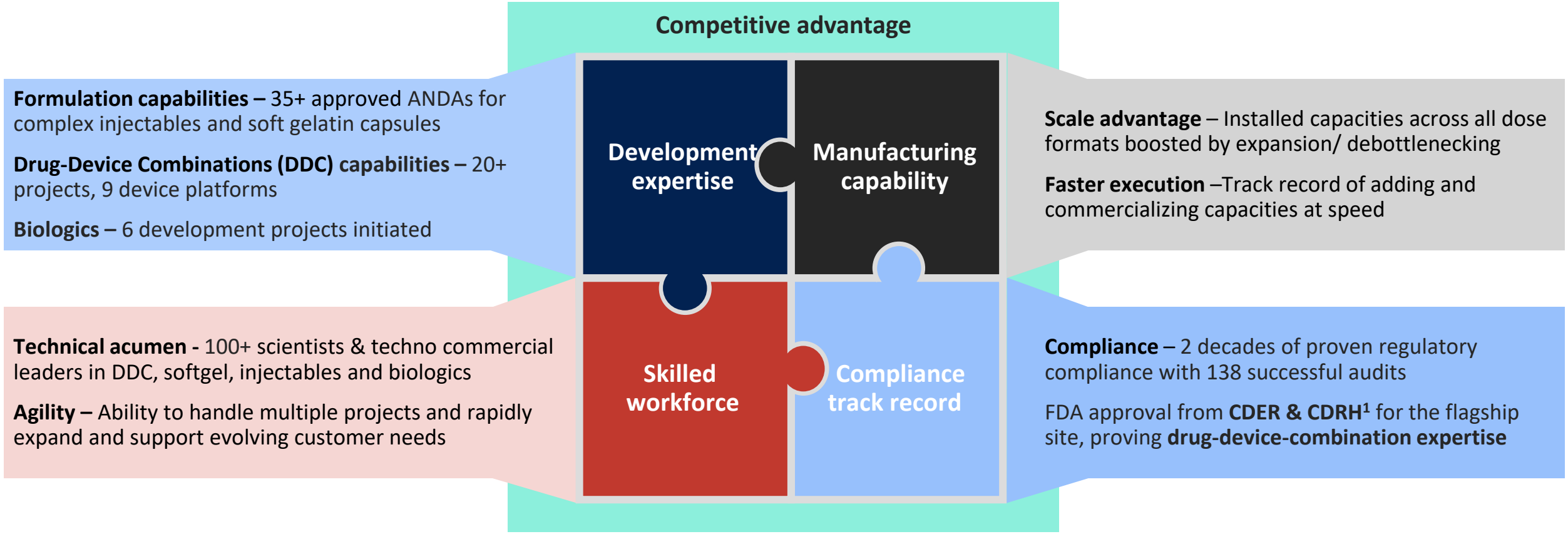
- Process & Analytical Development
- Quality Assurance Quality Control
- Tech Transfer and Scale-up
- cGMP Manufacturing
- Program Management

1. Proposed expansion to the CDMO offering

Source: Secondary research, company websites

Strong expertise in 'Development' with end-to-end capabilities, installed capacities and compliance track record

OneSource



1. CDRH - Center for Devices and Radiological Health

Globally accredited, state-of-the-art facilities with capacities to produce >100 million sterile dosages and ~2.4 billion capsules per year

OneSource

Drug-device combinations

Integrated Biologics and drug products site

Soft gelatin capsules[1,2]

Complex injectables[1]

Penicillin fill finish[1]

Multi-modal Biologics development centre

Area (Sq ft)	450,000		60,000	70,000	42,000	100,000
Capability & Capacity[3]	Microbial: 1x1KL SS	Cartridges: 40 million	Capsules: 2.4 billion[3]	PFS: 10 million	Vials: 18 million	Microbial: 1x 50L
	Mammalian: 2x 2KL SUB	PFS: 28 million		Vials: 16 million		Fill finish: Clinical supplies
		Vials: 12 million				
Major accreditations	FDA, EMA, TGA	FDA, ANVISA, EMA, TGA	FDA, ANVISA, EMA, TGA	FDA, ANVISA, TGA	EMA	

Sterile Injectable and DDC capacities to reach >200 million dosages in next 3 – 4 years

1. These facilities from Strides and SteriScience will be part of OneSource after the regulatory merger process is complete (2) Tolling agreement between OneSource and site operators (3) To be operational, by October 2024

Facilities are digitally enabled with industry-leading QMS[1]

OneSource

Company quality policy

*"To develop and deliver products of **high** and **consistent quality** that will meet the expectations of our customers while **adhering to the highest standards of worldwide statutory and regulatory bodies**. We achieve this **by design** and through **effective deployment** of a **quality management system."***

Select systems / applications installed at Unit 2

Enterprise Resource Planning & Material Management	SAP
QMS Management	TrackWise
Document Management	EDMS (BIOVIA)
Training Management	NetDimensions Talent Suite (BIOVIA)
Laboratory Information Management*	ONE LAB (BIOVIA)
E-Log Books*	LEUCINE
Validation Management System	VALGENESIS
Cleaning Validation System	CLEEN

Company aspires to be the CDMO industry leading 'Light House' in quality management and has an ongoing transformational program with leading global consulting firm

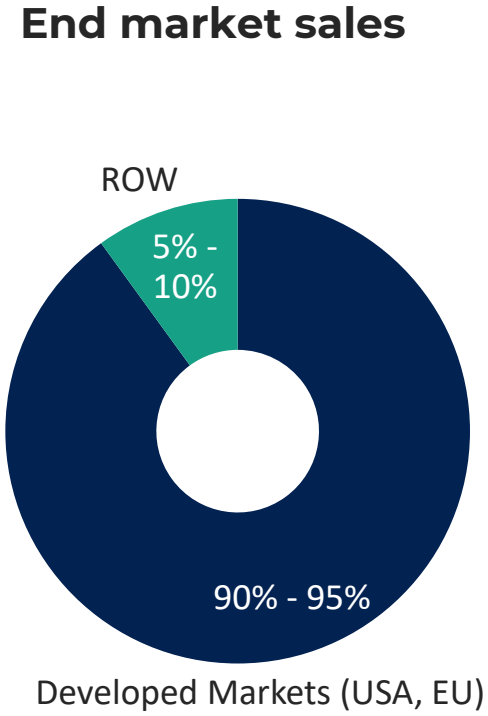
** Under Implementation*

1. QMS: Quality Management Systems

A diversified customer base with end sales primarily in regulated markets

Customer domicile

End market sales



Note: As of June 2024

Strong management team with average ~23 years of experience

Neeraj Sharma, CEO

Neeraj has 28+ years of global experience in pharma. He has been an integral part of the group for more than 3 years overseeing SteriScience. He was earlier Head of generics business for Western Europe for Sun Pharma

Prateek Gupta, Head of R&D and Scientific Services

Prateek, a PhD from Cornell, has 16+ years of experience in biologics product development. Prateek was Head of Process Science, R&D at Intas Pharmaceuticals. He has also worked with Pfizer and Genentech-Roche

Anurag Bhagania, CFO

Anurag has 25+ years of experience. Prior to joining OneSource, Anurag held the position of CFO at Kirloskar Oil Engines. He has also worked with large global automotive and industrial companies like SKF, Honeywell, General Electric

Ravi Kumar, Head of Strategy

Ravi has 17+ years of global experience in pharmaceutical industry and management consulting. He was head of strategy, M&A and portfolio at Xellia and instrumental in turning around anti-infective division at Sandoz. He has also worked with Kearney consulting and Yamaha Motors before.

Biju Matthews, Head of Operations

Biju has 26+ years of pharma experience. He was responsible for building the state-of-the-art drug product and drug substance manufacturing facility (Unit 2) at Stelis. He was earlier Head of Quality at Wockhardt Bio Pharma and Mylan

Murari Madhab Mishra, Head of Human Resources

Madhab has 17+ years of experience working in pharmaceutical, energy and digital technology space. He brings extensive domain expertise in org design, talent management, leadership development, succession management. Madhab has earlier worked with Dr. Reddy's and Reliance Jio.

3 disruptive changes provide tailwind for OneSource CDMO offerings

GLP-1s rise

Obesity and Diabetes are major societal challenges → GLP-1s bring transformative innovation to patients

- LOEs provide near and mid term opportunity for established players with DDC capacities
- Players with demonstrated DDC capabilities to benefit from **rising demand for fill finish and assembly by generic entrants**

BIOSECURE act

Prohibit U.S. federal funding in connection with biotech equipment/services produced/ provided by China …

- US and Japanese companies are looking for alternative destination for their clinical as well as commercial supplies
- **Indian CDMOs well-positioned** for increased growth due to their cost effectiveness and highly skilled workforce

Acquisition of a large CDMO

Acquisition of a large CDMO by a Pharmaceutical major has puts pressure on already constrained supply for injectables and soft gelatin capsules

- New drug developers and generic entrant are seeking independent CDMOs for diversifying their supply chain
- **CDMOs with scale, cost advantage and broad spectrum of offering** to benefit from ensuing supply chain risk mitigation

OneSource has witnessed significant jump in RFPs over last 2 quarters → 35+ RFPs at various stages of discussion

OneSource is well positioned to capitalize on the emerging opportunities and capture a large part of the addressable market

1	**Differentiated CDMO play** with **full-service capabilities** and strong focus on **'Development'** across **multiple technology** platforms
2	**Best in class manufacturing** infrastructure with 5 state of the art facilities (integrated DS-DP from single site, state-of-the-art barrier systems/isolator lines) with ongoing capex projects **to add capacity ahead of time**
3	**Impeccable quality, compliance and supply track record spanning more than 2 decades**
4	**Proven development capabilities** (DDCs, Biologics, Soft-gelatins, Injectables) with 35+ ANDAs and >75% repeat business
5	**Fully institutionalized platform** with **strong corporate governance** and processes **backed by an experienced leadership team**

Drug-Device Combinations

OneSource is a pioneer DDC solution provider with full-service offering

OneSource

2
NCE-1 GLP-1 Projects

9
Molecules in portfolio incl. GLP-1s, biologics & small molecules

9
Device platforms / formats being handled

55+
Years of cumulative Device and CMC experience

17
Customers including 4 of top 5 global generics

20+
Qualified assembly machines to provide customized solutions

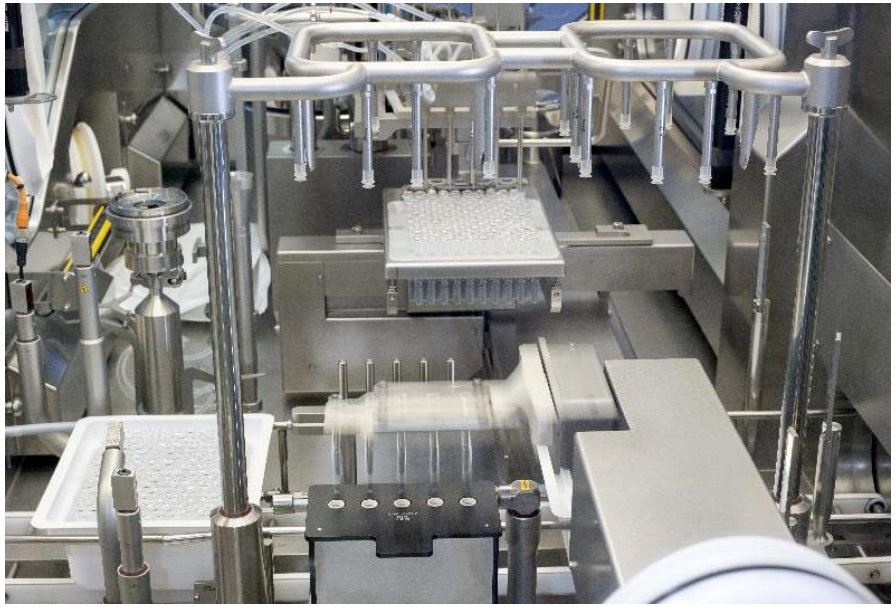
20+
Years of vendor relationship for sterile manufacturing & assembly

24
Ongoing / completed DDC projects

140+
Tech transfer batches successfully completed in last 15 months

Bausch and Strobel filling line integrated with isolator for cartridge fill finish

OneSource



20+ automatic and semi-automatic assembly stations to support multiple device formats

GLP commercial supplies to start from Q4[1] FY25 onwards

OneSource

MSA CSA

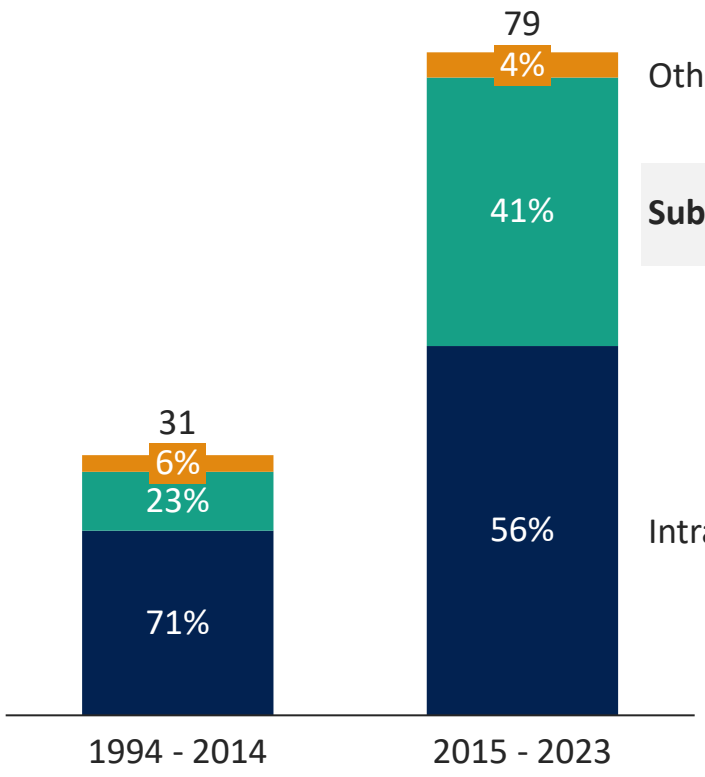
Molecule	Key Customers	FY '24	FY '25	FY '26	FY '27	FY '28	FY '29	FY '30
GLP-1 Molecule A	3 of the top 5 global generics + Others			Started receiving Purchase Orders (Q4 FY25 launch[1])				
GLP-1 Molecule B	Top 3 global generic + Others				Launch starting FY '26 in several markets			
	2 of the top 3 global generics + Others				Launch starting FY '26 in several markets			
GLP-1 Molecule C	Top 3 global generics + Others							LOE in 2036

1. Subject to regulatory approval for customers

OneSource has significant DDC opportunity beyond GLP-1s

DDCs are critical for self administration via subcutaneous route and are increasingly being preferred for delivering biologics

E.g., delivery route for approved mAbs



- Subcutaneous (SC) route is becoming increasingly important for the administration of biologics
- With advancements in SC injection devices, DP development continues to shift towards patient centricity by enabling self-administration
- Innovators are transitioning from intravenous (IV) infusion to SC administration for life cycle management
- Instances of biosimilars being developed for SC administration when originators were solely available for IV

Source: secondary research and publications

Significant opportunities beyond GLP-1s

10 *Non GLP-1, DDC projects under execution*

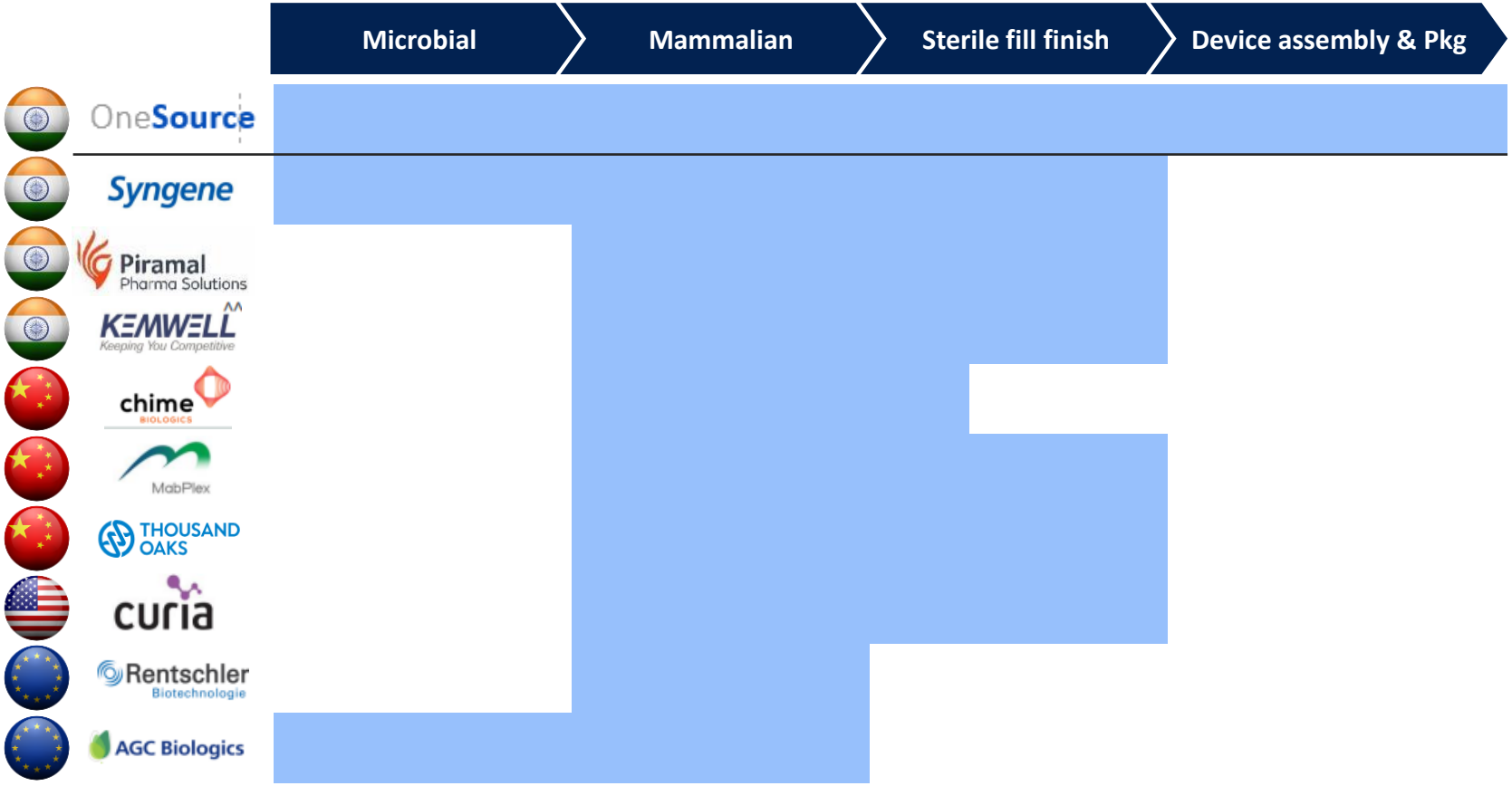
3 *Of the top 10 global generics as customers*

FY 25 *1st biosimilar DDC launch*

Biologics

Widest offering amongst the peer group to benefit from multiple tailwinds including BIOSECURE act

Mid sized CDMOs offerings and coverage in Biologics (Non exhaustive list)



OneSource opportunity

End to end offering – Offers DS and DP at the same site with multiple DS and DP formats

Microbial – One of the few CDMOs with microbial capacity at scale (along with planned expansion)

BIOSECURE Act - Diversification and supply chain risk mitigation for EU/ NA based companies looking for alternative to China

Source; Secondary research, company websites, LEK consulting

Our sites offer integrated Biologics development & manufacturing

OneSource

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

State-of-the-Art Facilities

Process Development:

- Mammalian platform
- Microbial platform

Analytical Method Development

- In-process
- Release & Stability
- Characterization

50L DS Manufacturing

QC Lab for DS MFG

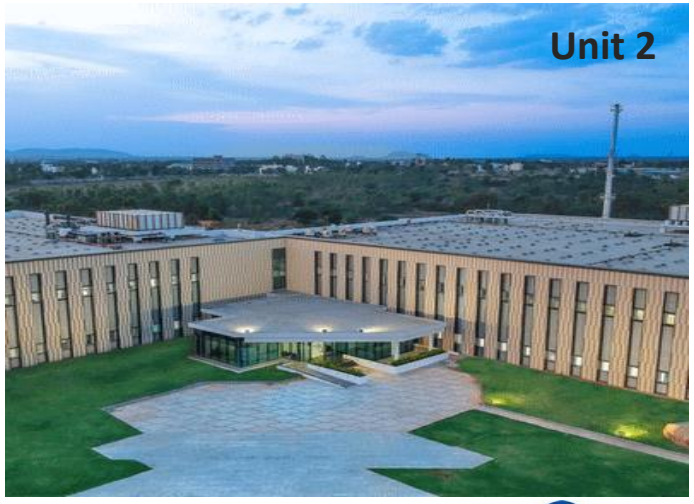
DS Manufacturing:

- 1000L for DS from Microbial platform
- 2000L x 2 suites for DS from Mammalian platform

DP Manufacturing:

- Vials, PFS, Cartridges
- Device Assembly

Common QC Lab



FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Fully integrated DS and DP (all formats) provides significant value proposition for clients

Uniquely placed amongst the few CDMOs with significant & flexible microbial capacity (50L – 1KL)

Flexible scales allow to onboard projects for Clinical & Commercial supplies

Our high-volume commercial use facilities were designed with FDA consultation

Dedicated R&D Centre for Process, Analytical & Formulation Development

End-to-end capabilities enabling biologics asset development for regulatory approvals

OneSource

Clone Development & Selection

- Robust clone/strain with good growth and productivity indicators
- Desired PQ modulation

Lead and Back up clones with full characterization

Process development & Formulation Lock

- Single-cycle PD (Fed batch/ Perfusion)
- Commercially superior yields with right CoGs
- Comparable PQ attributes
- Non-infringing formulation (as required)

Tox and CT material

Process Characterization & Validation

- Process Risk Assessment
- Scale-down model (SDM)
- CPP Identification
- Control Strategy for PPQ batches

Successful PPQ campaign

Clinical & Commercial Manufacturing

- Increasing Mfg. Experience,
- Updated Process Risk Assessments
- Control Strategy for BLA/MAA

Robust and consistent mfg.

Stage-appropriate analytical methods to accelerate development as well as build deep process and product understanding

OneSource has leading capacities and capabilities in the Biologics space

1

of the few sites globally to offer integrated DS-DP mfg. from same site

1st

Innovator molecule onboarded with a top 3 animal health company

10+

Ongoing projects and RFPs

1,000

Liters microbial capacity planned to be expanded by 5,000 liters

4,000

Liters of installed mammalian capacity with 20,000 liters capacity ready to install

Sterile fill finish

Focused on critical care injectables frequently in shortage; Strong supply and compliance track record enables industry leading margins

OneSource

OneSource focus

Product shortages – Portfolio (ANDAs and dormant IPs) addressing market needs in shortage areas

Penicillin – One of the few (<10) US FDA approved and dedicated Penicillin site globally and has been in continued operation for 17 years

Customer-centric – Focus on providing high value to customers and consistent supply to patients

Regulatory compliant operation – Exemplary track record for ~2 decade

Source; Secondary research

Significant installed capacities across multiple dose formats

OneSource

Aseptic liquid filling lines for all formats: Vials (Liquid and Lyo), PFS, Cartridge and Device. Vial line for TS products.

Cold rooms for storage of product at various stages

Highly automatic packaging line

High-capacity warehouse

Tertiary packaging area

100% visual inspection

Track and trace systems

Dosage format	Capacity per annum
Pre-filled Syringes	~38 million
Liquid Vials (Aseptic)	~28 million
Dry Powder Vials	~18 million
Lyophilized Vials	~4 million

OneSource has stellar compliance and supply track record in sterile injectables

20+
Years of development and manufacturing experience

1
Of the few FDA approved mfg. sites for Penicillin globally

30+
Formulations developed in-house

70+
Million eaches installed capacity

15+
Customers in regulated markets

Oral Technologies

OneSource is one of the largest prescription focused softel capsules manufacturer

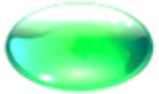
3
Decades
of rich experience in soft gel R&D and manufacturing

2.4
Billion
Capsules manufactured every year

Global
Presence
Our products are sold in all regulated markets


Softgels


Enteric Coated


Vegan


Chewable


Vaginal Pessaries


Liposomal


Applicaps


Suppositories

Masters in a Spectrum of Technologies in Soft Gelatin Capsule Formulation

Uniquely placed with full value chain coverage

OneSource

Vendor network

- **Strong network of Gelatin and HPMC suppliers** with diverse sources
- Long-term technical collaboration and **trouble-shooting agreement with Pharmagel,** Italy

R&D

- Design niche and novel patentable formulation
- Handy self-micro emulsifying delivery system (SMEDS). Droplet size of less than 50 microns to achieve higher availability
- Varying shapes and sizes of capsules, from 2 – 40 oval and 5 - 22 oblong
- Highly skilled team has **successfully eliminated the widespread issue of capsule leakage**

Manufacturing

- 4 highly sophisticated encapsulation lines ➔ 2.4 billion capsules annually
- High-speed contact printers to print capsules with a high-speed camera-based inspection system
- Symetix (in-house design) installed for Single operation of Lubrication + Inspection, zero manual intervention – zero hairline fracture
- Regulatory approvals, including US-FDA, MHRA, ANVISA, TGA, WHO and MCC, amongst others

Legacy of ~3 decades of development and manufacturing softgel capsules

OneSource

30
Years of development and manufacturing experience

30+
Products developed fully in-house

~20
Products commercialized in US

Top 4
Manufacturer of prescription focused softgel capsules globally

40+
Customers in regulated markets


Encapsulation line

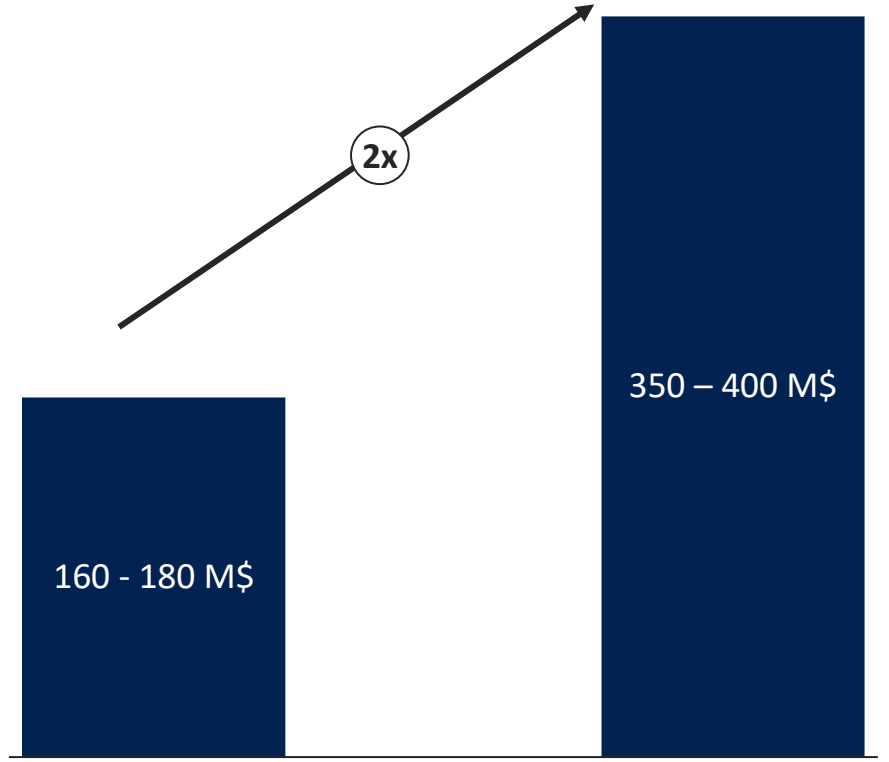
Automatic inspection system


Integrated container filling machine


Integrated blister machine

OneSource
Mid term guidance

OneSource



	FY 2025E	3 – 4 years
EBITDA%	~34%	>40%

OneSource