

## **Strides Pharma Science Ltd**

Feb 2024

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**Safe Harbor** 



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.

### **Strides Reset Completed, Now Poised for Growth**



(In INR Crores)	FY22	FY23	YoY %	9MFY24	YoY %*
Revenue	3,095	3,704	+20%	2,997	+17%
Gross Margin	51.5%	56.1%	+463bps	59.2%	+300 bps
Employee Cost	647	732	+13%	552	1%
Operating Cost	931	899	-3%	677	8%
Total Cost	1,578	1,631	+3%	1,229	-4%
EBITDA	4.2	446	N/A	544	+147%
EBITDA Margin%	0.1%	12.0%	+1190bps	18.1%	+791bps

Particulars	FY22	FY23	9MFY24
Net Debt / EBITDA	N/A	5.4x	3x
Net Working Capital Cycle	152	140	136

#### Consistent Revenue growth of high teens over last 18months

Significant pick-up in B2B business via synergICE

New Product Launches in the **Front-end business via Chestnut Ridge**  Expansion of product offerings to new geographies through portfolio maximization

**Gross Margin Revival** 

Nearing historical levels of ~60% driven by Ramp-up in US business and Easing of Supply chain disruption

#### Cost Efficiency: Operating Cost base brought down to \$ 200m p.a.

FY22 Cost Base: \$230 M

Reduction in **Logistics & Warehousing** Cost

**FY23:** \$202 M

Reduction in Manufacturing **Under recoveries** 

**FY24:** ~\$200 M

Optimizing R&D Cost

Successful Deleveraging

Net Debt to EBITDA reduced from  $^{\sim}8.3x$  in Q1FY23 to 3x by Q3FY24

<sup>\* 9</sup>MFY24 YoY growth adjusted for UCL, Kenya operations which got deconsolidated effective Sep 30th 2022

## Way Forward for Strides Excluding Soft Gelatin Capsule Business (Divested to OneSource)



Mid-Teens Revenue Growth + EBITDA Margin Expansion + Capital Efficiency = Improving ROCE towards 20%+ levels

FY25 Target\*

Revenue Growth:

>15%

wth:

~\$200mn

Opex:

EBITDA Growth:

>30%

750crs+

Net Working Capital Cycle:

**Cycle:** < 2.0x 120days

Net Debt to

**EBITDA:** 

ROCE:

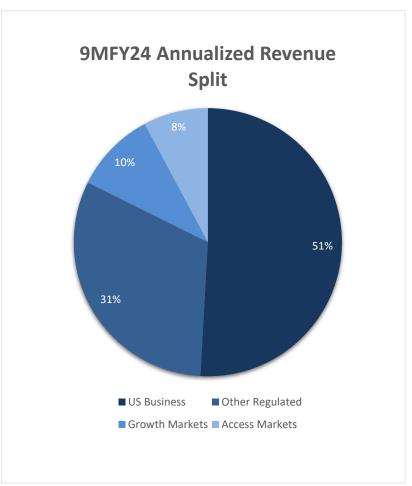
~20%

(Exit runrate)

### Strides at a Glance: A Pharma Formulation Exports Player







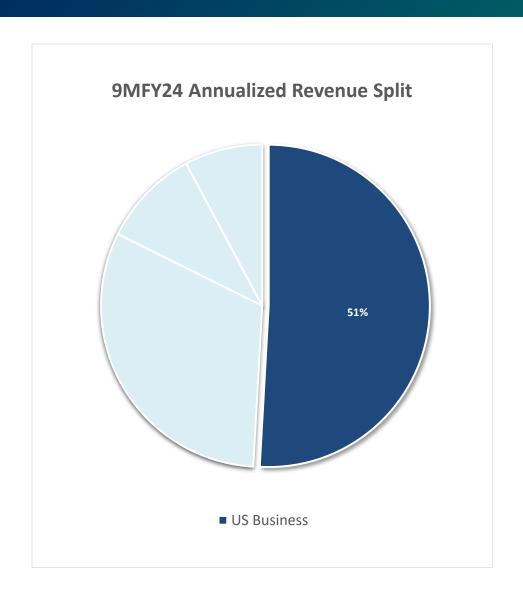
Manufacturing Footprint7 Mfg. Plants including4 USFDA approved facilities

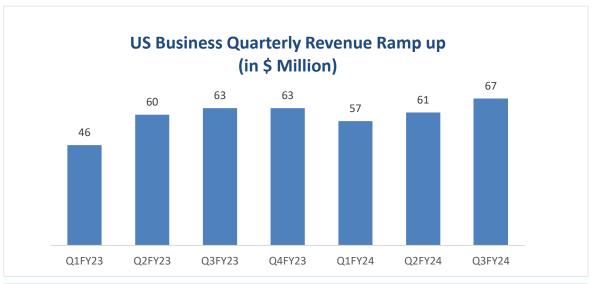
Quality Compliance
Successful compliance track
record with Global regulatory
agencies over the years

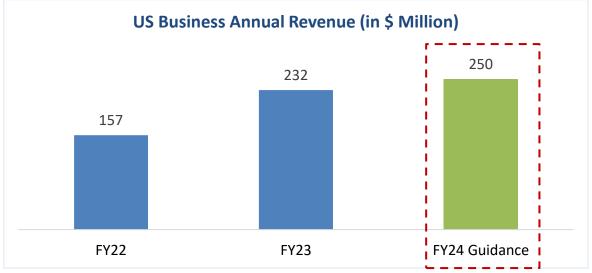
Globally Diversified
4600+ Workforce with exports
to 100+ Countries

## US remains a focus market for Strides; Reset for Profitable Growth









### Large Approved Portfolio provides sufficient Leeway to Scale up the US Business



#### **Existing Portfolio Strength**

260+ ANDAs filed 235+ ANDA Approvals

65+ Commercial products

Ranked #1 in 19 Products & Ranked among Top 3 in 34 products, that contribute 75% of its U.S. Revenue

#### **Growth Levers in Place**

Pipeline of 100+ Approved products of which 50+ products to be launched over the next 36 months

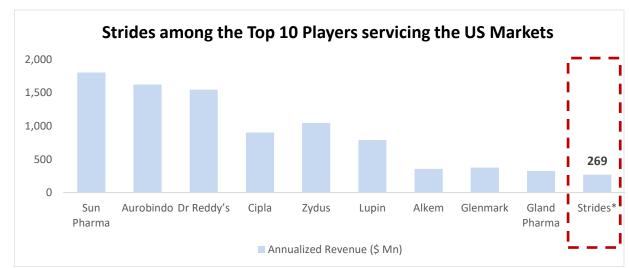
New domain additions comprising of Controlled Substances, Hormones, and Nasal Sprays through Chestnut Ridge

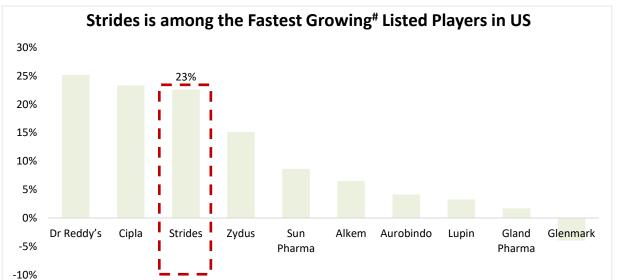
Targeting few High-ticket Launches: \$15M-\$20M per product
(vs. \$5M-\$7M historically)



### Strides among the Leading Indian Players in the US Market







#### \*Strides Q3FY24 US Revenues Annualized at \$269 m # Growth is based on CAGR from FY22 to H1FY24

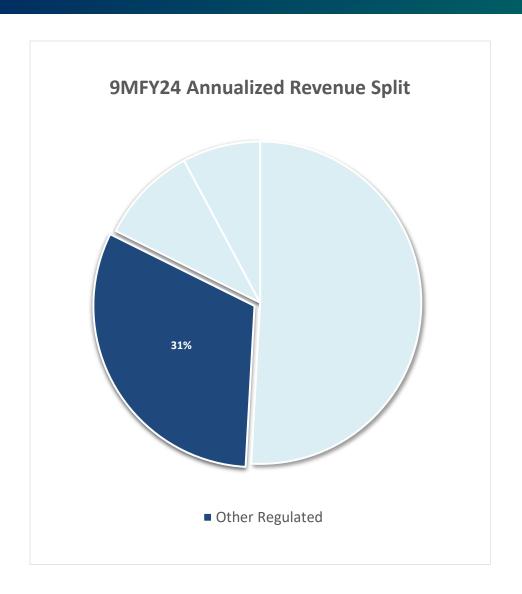
### Strides has a differentiated strategy for its US Business – Market Leadership in Niche Products

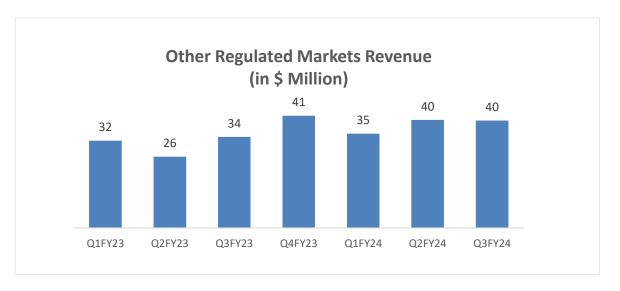
- Unlike other Generic Pharma Players, Strides has Profitably established its US business by implementing a Calibrated strategy for product launches, maintaining pricing discipline & preserving its margin profile.
- Despite facing a challenging environment in the US, this strategy has enabled the company to maintain its \$250 million business outlook.
- With Approved Manufacturing Facilities and R&D Investments largely done, Strides possesses an extensive portfolio of approved products.

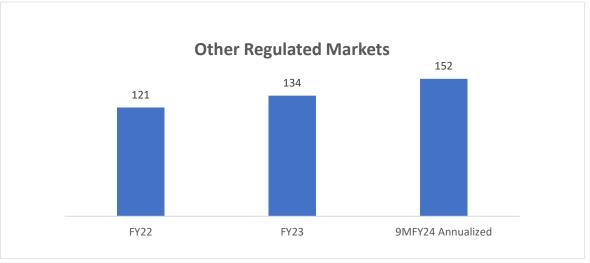
  This should help us launch 50+ products, thereby propelling us toward the \$400 million target for the US business within the next 3 years.
- Strides' emphasis in its US business lies not in rapid growth, but rather in **prioritizing margins, compliance, and ensuring a steady supply**. The extensive pipeline of products serves as guardrails that enable the company to maintain these key factors.

## **Other Regulated Markets: Growing at a Steady Pace**









## Portfolio Maximization and Strategic Partnerships to Drive the Other Regulated Markets Growth



## Front End Markets

The UK and other front-end markets have returned to their previous levels of growth and profitability

- Portfolio of **40+** launched Products with Top 3 Rank in 1/4<sup>th</sup> of the Portfolio
- Pipeline of 30+ products to be launched over next 12-18 months
- Tapping multiple distribution channels for Rx and OTC products Direct wholesalers, NHS supplies, and Clinical commissioning groups (CCG)

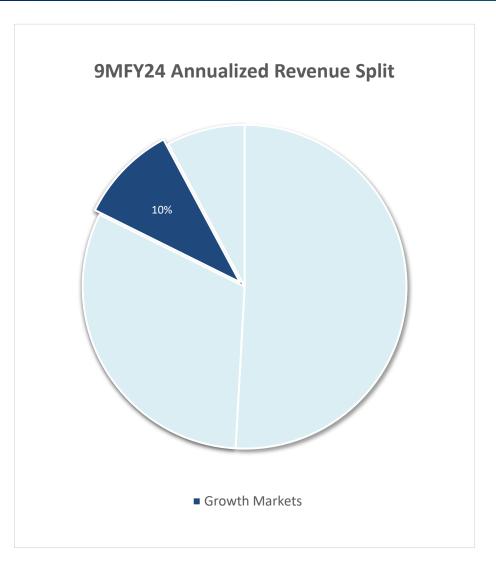
IP Led B2B Partnerships

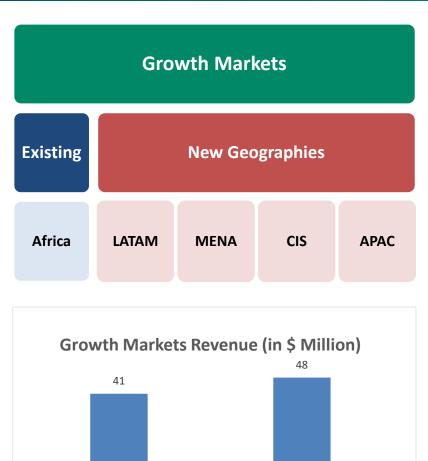
- 150+ R&D filings to build a strong partner led business across 20+ EU Markets
- Leveraging 10-year Supply contract with Arrotex, Australia's leading generic company
- Expansion of product offerings to New geographies through portfolio maximization & Strategic Alliances to drive growth

Aspiring to Mirror the US Business over the next 4-5 Years (\$400 M Revenue)

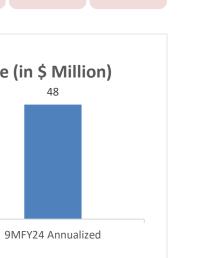
## **Growth Markets: Positioned for strong growth via new geographies & new products**







FY23



**Aspiring to grow Emerging markets** (Growth & Access) to \$ 200m over the next 4-5 years

## Deepening Presence in Existing Geographies & Establishing Footprint in New Focus Geographies



#### **Established Geographies**

#### **South Africa Business**

Portfolio offering of **100+** molecules

Strong relationship with **Dischem** (a Prominent Player)
to provide easy access for new products.

Future growth to be driven by
Foraying into tender and
Newer Private Market

#### **Africa Business**

African Pharma market is expected to grow at 10%+ with Branded generic to grow faster than Originators

Medical field force with coverage of 20,000 Healthcare professionals ensuring a well-established position

Territory **expansion** & Entry into **New Therapies** 

#### **New focus Geographies**

#### **Focused Expansion**

#### Latin America (LATAM)

One of the historical markets for the group with deep experience

#### Asia Pacific (APAC)

Significant registered portfolio for re- entry

## Commonwealth of Ind States (CIS)

Significant registered portfolio for re- entry

### **Strategic Partnerships**

#### China

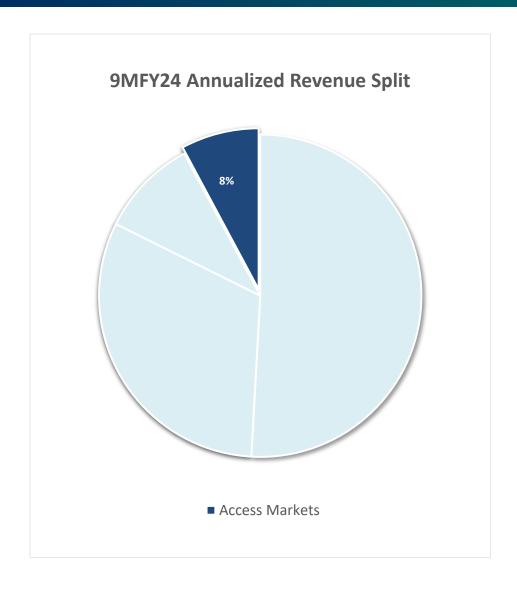
JV with Sihuan with 3 products under registration process

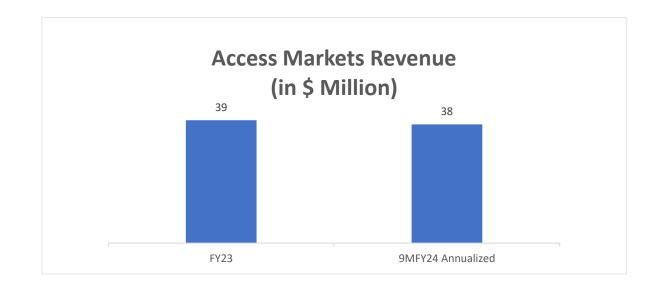
#### **Middle East**

Potential to forge partnerships with at least 3 leading companies

## **Access Markets: A Tender-driven Business; Not a Primary Focus for Strides**







#### **Access Markets Key Highlights**

- Access markets Revenues continues to be lumpy as the business is
   Tender driven, however this business recovers for the facility opex
- Continued focus on CIPs with vendors to reduce COGS and enhance competitiveness



## OneSource: Years of Investments, Time for Fruition

- > Strides announced creation of "OneSource" in Sep'23
- > An independent Specialty Pharma CDMO
- Will unlock value to shareholders
- > Listing\* expected in next ~12 months

## **Value discovery and Unlocking Potential**



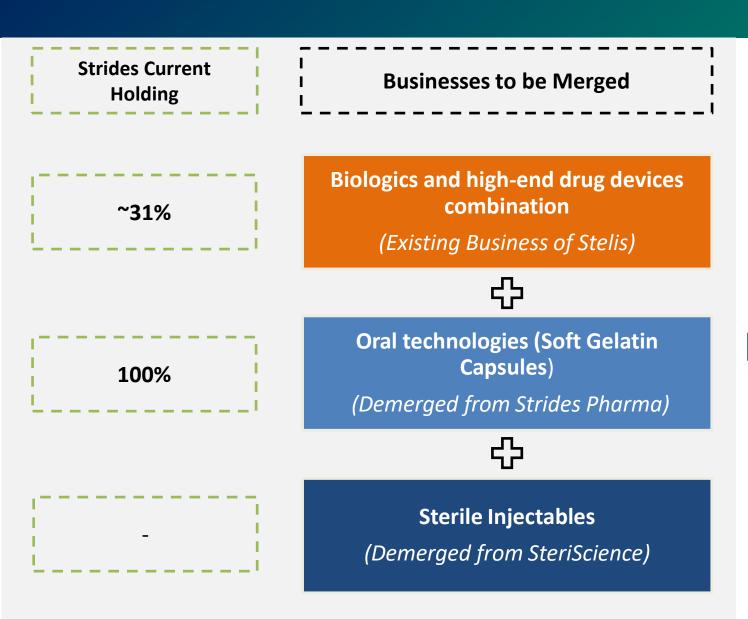
- India's first Specialty Pharma CDMO covering Biologics, complex Injectables and Oral Technologies (Softgelatin capsules)
- Set to emerge amongst India's Top 5 pure play CDMOs
- Full potential of Soft gelatin business residing in Strides unlocked at superior multiple (EV/EBITDA~17x)

#### **Value unlock for Strides Shareholders**

- Creation of two distinct operating entities with focused executive teams
- Strides shareholders to participate in value discovery by holding 44% in OneSource (implied value INR 364 per share of Strides)
- Strides shareholders to receive 1 share of OneSource for every 2 shares of Strides, Swap Ratio of 1:2
- Allows Shareholders and Investors to value both business independently
- Investment strategies aligned with pure play CDMOs
- Efficient capital allocation and focused leadership to drive growth
- Continued focus on superior governance standards

### **OneSource: Creation of India's first Specialty Pharma Pure Play CDMO**





**Strides Shareholders will own 44%** of the economics of OneSource



India's first specialty pharma pure play CDMO

The Implied value of proposed Shares issued by OneSource to Strides shareholders is **INR 364 per share** 

## **Resultant Cap Table of OneSource (Currently Stelis)**



Category	Pre – Sch	neme*	Post - Scheme		
	Number of Shares	% Share Holding	Number of Shares	% Share Holding	
Promoter and Promoter Group	12,586,085	29.93%	42,321,592	39.00%	
Strides Group**	12,929,220	30.74%			
Public	16,541,349	39.33%	66,205,489	61.00%	
Total	42,056,654	100.00%	108,527,081	100.00%	

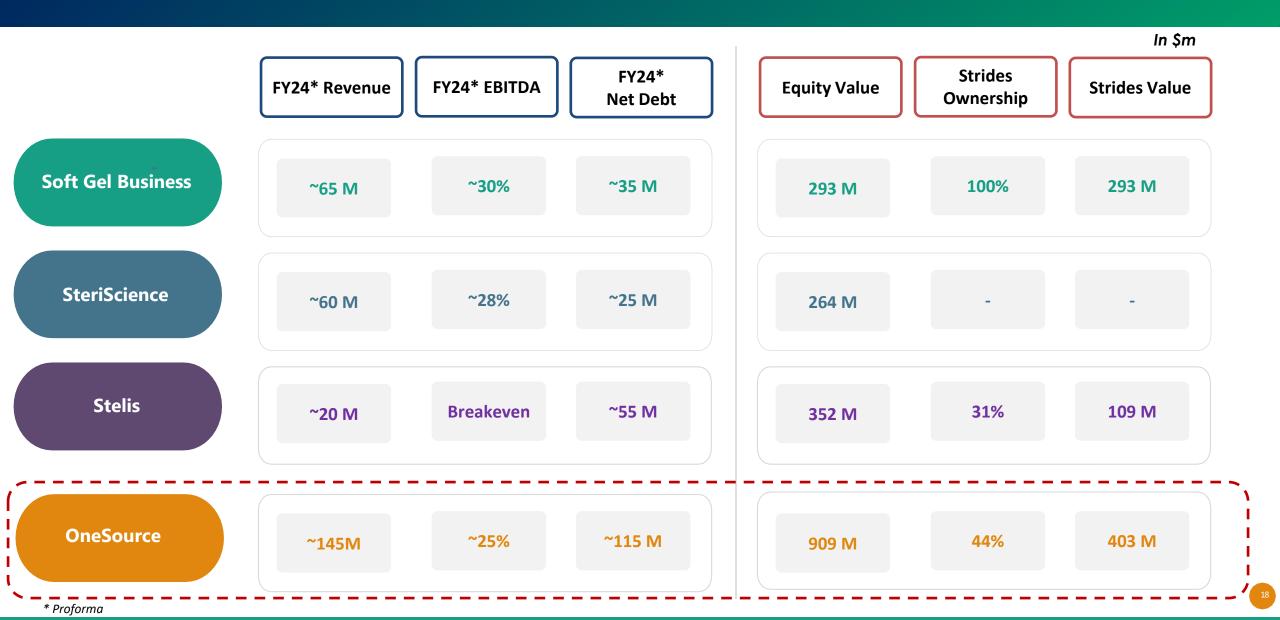
<sup>\*\* 11,089,320</sup> shares held by Strides in Stelis will be cancelled through the Scheme

<sup>\*</sup>The pre-scheme shareholding pattern of Stelis and SteriScience includes, 510,144 shares and 1,649 shares respectively under employee stock options and under other commitments which the management intends to issue before the effectiveness of the scheme.

## Financials & Valuation Synopsis:



Valuation of OneSource based on valuation report of PWC and fairness opinion of Jefferies



## Way Forward, Set for Profitable Growth



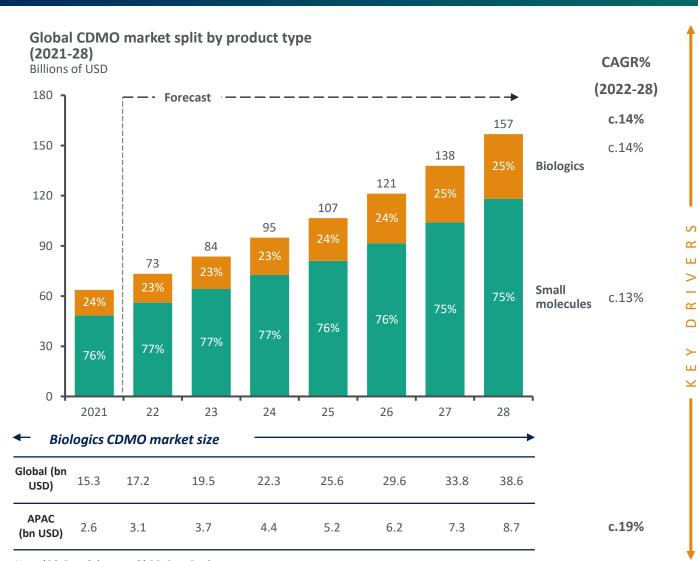
Target	FY24	FY25	Medium Term Outlook
Revenue	~\$145 M	~\$190 M	
EBITDA Margin	~25%	~30%	OneSource has potential to double its scale in 3-4 years mainly from
Net Debt	~\$115 M	~\$50 M	the momentum from biologics and high-end drug device combinations in GLP-1 products
ROCE %		25%+	
			EBITDA to FCF generation : 60+%
			Net Debt Free by end of FY26



**OneSource: Growth Enablers** 

## The global pharmaceutical and biologics players are leaning towards a partnership model for developing and manufacturing their existing products





Outsourcing to specialized organizations helps global players lower drug development costs, optimize manufacturing networks and improve efficiency.

The industry has high entry barriers due to initial investments in establishing high-end capabilities, long gestation periods, high switching costs for the innovator, and, most importantly, the ability to protect intellectual property rights.

Continued R&D spending will drive significant outsourcing growth (>6% CAGR between 2021-2026, estimated to reach \$1.6 trillion), driven by the anticipated launch of novel therapies addressing unmet needs and volume growth from expanding global access to medications.

The outsourcing trend is also being driven by new small pharmaceutical companies, biotechnology startups and virtual pharmaceutical companies who do not have their own developmental and manufacturing facilities

Note: \*DS: Drug Substance; \*\* DP: Drug Product

Source: Frost & Sullivan (2020); Azoth Analytics Report (2022), L.E.K. research and analysis

## Strides group is combining its assets to build one of most advanced technology led specialty CDMO





Microbial biopharmaceuticals

Mammalian biopharmaceuticals

Cell and Gene therapy

RNA, Adherent and suspension-based products





Rx Soft gelatins Out-licensing

OTC / Consumer Health partnerships

Development & Manufacturing services

Regulatory support







Formulation development

Clinical, analytical and stability studies

Fill-finish services

Regulatory support

Phase 1/2

Phase 3

**Commercial manufacturing** 

## Our robust capabilities form the bedrock for addressing a substantial market opportunity within the expanding CDMO landscape.



#### **Growth Enablers**



- Fully integrated capabilities from cell line development to commercial manufacturing
- Two manufacturing sites with capabilities in a microbial and mammalian expression system, including wild strains
- USFDA and EMA recently approved Flagship Facility.
- Significant order book to break even in FY24 and fast expand from FY25 as the commercial sales for the partners initiate.



## Soft Gelatin capsules

- 15+ years of soft gel experience in Rx/Prescription led specialized products.
- One of the largest Global Rx platforms for the soft gels manufactured in technical collaboration with Pharmagel, Italy
- Significant market share (partner-led) in all the commercialized products Globally
- Recent foray into OTC and CDMO led partnerships
- Large scale capacity with 2 billion annual units and planned expansion. Facility approved by US-FDA, MHRA, ANVISA, TGA, WHO, and MCC



**Specialties** 

## Complex and ready to use products

- From the team that delivered significant outcomes with Agila, India's first truly global injectable platform.
- Long term contracts with leading global players across multiple products
- Capabilities to develop and manufacture complex products in differentiated formats including vials, lyophilized vials, Pre-filled Syringes and dry powder.
- Two manufacturing facilities in India with approvals from USFDA, EU-GMP, Health Canada, and UK MHRA.

### **OneSource Capability Set Snapshot**

Five manufacturing facilities have received certification from international authorities, and OneSource is making bigger plans for the future









- Cell line and strain development, selection & characterization
- Upstream and downstream process development:Mammalian & Microbial
- Analytical development physicochemical, bioassay & characterization methods

#### Speciality:

- Expertise in Ready-to-use and complex injectables including suspensions, microspheres, and liposomes.
- Capabilities and experience in developing products across dosage formats of vials, pre-filled syringes, bags, ampoules, cartridges, and auto-injectors



#### Soft gelatin capsules

- Installed capacity is one of the largest in the World.
- 4 Encapsulation lines from Pharmagel Italy
- High speed Contact printers to print capsules with High speed camera based inspection system to detect any visual manufacturing defect
- Robust quality and compliance track record with any time audit preparedness
- All regulatory approvals including US-FDA, MHRA, ANVISA, TGA, WHO and MCC amongst others



#### Biologics, Bengaluru, India

- Approved by USFDA and EU-GMP
- Microbial: Hybrid drug substance manufacture clinical and commercial
- Mammalian: Single-use bagsbased drug substance manufacture – clinical & commercial
- Drug Product manufacturing:
   Vials, PFS & Cartridges. Pen
   Device Assembly and release as per ISO standards
- Regulatory, Clinical, Validation services, stability studies & misc. support services



#### Specialty, Bengaluru, India (1)



- The site has industry-leading expertise in lyophilization techniques and tremendous experience in cycle-time optimization.
- The facility also hosts an autoinjector device line that allows us to offer patient-friendly drug delivery solutions with capacities to produce 16 million autoinjectors annually.

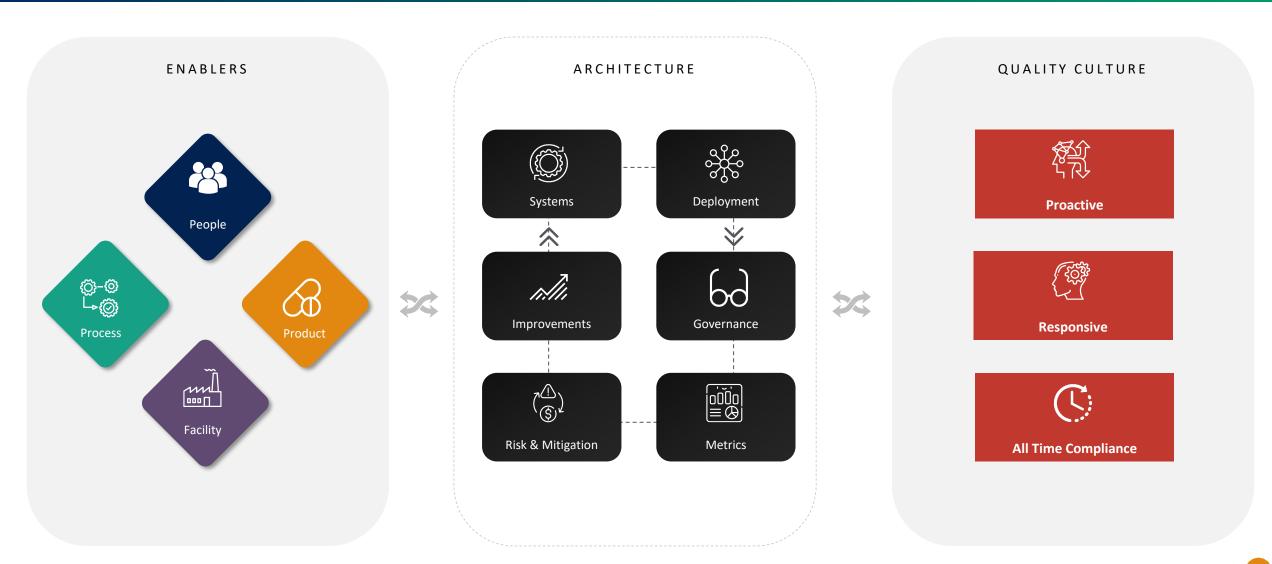


#### Specialty, Bengaluru, India(2)

- ► A US-FDA approved dedicated penicillin facility; situated on an area covering 3900 square meters in Bengaluru, India, and caters to global markets including US, Australia & Brazil.
- Supply chain disruptions highlight a key vulnerability for penicillin production worldwide, with increased manufacturing capability for these life-saving drugs becoming imperative for ensuring continued access.
- The facility comprises two sterile dry powder lines with an annual capacity of 32 million units.

## Significant investments in quality systems and compliance with industry leading quality governance framework







# Growth lever 1: Biologics and Drug-Device combinations Our capabilities are tailored to provide development and manufacturing services throughout the lifecycle of biologics and complex products

## In the CDMO business, OneSource would offer a fully-integrated biopharmaceutical platform providing one-stop-shop offering for biologics



#### **Truly One-stop Offering**

**Cell-line Development** 

Master and Working Cell Bank

Cell Culture Production

Filtration and Purification

**Formulation** 

Fill and Finish

Packaging

Integrated end-to-end provider with high quality tech transfer, process development, manufacturing, fill and finish and release biologics capabilities

#### **Process Development**

- Upstream and downstream development for all clinical phases and injectable formats
- Highly streamlined tech transfer approach



#### **Drug Substance**

- Mammalian and microbial platforms
- Single-use bioreactors for lower cost, reduced contamination risk and higher uptime



#### **Drug Product**

- Clinical batches to high-speed commercial lines inc. both liquid and lyophilized vials
- Single-use manifold systems allowing customizable assemblies



#### **Quality & Regulatory Services**

Highly-experienced regulatory personnel with worldwide regulatory knowhow: a GLP-1 filing completed in <200 days with approval in the first cycle



Single solution for developers seeking a turnkey CDMO partner that can serve across the full project lifecycle

## A strong biologics CDMO division with world-class capabilities and capacities enabling cost-effective solutions





#### One Stop Capabilities

- Pure play biopharmaceutical CDMO covering drug substances capabilities across mammalian and microbial expression systems fully integrated with a wide variety of sterile drug product formats.
- Offers a complete spectrum of services, from cell line tech transfer to clinical and commercial manufacturing.



#### Mfg. capacities

- 4X 2KL SUB capacity available for Mammalian and 1KL SS capacity for Microbial based products
- Drug product capacities available for all injectable formats (vials, PFS, PFC) and exceed 200 million units per annum
- Agility and space to expand capacity with industry-leading speed whilst catering to bespoke manufacturing requirements



#### Flexible and Partner Centric

- ► Two state-of-the-art facilities, with ~550,000 square feet of Process Development (PD) and manufacturing space for microbial and mammalian programs.
- Tech transfer and scale up activities can be completed in existing facilities whilst bespoke manufacturing expansions are deployed to optimize program timelines.



#### Worldwide Quality and Compliance

- Flagship facility approved by the USFDA, EUGMP
- EU-approved process development capabilities
- Highly experienced quality and regulatory personnel to meet the highest global quality standards, ensure compliance and guide our clients through the regulatory approval process.





## Business model for biologics is uniquely poised to recover several income streams until the product approvals are secured



#### **Biologics CDMO Division Business Model**

Manufacturing Services
Agreements
(MSA)

- First part of the CDMO contract which typically includes the technology transfer, process development, process scale and execution of Performance Qualification (PPQ) batches
- Includes the base work required for securing the regulatory approval, and consequently contract for manufacturing
- Typical revenue size in the range of \$1-2m for drug product and \$4-5m for drug substance

Commercial Sales
Agreement
(CSA)

- Second part of the CDMO contract, includes the value of business which is secured through the commercial supplies of the products which are developed for the partner under the MSA
- Typically, a duration of CSA would be 3-5 years and is secured by capacity commitment ensuring annuity of revenues

As more MSAs translate into CSAs, the P&L would be able to scale up its business significantly results in high profitability with no major increase in costs

Commercial supplies of Integrated DS and DP Mammalian Drug Substance(DS) Microbial Drug Substance (DS) Drug Product(DP) Fill/Finish

## OneSource would have a balanced Generics and Innovators' commercial strategy to deliver near and long-term results

~\$1.5m

Value per

MSA

3-5

Years to

approvals



Complex Generics & high-end devices	Biologics
Initial commercial focus leveraging spare capacity.	Long term core strategy with good risk-reward
Faster ramp up to commercial scale projects and capacity fill	Ideal technology set-up to serve a variety of project types
Lower development risk, de-risking near-term revenue streams	Opportunity to become a top 5 player in APAC market
Leverages group's contacts and goodwill	<ul> <li>Untapped market opportunity with large CDMOs unwilling to allocate capacity / provide quality service to smaller biotech</li> </ul>
Benefits from high market demand for sterile fill-and-finish	Complex to manufacture products which will benefit from higher margins
Establishes track record to support innovator BD efforts	Follow the molecule opportunities, fueling outsized revenue potential once approved
Near-term advantage	Long-term advantage

**Balanced** and

flexible approach

\$3.5m

Value per

MSA

5-8

Years to

approvals

### **Proven Drug Substance Capability**



Talented scientific and cross functional team has proven experience in trouble shooting and delivering innovative solutions to clients globally



End-to end-development and manufacturing (DS + DP) of teriparatide biosimilar an E. coli-derived recombinant peptide approved by EMA



Successful tech transfer and scale-up of cell culture based adenoviral vector process from 50L to 2000L scale



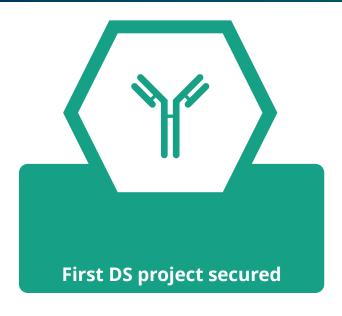
**Developed and validated analytical methods** (in-process and release) as well
performed **exhaustive product and impurity characterization** for peptides,
mAbs and recombinant proteins



Successfully developed and scaled up (from 10 L to 1000 L) the technology of multiple *Insulin analogue molecules*, including extensive method development and characterization.

## Drug Substance manufacturing kicked-off in partnership with a global generics major; Mammalian DS development and manufacturing of a biosimilar for one of the largest biologics





Partner is a top 5 global Pharma Gx company

Monoclonal antibody development aimed for global markets, including US, EU and RoW

Technology transfer in development labs at 10 L, process scale-up to 2 KL, clinical trial material generation batches, PPQ campaign and commercial DS and DP manufacturing



## Unique competitive edge with GLP-1 is a significant factor for future success while the biologics business has also picked up



- From a low base in FY20, we have added several new customers after receiving USFDA approval in FY23 (Two inspections included in CY2022- PAI, Drug Device, and GMP)
- Our business continues to grow as we propel our geographical marketing efforts and attract new partners.
- Our contracting of new manufacturing services agreements (MSAs) has intensified.
- From FY20 to Dec FY24, We secured \$74 million in MSAs, of which \$43 million were secured in FY24 alone so far. 9 Partners including top global companies have been added to our total unique clientele of 16 after USFDA approval.
- We secured our first significant DS contract with a top 10 global pharmaceutical company for an important product. In addition, the company won several new contracts from our existing partners, demonstrating our execution capabilities for their existing projects with a strong focus on client satisfaction and on-time delivery.
- Made our first commercial shipment, indicating the beginning of commercial supplies for our partnered products. Most Commercial Supply Agreements (CSAs) commence in H2, ensuring this division breaks even on EBITDA in the second half of FY24. In FY25, the division will have a positive PAT.

~\$31m

Cumulative value of MSAs won between FY20 and FY23

~\$43m

Value of MSAs won in FY24 so far

~\$792m

Cumulative value of CSAs for GLP between FY24 and FY32

\$282m

Cumulative value CSAs for Non-GLP between FY24 and FY32

~\$36m

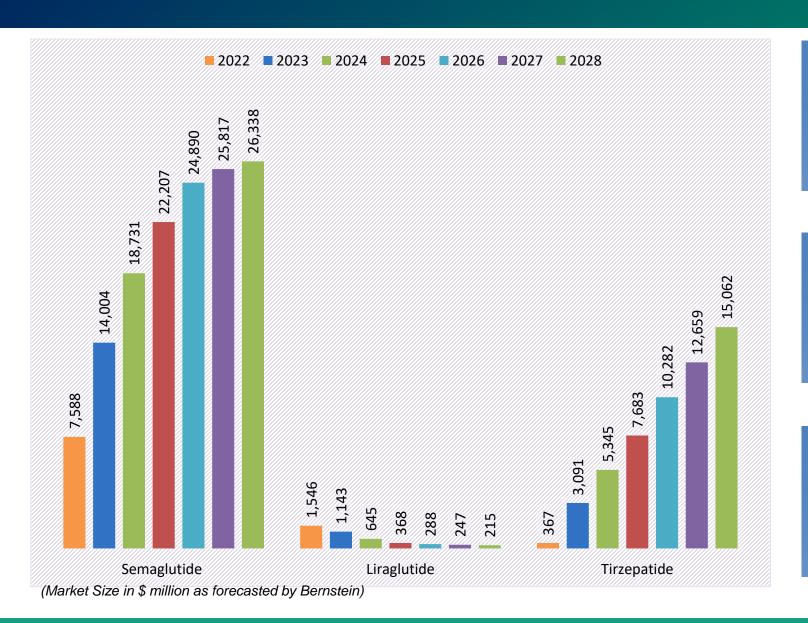
Value of business under advanced discussions

**16+** 

9 Partners including top global companies onboarded after USFDA approval

### OneSource in a sweet spot to capitalize on the upcoming GLP-1 opportunities





#### Semaglutide

- Sold as Ozempic® (diabetes) and Wegovy® (Weight loss/obesity)
- Stelis is partnered with multiple players including 2 with NCE-1 filings in US
- Stelis has strategic advantage of end-to-end drug device assembly with state-of-the-art fill-finish services
- Early commercial revenue opportunity starting 2026

#### Tirzepatide

- Tirzepatide is a once-weekly GIP receptor and GLP-1 receptor
- It was approved as Mounjaro® by the FDA on May 13, 2022.
- Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Stelis has partnered with 2 leading global companies

#### Liraglutide

- Sold as Victoza® (diabetes) and Saxenda® (Weight loss/obesity)
- Stelis is partnered with multiple players with filings in US & EU
- Stelis has strategic advantage of end-to-end drug device assembly with state-of-the-art fill-finish services

### With access through own JVs & CDMO partners, including two first-to-files, Stelis poised to gain significant value from the GLP-1 growth story



#### Semaglutide

### Liraglutide

**CDMO** 

#### **Tirzepatide**

#### **CDMO**

#### **Partnered CDMO**

 Leading Indian Generic player 1<sup>st</sup> to file [NCE-1]

**CDMO** 

• 2 Leading European Generic players

#### **Partnered CDMO**

- Licensed to global top 3 generics major – First to file [NCE -1] [Regulated Markets]
- 6 customers including top Indian and Global players

- Global Top 2 generics majors
- 1 Leading European player

- MENA No.1 Player
- LATAM No.1 Player



## **Growth lever 2 : Soft Gelatin Capsules**

One of the leading global players in soft gelatin technologies with a strong funnel of opportunities and a robust partner led Rx-penetration

## The global soft gelatin market is continuously expanding, and the introduction of new products is driving demand for CDMO services. We are amongst the top 5 players globally in SGCs



\$11.5b

Global Market Size for Soft gelatins across generics and NCE-1

\$5.5b

North America\*- the largest market for soft gelatins

9%

European Union is the fastest region for growth of soft gelatins

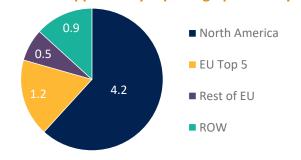
#### US is the largest market and a significant growth pick up is led by the EU and ROW regions

Region	Market size (bn\$)	Volume (bn units)	Sales CAGR**	Volume CAGR
NA*	5.5	6.2	6%	-5%
EU Top 5	1.8	2.0	9%	1%
Rest of EU	1.0	2.8	6%	9%
ROW	3.0	9.4	8%	4%
Total	11.5	20.4	7%	1%

#### The new generics opportunity is emerging from the Ex-US regions

Region	Market size (bn\$)	Volume (bn units)	Sales CAGR**	Volume CAGR
NA*	877	3604	-6%	-12%
EU Top 5	150	516	3%	3%
Rest of EU	138	378	8%	7%
ROW	706	1410	2%	3%
Total	1871	5908	0%	-2%

#### NCE-1 Opportunity is picking up and only specialized players have the ability to capitalize



- Increasing intake of soft gelatins in developed and developing countries
- Increasing use of halal-certified bovine and fish gelatin along with soft gel capsules made from vegetable ingredients such as cellulose gum, modified starch, and other plant gums driving its growth in Islamic countries.
- c. Switch to vegetable oil

## In technical collaboration with Pharmagel, Italy, our Soft Gelatin Platform under One-Source has been successful in delivering 15 ANDAs, with over 15 years of cumulative Rx soft gel experience.



#### Our Capabilities for a strong B2B or a CDMO led strategy



- All products developed and manufactured with Global orientation including portfolio for oncology and cytotoxins
- Caters to both Rx and OTC markets with commercialized products having high teen market share
- Capabilities in varying shapes and sizes of SGCs from Oval , Oblong from 2 40 oval and 5 to 22 oblong



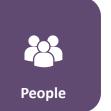
**Plant** 

- Facility based in Bangalore, India with technological collaboration with Pharmagel, Italy, with 4 Encapsulation lines
- All regulatory approvals, including US-FDA, MHRA, ANVISA, TGA, WHO and MCC, amongst others
- Planned expansion to more than double SGC capacity by FY 24 (2.4 billion plus)



**Processes** 

- High speed Contact printers to print capsules with high-speed camera-based inspection system to detect any visual manufacturing defect
- Robust quality and compliance track record with any time audit preparedness



- Dedicated capability pool for soft gelatin expertise
- Focused on domain specific strategy for expansion and operational excellence
- Continuous innovation and new product introduction through in-house capabilities





## Amongst the Top 5 Player globally in SGCs with a sizeable presence and a strong pipeline of products to further augment the CDMO business



#### Strong funnel of opportunities and a robust partner led Rx-penetration

\$11.5 B Total Soft Gelatin Market with \$7.0b in NCE-1

**\$4.4 B** Total Generics opportunity across several products

\$2.5 B Market Opportunity for Approved Product Portfolio

Largest soft gel manufacturer by volume

**15** Total approved portfolio

#4

14

5

Products under Development

NCE-1 coming off-patent in next years



**Plant** 

#### **Facility based in Bangalore**

Regulatory approvals: US-FDA, MHRA, ANVISA, TGA, WHO & MCC

To more than double SGC capacity by FY24 (2.4Bn+)



#### Caters to both Rx and OTC markets

Commercialized products having high teen market share, recently launched Gx Vascepa

Capabilities in varying shapes and sizes



Recently concluded multi-year deal with top-4 US private label supplier for 2 OTC SGC products

In Contract finalization stage with leading OTC global player for supply of 500million units of Ibuprofen SGC

Potential opportunity in China through our licensed SGC products with a leading Chinese company



## **Growth lever 3 : Complex and Specialty Injectables**

Significant experience in injectables with wide capabilities makes us a very strong CDMO player for complex and ready to use products

# The long-term fundamentals for small molecule complex injectables CDMO opportunities remain intact as more products lose exclusivity and high complexity of products elevates the barrier to entry for new players.



Generic injectables are increasingly considered the next growth engine by large generic players in the US

Most new entrants focus on complex injectables to differentiate themselves from the large incumbents

Nearly every generic player with some scale in the US has about increasing investments in injectables and stepping up on filings at the FDA in the last few years

Injectables seem to be the new mantra for growth in the US market, which has been plagued by competition and pricing squeeze by the wholesalers.

#### Brands LOE by route of administration (\$ billion)<sup>1</sup>

Dosage	Un genericized	2022	2023	2024	2025	2026	2027	Total
Simple injectables		3.2	0.2	0.6	0.5	1.0	3.0	8.6
Complex Injectables	7.8	1.6		0.8		1.1	0.3	12.1
Inhalation	4.2		0.2		1.3		2.5	8.3
Others	0.8	0.3	0.2	0.1	0.6	0.6	0.8	2.9

1. Source: Evaluate, Bernstein estimates and analysis LOE - Loss of exclusivity; Sales in the year before LOE

## The current environment in injectables presents opportunity for new players that can scale with capabilities



SEVERE INJECTABLE SHORTAGES PERSISTING –
HITTING A 10-YEAR HIGH – MAJOR LACK OF SUPPLY
RELIABILITY

INCREASED SCRUTINY FROM REGULATORS ON FACILITY INSPECTIONS EMERGING POST COVID

ABILITY TO OPERATE LARGE-SCALE, HIGH-QUALITY MANUFACTURING KEY TO SECURED SUSTAINABLE GROWTH

ACUTE SHORTAGES DRIVING CHANGE IN MARKET BEHAVIOURS WITH NEW PLAYERS LIKE CIVICA DISRUPTING STATUS QUO



**₩**....







## One of the largest platform for sterile injectables with strong capabilities across dosage formats



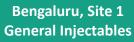
#### DOSAGE FORMATS

**Liquid Vials** 

Lyophilized Vials

**Auto-injectors** 

**Pre-Filled Syringes(PFS)** 





- State-of-the-art USFDA approved facility offers a wide range of parenteral drug products with over two decades of experience supplying to the US, Europe and Australia markets.
- ► The site has industry-leading expertise in lyophilization techniques and tremendous experience in cycle-time optimization.
- ► The facility also hosts an autoinjector device line that allows us to offer patient-friendly drug delivery solutions with capacities to produce 16 million autoinjectors annually.

Bengaluru, Site 2
Dedicated to Penicillins



- ► A US-FDA approved dedicated penicillin facility; situated on an area covering 3900 square meters in Bengaluru, India and caters to global markets including US, Australia & Brazil.
- Supply chain disruptions highlight a key vulnerability for penicillin production worldwide, with increased manufacturing capability for these life-saving drugs becoming imperative for ensuring continued access.
- Facility consists of two sterile dry powder lines, with an annual capacity of 32 million units.





- Strong R&D team with 100+ years of domain expertise and rich experience in injectables
- Expertise in Ready-to-use and complex injectables including suspensions, microspheres, and liposomes.
- Capabilities and experience in developing products across dosage formats of vials, pre-filled syringes, bags, ampoules, cartridges, and auto-injectors





- In-house development of ANDAs on behalf of the partners,
   with 5 launches in the US market and another 4 planned in the
   next 6 months
- Targeted B2B strategy for the portfolio with more secured economics and shorter working capital cycles
- Business model includes secured margins on transfer price,
   with additional profit sharing and royalty earnings



- **CMO contracts with legacy partners**, as part of the acquisition of the manufacturing sites
- Pure play CMO with revenues at transfer price value, ensuring a fully loaded COGS + margin model
- IP ownership is with the contract giver, with Steriscience
   bringing in the manufacturing expertise



## One-Source will target a global opportunity with very few players that attract industry-leading multiples



#### **Trends in CDMOs**

Flexible CDMOs support pharmaceutical companies at all stages of the process of making medicines shifting their business model

CDMO M&A is on the rise, trailblazing with new manufacturing capabilities and scale

CDMO value chain is moving toward a "one-stop-shop" service portfolio with CDMO value chain becoming broader

CDMOs at scale have the purchasing power to move into new areas quickly, to extend their business model broadly

Structural shift to large molecules, the introduction of new modalities, deep pipeline, and R&D funding is expected to drive solid double-digit end-market sales growth

#### **Leading Global players and their valuations**

Segment	АРІ	FDF	Biologics	Revenue (\$b)	Market Cap (\$b)	EV/EBITDA (x)
Wuxi		•	•	2.3	11.5	14
Lonza	•	•	•	7.5	37.3	22
Samsung		•	•	2.8	44.2	39
Catalent		•	•	4.3	9.3	9
Thermofisher		•	•	42.9	208.2	23

#### Top Indian players and their valuations

Segment	АРІ	FDF	Biologics	Revenue (\$m)	Market Cap (\$b)	EV/EBITDA (x)
Divis	•			955	11.7	49.8
Suven	•	•		166	2.0	27.8
Piramal	•	•	•	882	2.2	21.8
Gland		•	•	518	3.9	28.7
Syngene		•	•	398	3.6	29.7
One-Source (FY25)		•	•	190	1.0* (listing)	17x (1y Fwd)

<sup>\*</sup> Basis independent valuation as announced



**Thank You**