

September 25, 2023

To, **BSE Limited**Phiroze Jeejeebhoy Tower,
Dalal Street, Mumbai – 400 001,
Maharashtra, India

BSE Scrip Code- 532531

To,

**National Stock Exchange of India Limited** 

Exchange Plaza, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051,

Maharashtra, India
NSE Code- STAR

Dear Madam/Sir,

Sub.: Intimation of Scheme of Arrangement, pursuant to Regulation 30 of the Securities and

Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations,

2015 (SEBI Listing Regulations)

In terms of Regulation 30 read with Schedule III of the SEBI Listing Regulations, we hereby inform you that the Board of Directors ('Board') of the Company in its meeting held today i.e., September 25, 2023, based on the recommendations of the Audit Committee and Committee of Independent Directors, approved a Scheme of Arrangement amongst Strides Pharma Science Limited ('Strides'/ 'Transferor Company 1'/ 'Demerged Company') and Steriscience Specialties Private Limited ('Steriscience'/ 'Transferor Company 2'/ 'Demerged Company 2') and Stelis Biopharma Limited ('Stelis'/ 'Transferee Company'/ 'Resulting Company'), (collectively referred to as 'Companies') and their respective shareholders ('Scheme'), under Section 230 to 232 of the Companies Act, 2013 (Act) and other applicable provisions of the Act and Rules framed thereunder.

The Scheme is subject to necessary approvals including that from the Securities and Exchange Board of India (SEBI), the shareholders and creditors of the Company and the Hon'ble National Company Law Tribunal (NCLT).

The Scheme shall be filed with the Stock Exchanges for obtaining their 'No Objection Certificate' in terms of the provisions of Regulation 37(1) of SEBI Listing Regulations in due course.

The disclosures required under Regulation 30 of SEBI Listing Regulations read with SEBI Circular No. SEBI/ HO/ CFD/ CFD-PoD-1/ P/ CIR/ 2023/ 123 dated July 13, 2023, in respect of the Scheme is enclosed as **Annexure 1**. In this regard, also enclosed is a presentation issued by the Company titled 'Strides announces OneSource' as **Annexure 2**.

The Board meeting commenced at 14:15 hrs IST and ended on 15:10 hrs IST.

Kindly take the above information in your records.

Thanking You For Strides Pharma Science Limited,

Manjula Ramamurthy Company Secretary ICSI Membership No.: A30515

Encl: As above



### **Annexure 1**

Disclosure under Regulation 30 of SEBI Listing Regulation read with SEBI Circular No. SEBI/HO/CFD-PoD-1/P/CIR/2023/123 dated July 13, 2023

| #  | Particulars   |  |  |  |  |  |  |  |
|----|---|--|--|--|--|--|--|--|
| 1) | Brief details of the division(s) to be Demerged   |  |  |  |  |  |  |  |
|    | Scheme of Arrangement involves the following entities:  |  |  |  |  |  |  |  |
|    | <ul> <li>Strides Pharma Science Limited ('Strides'/ 'Transferor Company 1'/ 'Demerg Company 1' / 'the Company');</li> <li>Steriscience Specialties Private Limited ('Steriscience'/ 'Transferor Company 'Demerged Company 2');</li> </ul>   |  |  |  |  |  |  |  |
|    |   |  |  |  |  |  |  |  |
|    | Stelis Biopharma Limited ('Stelis'/ 'Transferee Company'/ 'Resulting Company').   |  |  |  |  |  |  |  |
|    | Appointed Date for the proposed Demerger is April 1, 2024.  |  |  |  |  |  |  |  |
|    | Scheme of Arrangement shall comprise of the following:  |  |  |  |  |  |  |  |
|    | a) Demerger of the 'identified CDMO and Soft Gelatin Business of Strides' into Stelis   |  |  |  |  |  |  |  |
|    | b) Demerger of the 'identified CDMO Business of Steriscience' into Stelis   |  |  |  |  |  |  |  |
|    | The identified CDMO Business Undertaking is as under:   |  |  |  |  |  |  |  |
|    | "Identified CDMO Business of Strides" means the business in relation to the contract development and manufacturing of oral soft gelatins business carried on by Strides at the plant located at KRS Gardens, Bangalore, along with related assets, customer contracts, employees, and intellectual properties.  |  |  |  |  |  |  |  |
|    | The said business also comprises of investment in Strides Pharma Services Private Limited along with investment in its subsidiary Strides Softgels Pte. Ltd., Singapore.  |  |  |  |  |  |  |  |
|    | Further, the said business would also comprise of investment in Stelis, which is engaged in contract development and manufacturing activities across all phases of pre-clinical and clinical development and commercial supply of biologics.  |  |  |  |  |  |  |  |
|    | • "Identified CDMO business of Steriscience" means the business in relation to the contract development and manufacturing of sterile injectables business carried on Steriscience in the Special Products Division and Beta Lactam Division located Bangalore, along with related assets, customer contracts, employees, and intellecture properties. |  |  |  |  |  |  |  |
|    | Further, the said business also comprises of its strategic investment in Steriscience Specialties Pte. Ltd. Singapore, a wholly owned subsidiary of Steriscience.   |  |  |  |  |  |  |  |



2) Turnover of the demerged division and as percentage to the total turnover of the listed entity in the immediately preceding financial year/ based on financials of the last financial year

**Turnover of the Demerged Undertaking 1** for the year ended March 31, 2023 was ~INR 2,348 Mn representing ~13% of the total standalone turnover of the Company for the year ended March 31, 2023.

**Turnover of the Demerged Undertaking 2** for the year ended March 31, 2023 was ~INR 3,165 Mn representing ~99% of the total standalone turnover of the Demerged Company 2 for the year ended March 31, 2023.

## 3) Rationale for demerger

Board of Directors of the Companies involved in the Scheme are intending to build a one-of-a-kind specialty pharmaceutical Contact Development and Manufacturing ('CDMO') powerhouse with capabilities in biologics, oral soft-gels, complex injectables, sterile injectables, including other complex drug delivery systems.

In this regard, it is proposed to combine the Identified CDMO Business of Strides and the Identified CDMO Business of Steriscience under Stelis. The new platform will be able to offer development and manufacturing services covering platform technologies, specialty injectables, complex generics, biosimilars, and biologics.

### The proposed Scheme would inter alia have the following benefits:

- 1. Consolidation of the Identified CDMO Business of Strides and Identified CDMO Business of Steriscience, with Stelis, will result in integration of synergies and enable better supervision of the business.
- 2. Consolidation will allow the management to devise, implement and pursue independent business strategies for the contract development and manufacturing business which will enable a wider scope for independent collaboration, investment opportunities and expansion.
- 3. Consolidation will enhance business potential and result in an increased capability to offer a wider portfolio of products with a diversified resource base and deeper client relationships.
- 4. Consolidation would result in efficient utilization of the infrastructure facilities and optimum utilization of the available resources.
- 5. Further, the synergies arising out of the consolidation will lead to enhancement of net worth of the combined business and enhancement in earnings and cash flow would optimize the value of the Stelis and consequently enhance the shareholder's value.
- Consolidation will create and enhance stakeholders' value by unlocking the intrinsic value
  of the Identified CDMO Business of Strides and Identified CDMO Business of
  Steriscience, on listing of shares of Stelis.
- 7. Moreover, the Scheme is expected to increase long-term value for the shareholders of all the Companies and other stakeholders.



### 4) Brief details of change in shareholding pattern (if any) of all entities

There will be no change in the shareholding pattern of Strides and Steriscience.

Change in Shareholding Pattern of Stelis pursuant to demerger shall be as under:

| Category                       | Pre – So      | cheme *         | Post – Scheme |                 |  |
|--------------------------------|---------------|-----------------|---------------|-----------------|--|
|                                | No. of shares | % share holding | No. of shares | % share holding |  |
| Promoter and<br>Promoter Group | 1,25,86,085   | 29.93%          | 4,23,21,592   | 39.00%^         |  |
| Public                         | 2,94,70,569   | 70.07%          | 6,62,05,489   | 61.00%          |  |
| Total                          | 4,20,56,654   | 100.00%         | 10,85,27,081  | 100.00%         |  |

<sup>\*</sup>The pre-scheme shareholding pattern of Stelis includes 5,10,144 shares under employee stock options and under other commitments which the management intends to issue before the effectiveness of the scheme.

### 5) In case of cash consideration – amount or otherwise share exchange ratio

No cash consideration is payable under the Scheme.

Consideration for Demerger shall be discharged by issue of equity shares by Stelis/Resulting Company as per the following share entitlement ratios:

- for the allotment of equity shares of the Resulting Company, having face value of INR 1/- each to the shareholders of Demerged Company 1 as on the Record Date 1 (as defined in the Scheme), in consideration for the demerger:
  - "1 (One) equity share of Transferee Company (of INR 1/- each fully paid up) for every 2 (Two) equity shares of Transferor Company 1 (of INR 10/- each fully paid up)."
- for the allotment of equity shares of the Resulting Company, having face value of INR 1/- each to the shareholders of Demerged Company 2 as on the Record Date 2 (as defined in the Scheme), in consideration for the demerger:

"1,515 (One Thousand Five Hundred and Fifteen) equity shares of Transferee Company (of INR 1/- each fully paid up) for every 1 (One) equity share of Transferor Company 2 (of INR 10/- each fully paid up)".

Based on the above share entitlement ratio, if any shareholder(s) is entitled to fractional shares, then such fractional shares shall be consolidated and issued to and held by the Trust (nominated by the Board of the Transferee Company in that behalf) in dematerialised form and who shall sell such shares and the net sale proceeds will be distributed by the trustee(s) to such

<sup>^</sup> Prior to effective date of the Scheme, the Promoter and Promoter Group shareholding in Stelis/ Steriscience will be restructured by way of transfer of shareholding to the non-Promoters.



|    | shareholders in proportion to their respective fractional entitlements, in accordance with SEBI Master Circular dated June 20, 2023.               |  |  |  |  |
|----|--|--|--|--|--|
| 6) | Whether listing would be sought for the resulting entity   |  |  |  |  |
|    | Yes, Stelis/ Resulting Company is proposed to be listed on the BSE Limited and the National Stock Exchange of India Limited as part of the Scheme. |  |  |  |  |

\*\*\*\*



# **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 announces "OneSource"
- > An Independent Specialty Pharma CDMO
- Will Unlock value to shareholders
- > Listing\* expected in next 12 to 15 months

# Value discovery and Unlocking Potential

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

# **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/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 in both entities
- Continued focus on superior governance standards for both entities

# Strides Pharma: Strategic Reset announced in April '22 Delivered highest ever EBITDA performance in Q1FY24



# **FY22- A Challenging Year**

- Revenue Decline of 7.5%
- ✓ Compression in Gross Margins to ~51%
- ✓ Lowest ever reported EBITDA leading to first ever loss
- ✓ Challenging business environment
- Supply Chain headwinds
- ✓ Increase in financial leverage on the balance sheet

# Q1FY24 - Reset results delivered

- Significantly Improved Business performance
- ✓ YoY Revenue Growth across all Key markets
- ✓ Gross margins nearing historical peak , ~60%
- ✓ Highest ever Reported Quarterly EBITDA
- ✓ On track to achieve FY24 Outlook of INR
   7,000m (\$85m) to 7,500m (\$91m) EBITDA

**Debt Reduction tracking to our guidance of Debt/EBITDA under 3.0 for FY24** 

With our Continued focus on reset goals and free cash generation, we are confident to achieve Debt/EBITDA under 2.5 in FY25

# Stelis Bio-Pharma (an Associate of Strides Pharma) Significant progress achieved



# **Historical Challenges @ Stelis - FY23**

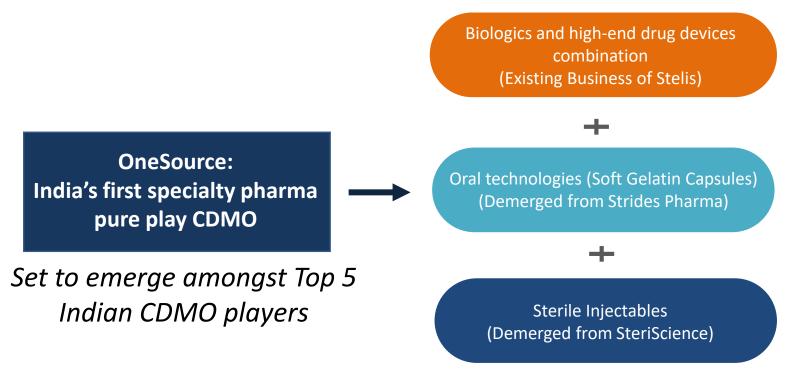
- Due to the geopolitical situation between Russia and Ukraine and sanctions against Russia and the Russian Direct Investment Fund (RDIF), Stelis inventories of the Sputnik vaccine remained unsold. The Company has already initiated the arbitration process in this regard.
- Stelis reported a loss of INR 1,263 million (\$16m) in Q4 FY23 and INR 7,998 million (\$99m) in FY23.
- Significant losses have been incurred due to provisions recorded for the write-down of Sputnik inventories, operating loss, and impairment of certain intangibles associated with its products division.



# **Business Updates**

- CDMO business continues to grow as the company propelled its geographical marketing efforts and attracted new partners.
- The Company's contracting of new manufacturing services agreements (MSAs) has intensified. From FY20 to Q1FY24, the company secured \$58 million in MSAs, of which \$25 million were secured in Q1FY24 alone.
- Stelis secured its first significant DS contract with a top 10 global pharmaceutical company for an important product. In addition, the company won several new contracts from its existing partners, demonstrating its execution capabilities for their existing projects with a strong focus on client satisfaction & on-time delivery.
- > The Company also made its first commercial shipment, indicating the beginning of commercial supplies for its partnered products. Most Commercial Supply Agreements (CSAs) commence in H2, ensuring the company breaks even on EBITDA in the second half of FY24. In FY25, Stelis will have a positive PAT.
- As the transaction with Syngene approaches closing, Stelis would use the proceeds to reduce its debt and restore its balance sheet strength. Stelis anticipates its External debt will decrease from ~INR 7,400 million in March 2023 to about INR 4,500 million by the end of FY24. Corresponding Strides guarantees expected to be around INR 3,500 million

# OneSource: Creation of India's first specialty pharma pure play CDMO



# **Enhanced Value to Shareholders**

**01** Strides Pharma shareholders to receive 1 share of OneSource for every 2 shares of Strides, Swap Ratio of 1:2

**02** Implied value of OneSource for Strides shareholders is INR 364/share

# **Valuation Synopsis**

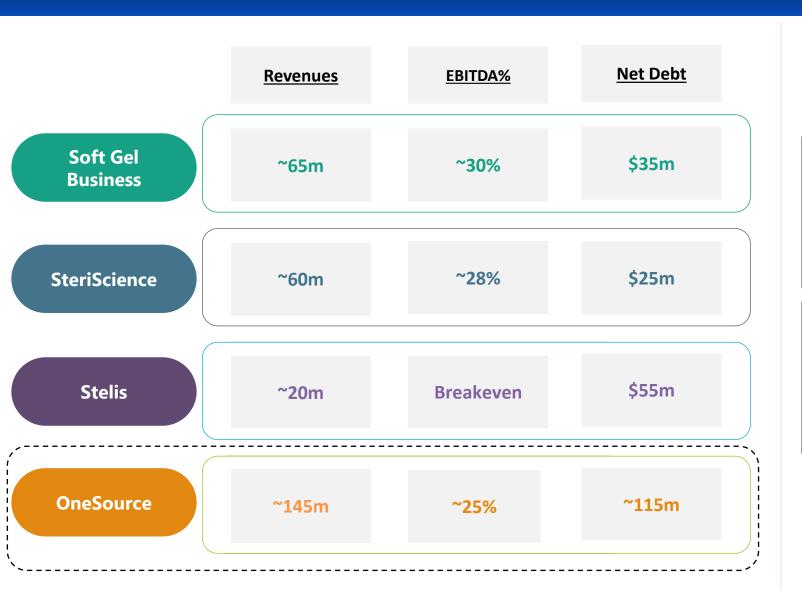
Valuation of OneSource based on valuation report of PWC and fairness opinion of Jefferies

|                      | Strides Equity value Shareholde Ownershi |      | <u>Strides value</u> |
|----------------------|--|------|----------------------|
| Soft Gel<br>Business | 24,335m                                  | 100% | 24,335m              |
| SteriScience         | 21,958m                                  | -    | -                    |
| Stelis               | 29,208m                                  | 31%  | 9,090m               |
| OneSource            | 75,501m                                  | 44%  | 33,425m              |

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

Strides Shareholders will own 44% of the economics of OneSource

# **OneSource – Delivering Strong FY24\* financials**



We expect the Business in FY25 to achieve sales between \$180m and \$200m with ~30% EBITDA margin based on strong orderbook on all 3 business divisions

OneSource has potential to double its scale in 3-4 years mainly from the momentum from biologics and high-end drug device combinations in GLP-1 products

# **Continuing Business of Strides Pharma**



- ✓ No change in **FY24 Outlook** (INR 7,000m to 7,500m EBITDA) as the scheme is expected to be effective in FY25
- ✓ Despite the demerged Strides Softgel business, Strides confident of achieving EBITDA of INR 7,500m+ for FY25 driven by growth across markets
- ✓ Existing strong pipeline of products and global market expansion will help the Company to grow and recoup the EBITDA drop due to demerger in FY25
- ✓ Free cash generation and debt reduction will enable the company to maintain FY25 Debt/EBITDA under 2.5 post push down of \$35m debt to OneSource
- ✓ Continue to focus on efficient capital allocation of resources

# OneSource – At a glance

- ► India's 1<sup>st</sup> pure play specialty CDMO platform
- Will be amongst the top 5 Indian CDMO Players
- OneSource will have Proforma Revenues between \$140m and \$150 million in FY24
- ► To deliver between \$180m and \$200m revenues in FY25 with ~30% EBITDA margin and a potential to double the scale in 3-4 year
- ► EBITDA to improve from FY26 onwards to ~35+% driven by GLP-1 contracts and significant synergies in combined CDMO business
- ► Four state-of-the-art USFDA facilities, process development & manufacturing space for soft gelatins, biologics and complex products
- Amongst the highest CDMO capacity to handle almost any level of business demand for wide range of modalities with agility to expand capacity with industry leading speed.
- ▶ 1,200+ employees with 200+ scientists and techno-commercial leaders











# Jefferies

**Fairness Opinion on Valuation** 



**Transaction Advisor** 



**Financial & Tax VDD, Valuation** 



**Grant Thornton** 

**Valuation** 



**Legal Advisors and Legal DD** 



# **Transaction Overview**

# Rationale for the Scheme



### Growth

H2'23 led by new launches and each of the varied businesses including CDMO business have significant potential for growth and profitability



# **Focused Strategy**

The nature of risk, competition, challenges, opportunities, and business methods for the CDMO is separate and distinct from other businesses being carried out by Strides



# **Separate Listed Entity**

Housing the CDMO Business of Strides in a separate listed entity (OneSource) would achieve growth and sustained value creation for shareholders through sharper focus on the business anchored on a differentiated strategy.



# **Multispecialty CDMO**

The consolidation of CDMO business would enable to build OneSource into a multispecialty CDMO with capabilities in biologics, oral soft gelatin technologies and complex injectables.



# **Strategically Valuable**

Strategically valuable and first platform of its kind in India, spanning capabilities and services that only few global companies have to offer

# **Mechanics of Transaction**

# Proposed Scheme of Arrangement (Appointed Date – 1st April 2024)

- Strides to demerge Oral Soft Gelatin business and Identified CDMO business (including investments held by Strides in Stelis) into Stelis.
- Upon demerger, the shares of Stelis held by Strides will be cancelled and shareholders of Strides will become shareholders of Stelis
- SteriScience (promoter group company) to demerge Identified Sterile Injectables CDMO business into Stelis
- Pursuant to the demerger, Stelis will issue equity shares to the shareholders of Strides and SteriScience on the recommended Share Entitlement Ratio determined by an independent valuer
- Pursuant to the approval of the Scheme, Stelis\* would be listed on NSE and BSE

# **Listing Process - Next Steps**

Obtaining Valuation Report, Fairness Board of Directors to approve the Scheme Filing of Scheme with Stock exchanges for Opinion, Independent Committee approval from SE and SEBI of Arrangement approval and Audit Committee approval Completed Completed Sending notices to the creditors and File notices of petition for approval from Filing of Application with NCLT shareholders of Strides for CCM and e-RD and ROC. Intimation to Income-tax (Post receipt of Stock Exchange approval) voting authorities E-voting and holding CCM for creditors Filing of Chairman Affidavit and Report Filing of Petition with the NCLT and shareholder of Strides with the NCLT Filing of Scheme with ROC to make Listing of shares of Stelis scheme effective and stamp duty 4 Final Hearing at the NCLT adjudication Indicative Timeline: ~ 12 months

# Impact on Shareholders

Common Promoter Interest - Valuation done by 2 independent reputed Valuers with fairness opinion from an International Banker

Valuation Approach - Multiple valuation methods with weightages

Management Bandwidth - Both businesses to be run by specialized management teams

Shareholders First

Capital Structure - Both businesses to have strong balance sheet with healthy leverage and sufficient liquidity

Risk Diversified through holding in two companies

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

| Category                    | Pre – Scheme*    |                 | 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.

<sup>^</sup> Prior to effective date of the Scheme the Promoter shareholding in Stelis/SteriScience will be re-structured by way of a transfer of part shareholding to Non-Promoters.

# **Investor Call Details**

# **Strides Pharma Science Investor Conference Call**



Monday, 25th Sep, 2023

5:00pm IST / 12:30pm BST / 7:30am EDT / 7:30pm HKT

# Strides Pharma Science Ltd

invites you to interact with the senior management

# Speakers:

Arun Kumar, Executive Chairperson & Managing Director Badree Komandur, Executive Director – Finance & Group CFO

# **Conference Call Details**

| Date:      | Monday, 25th September, 2023 Time:                          | 5:00pm IST / 12:30pm BST / 7:30am EDT / 7:30pm HKT                      |
|------------|---|---|
|            | India Primary   | +91 22 6280 1434 / +91 22 7115 8838                                     |
|            | USA   | 18667462133   |
| Conference | UK  | 08081011573   |
| Call       | Singapore   | 8001012045  |
| Details:   | Hongkong  | 800964448   |
|            | URL: https://services.choruscall.in/DiamondPas<br>6a6f78fb4 | ssRegistration/register?confirmationNumber=9861340&linkSecurityString=3 |



# Annexures



# OneSource Embarking on a new growth chapter

# OneSource – India's first pure play Specialty CDMO



**Biologics and high-end devices** 

Microbial biopharmaceuticals

Mammalian biopharmaceuticals

Cell and Gene therapy

RNA, Adherent and suspension-based products



**Soft Gelatin Capsules** 

Rx Soft gelatins Out-licensing

OTC / Consumer Health partnerships

**Development & Manufacturing services** 

Regulatory support



**Complex and Specialty Injectables** 

Formulation development

Clinical, analytical and stability studies

Fill-finish services

Regulatory support

**Pre-clinical** 

Phase 1/2

Phase 3

**Commercial manufacturing** 





# **Growth lever 1: Biologics and high-end devices**

Our capabilities are tailored to provide development and manufacturing services throughout the lifecycle of biologics and complex products.

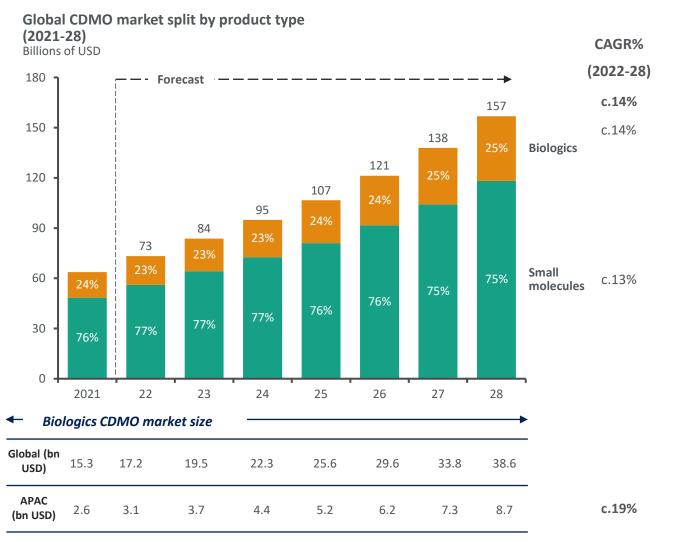
The global pharmaceutical and biologics players are leaning towards a partnership model for developing and manufacturing their existing products, and future pipeline and the overall CDMO market is anticipated to reach \$100 billion plus by 2026

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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

# In the CDMO business, we 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**

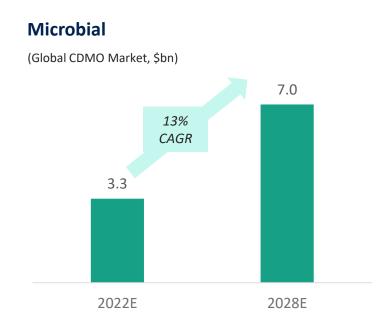
 Highly-experienced regulatory personnel with worldwide regulatory knowhow: a GLP-1 filing completed in <200 days with approval in the first cycle



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

# We are focused on attractive market where the client onboarding process is longer, but results in a highly sticky business





# (Global CDMO Market, \$bn) 4.8 2.3 2022E 2028E

**Drug Product (PFS, cartridges, vials)** 

# **Selected Drivers**







# 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, and TGA, Australia
- 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.





# 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 Aug FY24, We secured \$60 million in MSAs, of which \$30.3 million were secured in FY24 alone so far. In Q1FY24, five new partners have been added to our total unique clientele of 15.
- ▶ 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.

~\$60m

Cumulative value of MSAs won between FY20 and FY24 (till Aug)

~\$30m

Value of MSAs won in FY24 so far

~\$357m

Cumulative value of CSAs between FY24 and FY28

\$860m

Cumulative value of MSAs and CSAs for GLP between FY20 and FY32

~\$42m

Value of business under discussion for FY24

15+

Partners already signed up including top global companies





# **Growth lever 2 : Soft gelatin capsules**

We are one of the strong 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

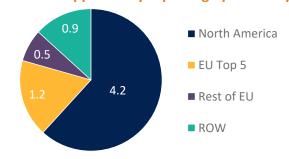
# US is the largest market and a significant growth pick up is led by the EU and ROW regions

| 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     | n Market size (bn\$) |      | 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

\*NA includes USA & CANADA; \*\*5 years (IMS MAT Q2 2021-2016)

# In technical collaboration with Pharmagel, Italy, Strides Soft Gelatin Platform 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



Product

- 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





# A sizeable presence in SGCs already and we have a strong pipeline of products to further augment our CDMO business







# Growth lever 3: Complex and ready to use products 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.

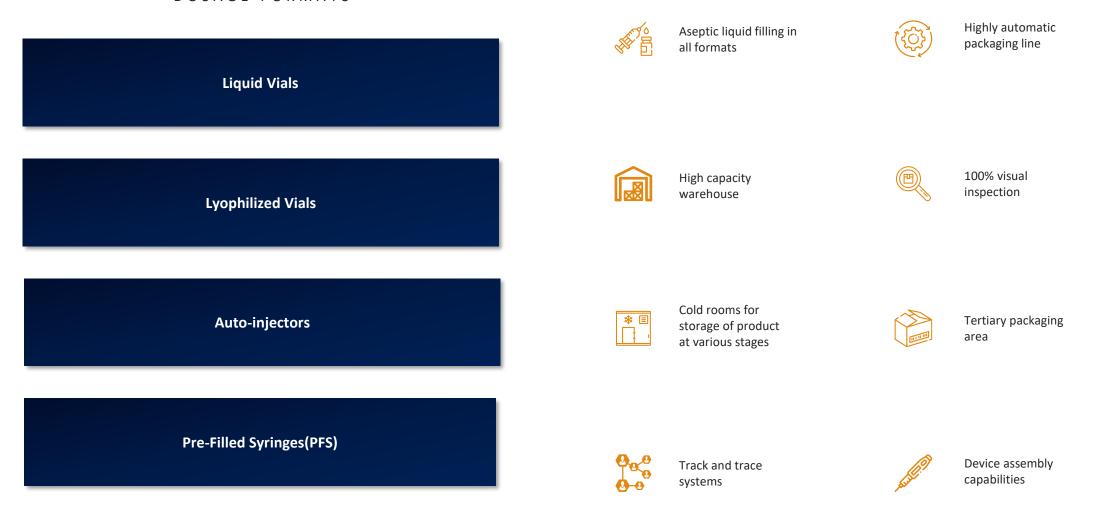
# Brands LOE by route of administration (\$ billion)<sup>1</sup>

| Dosage                 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | Total |
|------------------------|------|------|------|------|------|------|-------|
| Simple<br>injectables  | 3.2  | 0.2  | 0.6  | 0.5  | 1.0  | 3.0  | 8.6   |
| Complex<br>Injectables | 1.6  |      | 0.8  |      | 1.1  | 0.3  | 12.1  |
| Inhalation             |      | 0.2  |      | 1.3  |      | 2.5  | 8.3   |
| Others                 | 0.3  | 0.2  | 0.1  | 0.6  | 0.6  | 0.8  | 2.9   |

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

# We have one of the largest platform for sterile injectables led by industry experts in the domain with strong capabilities across dosage formats

### DOSAGE FORMATS





# Thank you