August 6, 2021

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai – 400 001
Scrip code: 532531

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

Dear Madam/ Sir,

Sub: Stelis Biopharma - Q1 FY22 Investor Update

Please find attached Q1 FY22 Investor Update issued by Stelis Biopharma Ltd., the biopharmaceutical division of Strides.

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

Manjula R.

Manjula Ramamurthy
Company Secretary

Encl. As above

Stelis Biopharma

An integrated biologics and vaccine player in the making

Stelis Biopharma Limited , Q1FY22 Investor Update | August 06, 2021

Stelis Biopharma

Introduction to Stelis:

A vertically integrated company with capabilities to take molecules from lab to market

Stelis is a vertically integrated biopharma and vaccine company ready to expand horizons

Large Scale Infrastructure

- 3 World class facilities with ~600,000 Square feet R&D and manufacturing space with capabilities in microbial, mammalian products and vaccines

One Stop Capabilities

- One-stop shop solution from cell line and process development to commercial manufacturing in biopharma
- End-to-end development & manufacturing of Drug Substance(DS) & Drug Product(DP)

Integrated vaccine suite

- Dedicated vaccine facility to cater to multiple vaccine types including viral vector, protein subunit, mRNA & DNA
- Separated from other two facilities eliminates any cross contamination

Flexible and agile model

- Multi-platform/multi-product Biologics capability
- Sterile injectable fill/finish for complex small molecules
- Flexible model for partner engagement

Strong Core Team

- Talented scientific and technical teams with experience from companies such as Merck, AGC, Amgen, Patheon, Fuji Diosynth, Selexis, P&G, Mallinckrodt, Pfizer, Lonza, Allergan amongst others

Embedded Compliance

- Quality and regulatory expertise with demonstrated experience in global compliance
- Operations designed, built and validated to meet regulatory market standard

Integrated and flexible capabilities for a varied range of biologics and vaccines

Dedicated R&D Setup

30,000 sq.ft. state-of-the-art process development; pilot/scale-up and small-scale biopharma CGMP facility

Core Capabilities:

- Cell line and strain development, selection & characterization
- Upstream and downstream process development – Viral, Mammalian & Microbial
- Analytical development – physicochemical, microbiology, bioassay & characterization methods
- Formulation development
- Regulatory, device and clinical strategy consulting

Large Commercial Capability

300,000 sq. ft. integrated commercial biopharma manufacturing facility catering to biologics DS and aseptic DP fill finish in different formats

Core Capabilities:

- Cell banking – MCBs and WCBs (including secure storage)
- Drug Substance manufacture Microbial and Mammalian – clinical and commercial *(2000KL by Dec'21 and 8000KL by Mar'22)*
- Drug Product manufacture *(Vials – 10 million or 4 million lyophilized vials, Cartridges – 40 million and Pre-filled syringes – 28 million)*
- Pen Device Assembly and release as per ISO standards
- Validation services, stability studies & misc. support services

Standalone Vaccine facility

250,000 sq. ft. dedicated DS and DP manufacturing facility for vaccines with ability to cater to multiple vaccine types including viral vector, protein subunit

Core Capabilities:

DS manufacturing

- Manufacturing Science and Technology (MSAT)– **8 X 200 L**
- Commercial Facility – **20 X 2000L** *(12 x2000L by Oct'21 and additional 8 x 2000L by Dec'21)*

DP Manufacturing

- Formulation development
- Secondary and tertiary packaging
- Cold chain inventory management
- Drug Product manufacture *(operational by Oct'21)*

Strategic oversight by Board of Directors with rich experience across diverse industries

Aditya Puri

Non-Executive Director & Chairperson

Former MD of HDFC Bank, India's largest private sector bank. He was the longest-serving head of any private bank in the country. India Today ranked him at #24 in India's 50 Most Powerful People of 2017 list. He is qualified as a Chartered Accountant with the Institute of Chartered Accountants of India and has many accolades in his fold

Vineeta Rai

Independent Director & Chairperson of Audit Committee

Former IAS officer and the first woman to hold the post of Revenue Secretary in the Ministry of Finance. She has held posts in the Ministry of Urban Development, Ministry of Health & Family Welfare and Ministry of Home Affairs in the Union Government. She was voted one of 25 Most Powerful women in Business in India in 2004

Arun Kumar

Founder

A first-generation entrepreneur with an intellect of picking "difficult to operate" domains with high scarcity value. Recipient of the E&Y Entrepreneur of the year award in the Healthcare sector in 2000, Business Today "India Best CEO Award (Mid-Sized Companies Category)," and the "Best CEO in the Pharma & Healthcare Industry" in 2014.

Ankur Thadani

Non-Executive Director

Partner at TPG Growth. He has worked on investments in multiple sectors, including healthcare, Energy, and Consumer sectors across India and the broader South-Asia region. He also serves on the Boards of Cancer Treatment Services International, Rhea Healthcare, and Sutures India.

Mahadevan N

Non-Executive Director

Senior Advisor, TPG Capital, Former Advisory Leader, Grant Thornton. He has significant experience in private equity, mergers and acquisitions, valuations, healthcare, medical devices, life sciences, business improvement, and capital markets

PR Kannan

Executive Director and CFO

20+ years of experience in the finance, strategy, taxation and M&A. He has been with the Group for over a decade and was earlier the CFO for SeQuent Scientific Limited. He is credited to have led SeQuent towards sustainable growth and delivered significant stakeholder value.

Appointed Mark W. Womack as the New CEO and MD designate

- The Board of Stelis is delighted to appoint Mark as the **CEO and MD designate of Stelis**. He assumes the role with immediate effect and will be stationed at **Stelis HQ in Bengaluru, India**
- Mark will drive the **growth strategy** around the **three business divisions** and will **provide strong leadership** to the Company as Stelis continues to build itself for the **next phase of growth and profitability.**
- Mark is an **organization builder** with a **track record of delivering unprecedented performance** and growth in his previous roles.
- Before joining Stelis, Mark was the **Chief Business Officer (CBO) for AGC Biologics (AGC)**, one of the world's leading global biopharmaceutical CDMOs. In his role at AGC, Mark led the **organization to nearly a 3x increase in new sales in just two years** and **drove the acquisition of most of the world's top large pharma companies into their portfolio.**
- Before AGC, leveraging his management consulting background, Mark led the global integration of three former CDMOs that were merged to create AGC Biologics.
- Mark has served over **25 years** as a **management consulting industry leader** and **C-level client advisor**, leading large-scale business transformations and guiding many of the world's renowned companies to achieve record highs in revenue and profit. During this time, he served as the **Chief Operating Officer (COO) for two international management consulting companies.**
- Before joining the management consulting industry, Mark led a **succession of US Navy units** to **unprecedented results**, including serving as a combat center leader on a destroyer class ship.

Operating three differentiated domains in the global market covering the entire value chain

Global CDMO Services

End to end service provider including process development, scale up and manufacturing services for biologics

Vaccines

A full services vaccines CDMO player with dedicated and integrated facility to cater to multiple vaccine types

Own Products

Building a portfolio of advanced biosimilars, peptides, and other leading products with our in-house development capabilities.

Stelis Biopharma

Global CDMO Services:

Deep expertise and high speed of execution in product development and large-scale manufacturing

Leveraging our scientific capabilities with World Class infrastructure having large scale capacities

27b+
Addressable Opportunity for Stelis

INDUSTRY DYNAMICS

- **Driven by growth** in biologics and strong value proposition of outsourcing
- **Sticky business** with high switching costs leading to better sustainability
- **Strong Operating margins** driving better financial outcomes for global Biologic CDMO players
- **High barriers to entry** driven by higher capex requirement and longer gestation period

STELIS STRATEGY

Our Vision

To be the fully integrated global CDMO partner of choice for the global biopharma industry

Our Mission

Enable global partners to accelerate the development and commercialization of biological and pharmaceutical products for unmet patient needs

Our Business Focus

- End-to-end service provider to global players leveraging our deep expertise and high speed of execution in product development and manufacturing.
- Comprehensive capabilities from cell line and process development through to scale up, cGMP manufacturing and fill/finish of proteins and peptides
- Core services include process development, scale-up, and manufacturing services for biologicals and sterile injectables.

Industry opportunity is the cumulative addressable opportunity identified for Stelis given its capabilities

Large Scale manufacturing offering speed and operation flexibility for drug substance(DS)

Microbial Capabilities

Fermentation

- Stainless steel fermenters (Sartorius) of capacity 50L, 300L & 1000L
- Homogenizer (GEA) and centrifuge (GEA) integrated with fermenters for efficient harvest operations
- Dedicated pre-culture area
- Dedicated autoclaves for sterilization and decontamination

Purification

- Flame proof area with high pressure chromatography system (Hanbon)
- Mix of single-use and conventional chromatography systems (Merck Millipore)
- High pressure chromatograph systems
- Filtration: viral filtration, ultrafiltration and dia-filtration
- Dedicated area for conjugation, bulk filtration & lyophilization

Hybrid model with stainless steel fermenter for upstream and single-use and conventional systems for downstream processing

Mammalian capabilities

Cell Culture

- 4 single-use trains up to 2000L
- Line-up: 50L→200L→2000L
- Capability of handling batch, fed batch and perfusion cell culture process
- Production, testing and storage of master and working cell banks
- Dedicated pre-culture suites, media & buffer preparation rooms

Purification

- Pre and post viral segregation
- Single use flow path - chromatography systems
- Filtration: viral filtration, ultrafiltration and dia-filtration
- Dedicated autoclaves for sterilization and decontamination
- Controlled freeze and thaw system

End-to-end disposable systems offer better regulatory compliance, no product carry over, less turn around time between batches and operational efficiency

State-of-the-art Drug Product(DP) Infrastructure With Significant Operational Flexibility

Aseptic liquid filling in all formats

Fully automatic packaging line

High capacity warehouse

100% visual inspection

Cold rooms for storage of product at various stages

Tertiary packaging area

Track and trace systems

Pen device assembly capabilities

Presentation	Equipment	Working Range	Annual Capacity (2 shift basis)	Status
Cartridge Filling with pen assembly for pharma and biopharma products	Bausch Strobel filling line integrated with Steriline isolator	Diameter 7mm to 14mm Height 40mm to 90mm	40 million	**Validated and available for commercial production**
Pre-Filled Syringe Filling for pharma and biopharma products	Bausch Strobel filling line integrated with Steriline isolator	0.5ml to 10ml	28 million	
Vials and lyophilised vials for pharma and biopharma products	Tofflon filling line integrated with isolator and Lyophilizer	1ml to 100ml Lyophilization - Commercial: 9.2 sq. m and Clinical: 5.11 sq. m	10 million vials and 4 million Lyophilised vials	
Additional Vial Line (Available for non-viral Vaccines)	Attached to vial filling machine for both clinical and commercial use	1ml to 30ml	60 million	

Q1FY22 Updates on global CDMO services business

Drug Product block commercialized with healthy order book for the next 18-24 months

- Drug product block running on high-capacity with healthy orderbook visibility over **18-24 months**
- **Filing on behalf of partners ongoing** for several markets including the US, and Europe
- The target to **achieve operational break even in FY22** is tracking as per **expectations**

On track to receive all major regulatory approvals in FY22*

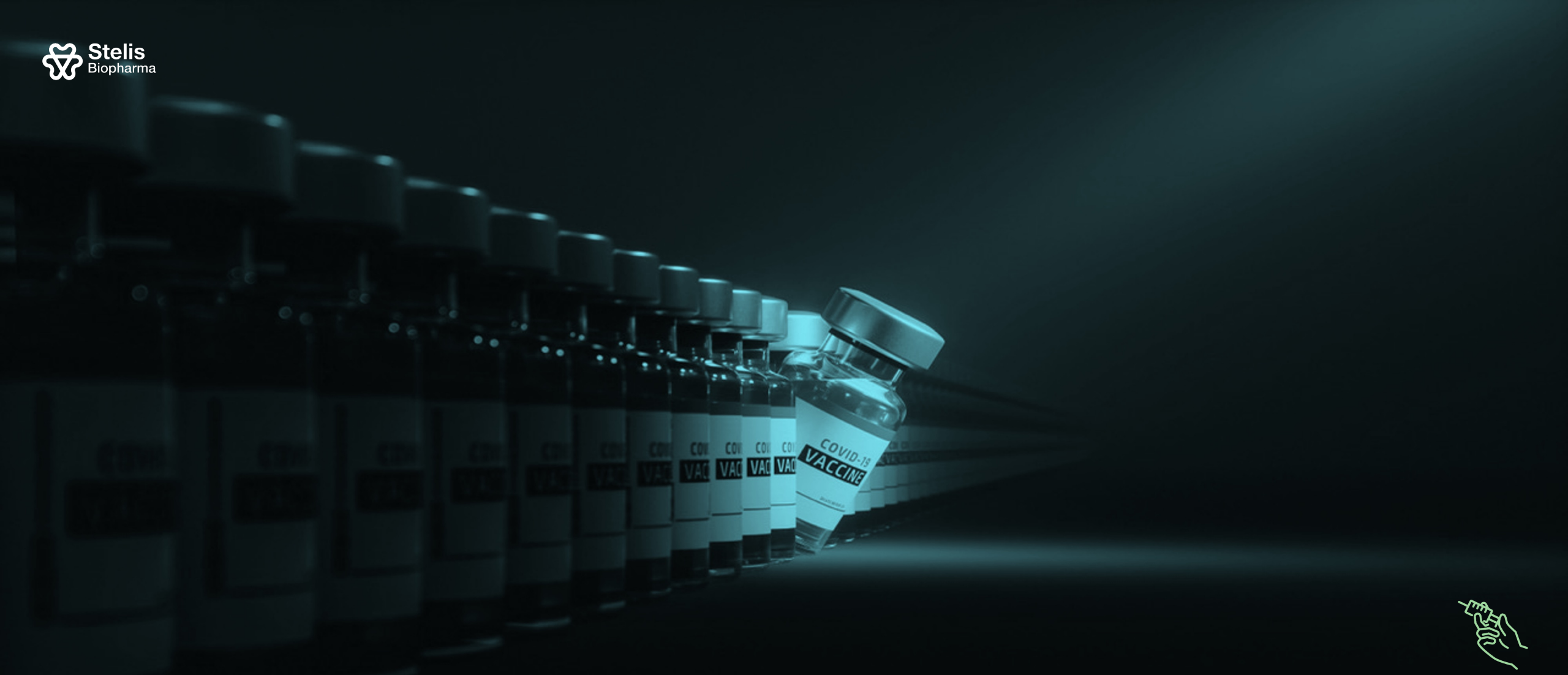
- **Partnered product filings** have triggered inspections from global regulatory authorities including the EU/EMA and USFDA*
- **Inspections expected at the site** , post the Covid related travel restrictions are eased

Microbial drug substance block already validated and attracting commercial traction

- **Microbial drug substance** fully validated and under partner inspections for new business
- A **funnel of partnered products** to be manufactured as exhibit batches and to initiate regulatory approvals for the site
- **Pending installation***(impacted due to Covid restrictions)* on **mammalian block** initiated, block to be **mechanically completed by end FY22**

**subject to Covid related travel restrictions being lifted*

Stelis Biopharma



Dedicated Suite for Vaccines :

New suite developed as per BSL 2 requirements with integrated capabilities

Building an integrated global vaccine CDMO business with large capacity and diverse capability

4b+
Addressable Opportunity for Stelis

INDUSTRY DYNAMICS

In last 5 years, multiple new products are **being developed for viral vectors**

3,000+ total viral vector products currently under development

130+ trials on-going with viral vector platforms (apart from Covid-19 - HIV, TB, Cancer, Flu etc.)

COVID has further increased interest in vaccine manufacturing space

STELIS STRATEGY

Our Vision

To be the partner of choice in vaccines for global biopharmaceutical companies

Our Mission

In the near term, Stelis aims to become a significant partner in the global fight against Covid-19. In the long term, We envision becoming a fully integrated vaccine player across various infectious disease categories

Our Business Focus

- To be a full services vaccines CDMO player with our foray into vaccines.
- Dedicated vaccine facility to cater to multiple vaccine types, including viral vector, protein subunit, messenger ribonucleic acid (mRNA) & Deoxyribonucleic Acid (DNA).
- While retaining focus on CDMO; we wish to pivot into emerging technologies using viral vector capacity

New vaccine suite designed to produce over a billion doses in a year

Current Capabilities	DS	DP
Viral vector	Yes	Yes
Protein subunit	Yes	Yes
m-RNA	Yes*(Planned)*	Yes
DNA	Yes*(Planned)*	Yes

Design and Unique features

- Use of single use manifold systems to reduce the cross contamination between the batches.
- Nanoparticle fill finish capability
- Manufacturing of Drug Substance and Drug Product for recombinant Antigen
- Phase 1 of the facility compliant to BSL 2 requirements designed to produce 6 million doses/month
- Facility built with modularly, phase 2 capacity to go on-stream from October 2021
  - Targeted Phase 2 Capacity of 60 million doses/month
- Plans to produce over 1 billion doses from this capacity
- Facility designed to commercialize DS and DP for RNA and DNA vaccines over the next 12-15 months

Q1FY22 Updates on vaccines business

Update on Sputnik V

- **rAD5 and rAD26 components** of the vaccine have been **validated on the small scale**
- **Scale up of the vaccine on track** to achieve commercial production
- Expected to launch **Sputnik V**(both components) in **Q3FY22**

Evaluating new vaccine partnerships

- **Significant ongoing interest** and discussions to partner with other **global players for vaccines manufacturing**
- Advanced discussions ongoing to **In-license new vaccine technologies**
- Plans to on-board **at least one CDMO Contract on vaccines** by **Q4FY22**

Stelis Biopharma

Own Products:

Commercially attractive products with leading assets nearing approval stage

Scaling a compelling biopharma franchisee built on global scale and a niche product portfolio

65b+
Addressable Opportunity for Stelis

INDUSTRY DYNAMICS

With $60 billion worth of brands losing exclusivity, biosimilars presents a large opportunity

Due to complexity, Biosimilars have limited competition offering attractive and sustained pricing for a longer period of time

Limited pure play biosimilar companies with margin accretive business and future opportunities

Recent guideline changes indicate better prospects for late entrants and the market are seeing high penetration

STELIS STRATEGY

Our Vision

To become a globally recognized biosimilar business delivering efficient solutions to patients for improving lives.

Our Mission

To develop and manufacture compliant and affordable biotherapeutics to address unmet global needs

Our Business Focus

- Building a portfolio of advanced biosimilars, peptides, and other leading products with our development capabilities.
- While exploring opportunities in different categories, our core focus is on building a strong diabetic portfolio to target an exponentially growing world problem
- Attaining leadership in commercializing high-quality, affordable products with deep technical expertise

Targeting 6 molecules in phase 1 with a combined market size of USD 40 billion

Molecule	Market Size ($b)	Indication	Development Stage	Latest Update
STLP001 Rh- Teriparatide	~2	Osteoporosis	Filed in EU/ Phase 1 ready for US	• EU file for MAA under review cycle, expected closure by Q4FY22 • More than 20 companies are under discussion to license the product to commercialize in different geographies.
STLI001(Glargine)	~13	Diabetes	Clinical	• Phase-1 clinical trial for India dosing completed, initial results are encouraging. Global filings for several markets starting FY23
STLI002(Aspart)	~9	Diabetes	Pre-clinical	• Program initiated and on track for late FY24 filing
STLI003(Lispro)	`7	Diabetes	Pre-clinical	• Program initiation and scale-up planned in Q2/Q3FY22
STLG001	~6	Diabetes	Scale-up	• On track for Q3/Q4FY22 filing via ANDA path
STLG002	~7	Diabetes	Scale-up	• Development initiated, on track for filing in FY23 via ANDA path
STLS001	~5	Anti- hemorrhoid	Pre-clinical	• Pre-clinical stage , post FY24 opportunities

Thank you

For details, please visit www.stelisbiosource.com

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