



Strides

Q2 and H1FY22 Earnings

November 10, 2021

ADAPT



PERFORM



GROW





We have reported an operational breakeven in Q2FY22 enabled by a bounce back in other regulated markets, growing 27% QoQ. The performance in other regulated markets was driven by improving demand scenario and resumption of our supplies to partners during the quarter post the Covid related manufacturing disruptions in Q1. Emerging markets continues to track well delivering growth both in Africa and Institutional business.

We continue to face headwinds in our US business. While we have been able to retain volume share on our key products, we continued to witness price challenges in our portfolio during the quarter, magnified by concentration towards acute products.

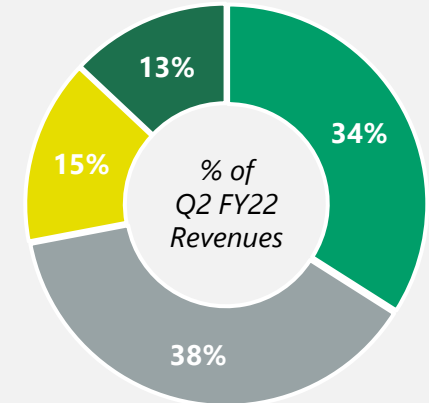
We have completed the strategic acquisition of Chestnut Ridge site in the US along with a portfolio of approved products which will enable us to accelerate new product launches. While there are near term headwinds, we remain optimistic on the US business in the long run. We will start witnessing improvement in our US business starting Q3FY22 and will continue the growth momentum there on. Given the volatile dynamics we believe we will only be able to achieve our current year guided outlook for US in FY23

A muted sales performance accompanied with a drop in gross margins and relatively higher operating costs has led to a negative operating leverage in H1. While cost measures have been initiated to improve operating leverage, the shift will be visible in the coming quarters.

**Dr. R Ananthanarayanan**

**Managing Director & CEO**






### Revenues Mix



■ US ■ Other Reg Mkts ■ Institutional ■ Africa



Revenues	EBITDA	EBITDA %
<b>₹7,360m</b>	<b>₹10m</b>	<b>0%</b>

	Q2FY22	Q1FY22	Q2FY21	QoQ%	YoY%	H1FY22	H1FY21	YoY %
 <b>REVENUES</b>	₹7,360m	₹6,919m	₹7,971m	6%	- 8%	₹14,279m	₹15,818m	- 10%
 <b>GROSS MARGINS</b>	₹4,113m 55.9%	₹3,428m 49.5%	₹4,886m 61.3%	20% 630 bps	- 16% - 540 bps	₹7,541m 52.8%	₹9,711m 61.4%	- 22% - 860 bps
 <b>EBITDA</b>	₹10m 0.1%	- ₹468m -6.8%	₹1,656m 20.8%			- ₹458 -3.2%	₹3,234m 20.4%	
 <b>PHARMA PAT<sup>1</sup></b>	- ₹847m	- ₹1,169m	₹792m			- ₹2,016m	₹1,580m	
 <b>PHARMA EPS<sup>1</sup></b>	- ₹9.4	- ₹13.0	₹8.8			- ₹22.4	₹17.6	

<sup>1</sup>. Adj PAT and Adj EPS for Q1 FY22 excludes exceptional items loss of ₹915m, Biotech and CHC share of loss of ₹195m, tax credit of ₹215m on exception items; Adj PAT and Adj EPS for Q2 FY22 excludes exceptional items loss of ₹599m, Biotech and CHC share of loss of ₹234m

**Regulated Markets**

Market	Q2FY22	Q1FY22	Q2FY21	QoQ%	YoY%	H1FY22	H1FY21	YoY%
US	2,502	3,016	4,047	-17%	-38%	5,518	7,785	-29%
Other Reg	2,825	2,232	2,386	27%	18%	5,057	4,992	1%
<b>Total</b>	<b>5,327</b>	<b>5,248</b>	<b>6,433</b>	<b>2%</b>	<b>-17%</b>	<b>10,575</b>	<b>12,777</b>	<b>-17%</b>

**Emerging Markets**

Market	Q2FY22	Q1FY22	Q2FY21	QoQ%	YoY%	H1FY22	H1FY21	YoY%
Inst. Biz	1,113	970	702	15%	59%	2,083	1,512	38%
Africa	920	701	836	31%	10%	1,621	1,529	6%
<b>Total</b>	<b>2,033</b>	<b>1,671</b>	<b>1,538</b>	<b>22%</b>	<b>32%</b>	<b>3,704</b>	<b>3,041</b>	<b>22%</b>

**Consolidated Group Revenues**

	Q2FY22	Q1FY22	Q2FY21	QoQ%	YoY%	H1FY22	H1FY21	YoY%
<b>Total</b>	<b>7,360</b>	<b>6,919</b>	<b>7,971</b>	<b>6%</b>	<b>-8%</b>	<b>14,279</b>	<b>15,818</b>	<b>-10%</b>

**Key Updates**
**Regulated Markets**
**US**

- US revenues at \$34m for Q2FY22, US contributed 34% of consolidated revenues in Q2FY22
- Demand continued to be impacted by Covid-19 related headwinds
- Market continued to witness price erosion in Q2 with more pronounced impact in the acute portfolio

**Other Regulated Markets**

- Other regulated markets revenues at \$38m for Q2FY22 versus \$30m in Q1FY22, Other regulated markets contributed 38% of consolidated revenues in Q2FY22
- Strong sequential bounce back in other regulated markets with 27% revenue growth
- Witnessing healthy traction across key frontend markets, partnership business benefits from normalization of manufacturing capacity post COVID impact in Q1FY22
- Healthy orderbook visibility and expansion of portfolio to drive business momentum

**Emerging Markets**

- Emerging markets revenues at \$28m for Q2FY22 versus \$23m in Q1FY21, business contributed 28% of consolidated revenues in Q2FY22
- Institutional business witnessed healthy growth during the quarter and benefitted from an improved customer offtake
- Africa business delivered a strong performance as Covid-19 related headwinds are now easing out

**Operating Cost**

- Logistics cost continues to be high despite improving mix towards sea shipments as freight rates witnessed significant jump during the quarter
- Logistics cost during the quarter were at ₹897m up 20% QoQ and up 135% YoY, logistics cost as % of sales at 12.2% for Q2FY22 versus 4.8% in Q2FY21
- Expect logistics cost to ease out in H2FY22 from current levels

**R&D Investments**

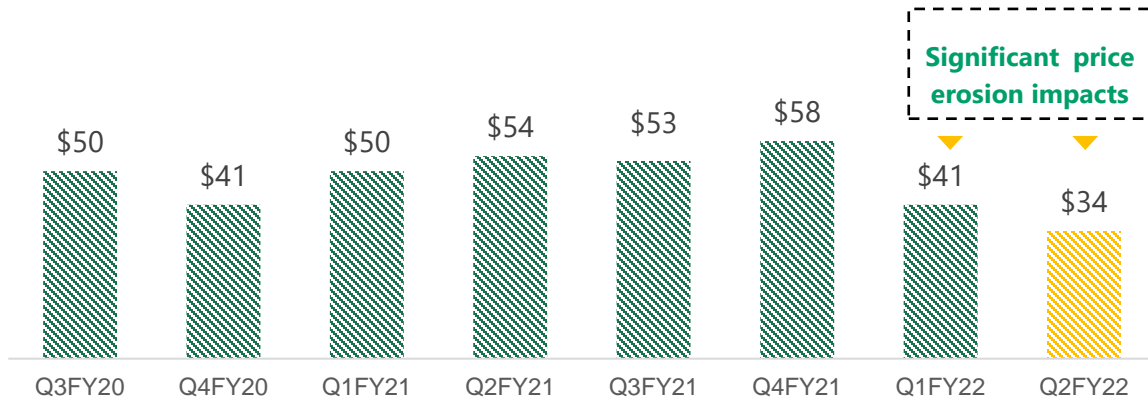
- R&D investment in Q2FY22 at ₹220m, 3 new products filed in regulated markets year till date



# Business Highlights

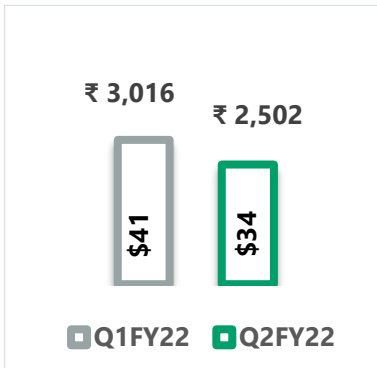


## US Revenues - Quarterly Trend (₹/\$M)



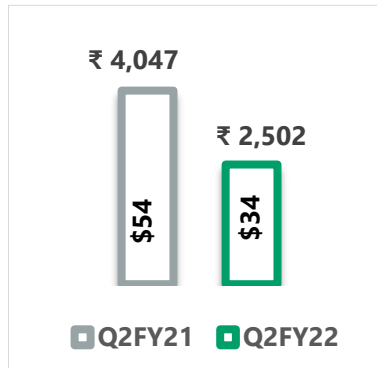
## Financial Performance (₹/\$M)

### QUARTER ON QUARTER



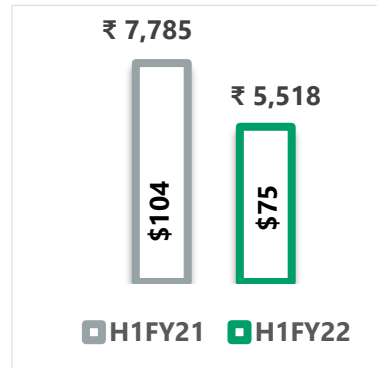
» - 17% QoQ

### YEAR ON YEAR



» - 38% YoY

### H1FY22 ON H1FY21



» - 29% YoY

YoY comparison in INR reported

## Business Updates

- Revenues from the US for Q2FY22 stood at ₹2,502 (\$34m), down 38% YoY, representing 34% of consolidated revenues for Q2FY22
- Continued price erosion in the portfolio, lack of new product launches and aggressive channel procurement during Covid has significantly impacted H1FY22 revenues
- Despite fall in prescriptions, Strides has been able to retain its volume market share on key products in a tough operating environment
- Higher dependence on acute portfolio magnified price erosion as Q2FY22 revenues dropped to \$34m, ~40% lower from a peak of \$58m (Q4FY21)

## Near Term Outlook

- While we are now witnessing a stable pricing environment, we expect prescriptions to recover over the next 2-3 quarters
- With the acquisition of ANDA's at Chestnut Ridge, the combined portfolio enables diversification with addition of chronic products and controlled substances.
- We have re-engaged with the customers for the acquired portfolio which got impacted during transition given the seller was not focusing on defending and growing this business
- We will start realizing the full benefit of Chestnut Ridge portfolio starting Q1FY23, identified first set of 20 products and actions underway to enable launches over the next 3-4 quarters
- Consequently, we believe we will only be able to achieve our current year guided outlook in FY23





## Transaction Update

- On August 6, 2021, **Strides inked definitive agreements with Endo to acquire its manufacturing facility in the US along with basket of ANDAs**
- The above-mentioned **transaction achieved its closure on October 20, 2021**
- Strides paid a **total of US\$ 24.9m** for the transaction and the same was **funded by a combination of Debt and equity**
- **The acquisition represents a key milestone in Strides strategy and will further cement company's position as a relevant player in the US generic industry**



## Strategic Outcomes

- Acquisition **strengthens Strides' portfolio, front-end presence and local manufacturing capability for the US**
- The acquisition **more than doubles the approved ANDA basket** for Strides including **20 commercial products** transferred to Strides on transaction closure
- The portfolio brings on board a **mix of acute and chronic products** that will help diversify product offering
- Readily available basket ensures **lower dependency on new ANDA filings and approvals** for growth given the Covid-19 induced travel restrictions and delay in site inspections
- Acquired Portfolio will help **accelerate new product launches in the US**
- Chestnut Ridge site **adds 2 billion units' annual capacity** across **semi-solids, liquids, nasal sprays and other oral solids**
- The facility is registered with the **Drug Enforcement Administration (DEA)** enabling manufacturing of **controlled substances**
- The acquisition will also **strengthen our ability to cater to federal contracts** with **100+ TAA compliant products**
- Consolidation of our loss-making West Palm Beach operations with Chestnut Ridge site **will deliver manufacturing cost synergies**



## Key Priorities

- Strides welcomes on board the **experienced team at Chestnut ridge site**, focusing on a **seamless integration of the team to the Strides global talent pool**
- **Integration of processes and systems** to Strides platform initiated
- Targeting to **commercialize 5-6 new product** every quarter from the combined portfolio
- Building an **efficient, reliable and competitive supply chain for the portfolio of already commercial and yet to be commercialized portfolio** will be another key priority for the company
- **Ramping up our VA business** leveraging a vast portfolio of TAA compliant products



Dosage Format	Strides Portfolio	Endo Portfolio	Combined Portfolio	Addressable Market Size US\$ m
Oral Solids ER	12	12	24	2,717
Oral Solids IR	94	120	214	12,574
Oral Suspension, Syrup	15	11	26	523
Topicals, Gels, others	5	4	9	434
<b>Total</b>	<b>126</b>	<b>147</b>	<b>273</b>	<b>16,248</b>

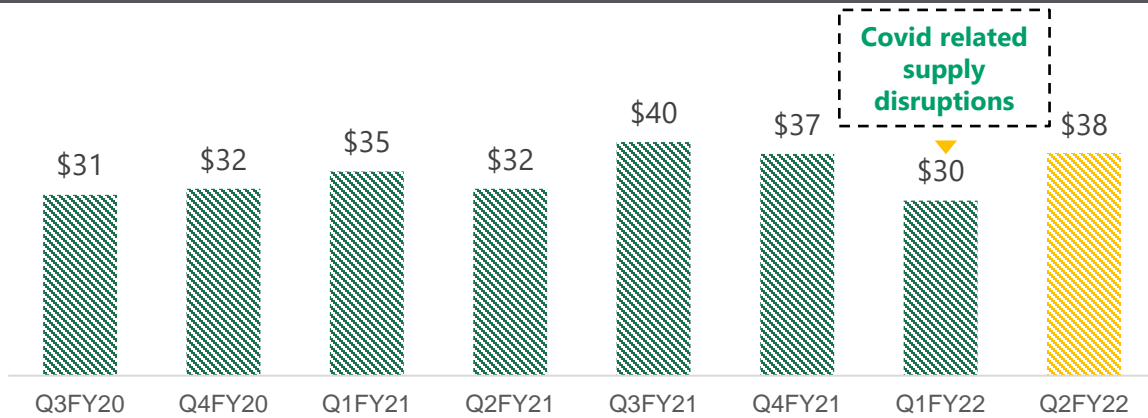


## Portfolio Highlights

- **Combined portfolio of 273 ANDA's** spread across multiple dosage format
- Acquired portfolio has an addressable market size of US\$4.7 bn , the Combined addressable **market size for the portfolio is pegged at US\$ 16 bn**
- Differentiated portfolio comprising of **Controlled Substances, Hormones, Nasal Sprays, Gels, Modified Release products, Liquids**
- Significantly expands our **middle of pyramid product basket** enabling sustainability of margins
- Access to a basket of **13 controlled substance (CII) products**
- Strides currently only has **40 commercial products in the US**. The Chestnut Ridge portfolio will **immediately add 20 commercial products and with 5-6 new product launches planned each quarter** we expect to have a **portfolio of 100+ commercial products over the next 2 years in the US**
- **100+ TAA compliant ANDAs** will allow us to broad base our offering to federal procurements



## Other Regulated Markets Revenues - Quarterly Trend (₹/\$M)

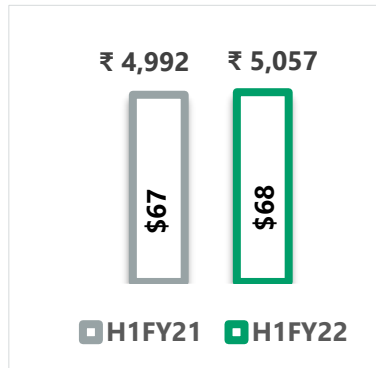
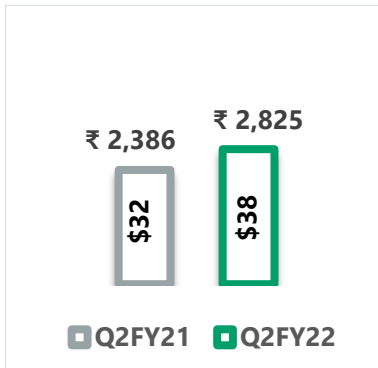
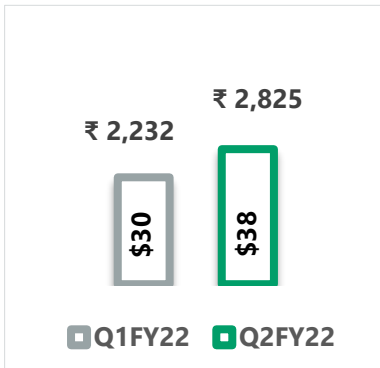


## Financial Performance (₹/\$M)

### QUARTER ON QUARTER

### YEAR ON YEAR

### H1FY22 ON H1FY21



» 27% QoQ

» 18% YoY

» 1% YoY

YoY comparison in INR reported

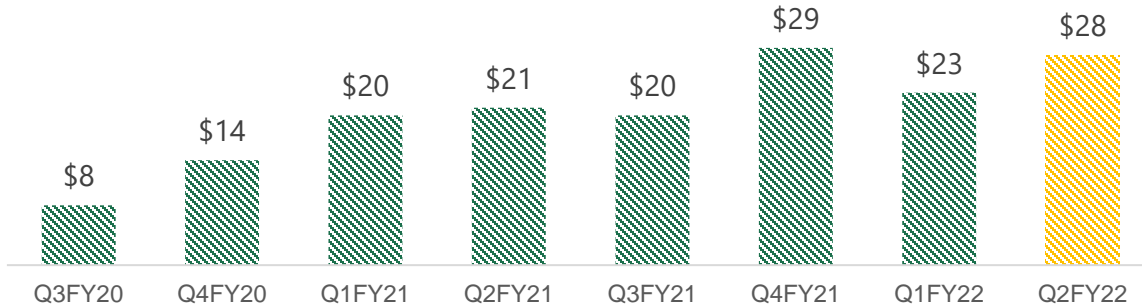
## Business Updates

- Revenues from other regulated markets for Q2FY22 stood at ₹2,825m (\$38m), up 27% QoQ and 18% YoY
- Other regulated markets represented 38% of consolidated revenues for Q2FY22
- Other regulated markets business witnessed a bounce back driven by improved prescription generations in key frontends and return to normalcy of supplies for our partnered business
- Other regulated markets has now reached closer to its historical peak sales (Q3FY21) and will continue its growth momentum

## Near Term Outlook

- Outlook for the business continues to be robust given a strong order book visibility
- Continued R&D investments in portfolio expansion to drive growth through new product launches across geographies

## Emerging Market Revenues - Quarterly Trend (₹/\$M)

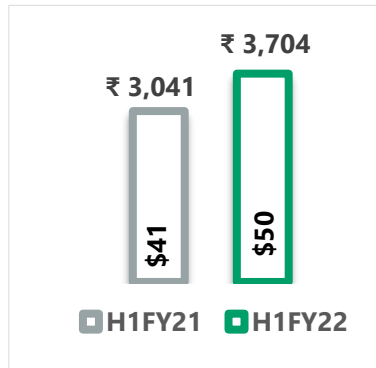
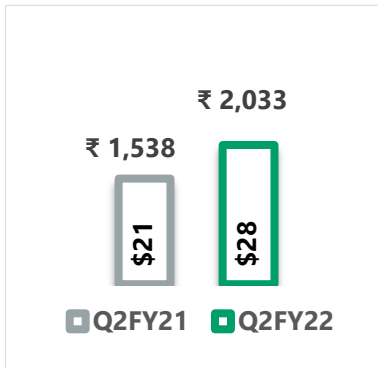
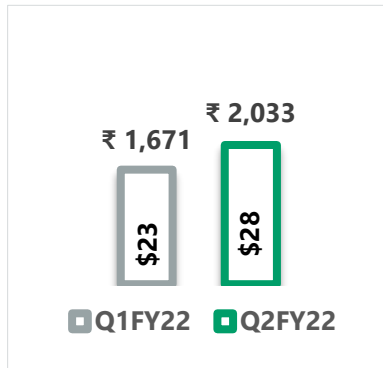


## Financial Performance (₹/\$M)

### QUARTER ON QUARTER

### YEAR ON YEAR

### H1FY22 ON H1FY21



» 22% QoQ

» 32% YoY

» 22% YoY

YoY comparison in INR reported

## Business Updates

- Revenues from emerging markets for Q2FY22 stood at ₹2,033m (\$28m), up 22% QoQ and up 32% YoY
- Emerging markets business represented 28% of consolidated revenues for Q2FY22
- The Africa business delivered a strong performance led by healthy demand for key brands, the business reported revenues of ₹920m in Q2FY22, up 31% QoQ and up 10% YoY
- Leveraging digital platforms for a better doctor connect, focus on new product introductions and improved MR productivity to drive growth for the Africa business
- Institutional business reported revenues of ₹1,113m in Q2FY22 up 15% QoQ and up 59% YoY led by better offtake from donor funding agencies
- Focussing on becoming a cost leader in the space with efficient supply chain



# Financial Performance



**Income statement (₹m)**

Particulars	Q2 FY22	Q1 FY22	Q2 FY21	QoQ	YoY	H1 FY22	H1 FY21	YoY
<b>Revenues</b>	<b>7,360</b>	6,919	7,971	6%	-8%	<b>14,279</b>	15,818	-10%
<b>EBITDA</b>	<b>10</b>	-468	1,656	101%	-100%	<b>-458</b>	3,234	-114%
<b>EBITDA %</b>	<b>0.1%</b>	-6.8%	20.8%	690 bps	-2070 bps	<b>-3.2%</b>	20.4%	
<b>Adj PAT<sup>1</sup></b>	<b>-847</b>	-1,169	792			<b>-2,016</b>	1,580	
<b>Adj EPS<sup>1</sup></b>	<b>-9.4</b>	-13.0	8.8			<b>-22.4</b>	17.6	

**Reconciliation of EBITDA (₹m)**

As per SEBI results	Q2 FY22	Q1 FY22	Q2 FY21
<b>Profit before exceptional items &amp; tax</b>	<b>-915</b>	<b>-1,330</b>	<b>853</b>
Less: Interest, Dividend income	77	100	93
Add : Depreciation and Amortization	566	549	528
Add : Finance costs	436	415	369
<b>Consolidated EBITDA as per press note</b>	<b>10</b>	<b>-468</b>	<b>1,656</b>

<sup>1</sup>. Adj PAT and Adj EPS for Q1 FY22 excludes exceptional items loss of ₹915m, Biotech and CHC share of loss of ₹195m, tax credit of ₹215m on exception items; Adj PAT and Adj EPS for Q2 FY22 excludes exceptional items loss of ₹599m, Biotech and CHC share of loss of ₹234m



Pharma Net Debt

As at June 2021  
**₹ 7,530m**

As at September 2021  
**₹ 9,301m**

Change over June 2021  
**+ ₹ 1,771m**



Investments in CHC & Biotech

As at June 2021  
**₹ 6,886m**

As at September 2021  
**₹ 6,937m**

Change over June 2021  
**+ ₹ 51m**



Total Net Debt

As at June 2021  
**₹ 14,416m**

As at September 2021  
**₹ 16,238m**

Change over June 2021  
**+ ₹ 1,822m**





*invites you to interact with the senior management on Q2 and H1FY22*



**WEDNESDAY, NOVEMBER 10, 2021**

4:00pm IST / 11:30am BST / 06:30am EDT / 06:30pm HKT

**Speakers:**



**Arun Kumar**

Founder & Non - Executive Chairman



**Dr. R. Ananthanarayanan**

Managing Director & CEO



**Badree Komandur**

Executive Director & CFO

Pre-register and join without operator



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Join through an operator using dial in numbers



India Primary	+91 22 6280 1434 / +91 22 7115 8838		
USA	18667462133	Singapore	8001012045
UK	08081011573	Hongkong	800964448

24-hour playback after the call



+91 22 71945757	+91 22 66635757
Playback Code: 43155	



# Thank You



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# An integrated biologics and vaccine player in the making

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Stelis Biopharma Limited | November 10, 2021





## Recap: 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



### Flexible and agile model

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



### One Stop Capabilities

- ▶ **One-stop shop solution** from cell line and process development to commercial manufacturing
- ▶ **Drug Substance manufacturing** Microbial and Mammalian – (8000L by Mar'22)
- ▶ **Drug Product manufacturing** - Vials, Lyophilized vials, Cartridges & Pre-filled syringes



### Strong Core Team

- ▶ **Talented scientific and technical teams** with experience from leading global Biotech and Vaccine companies



### Integrated vaccine suite

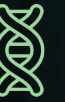
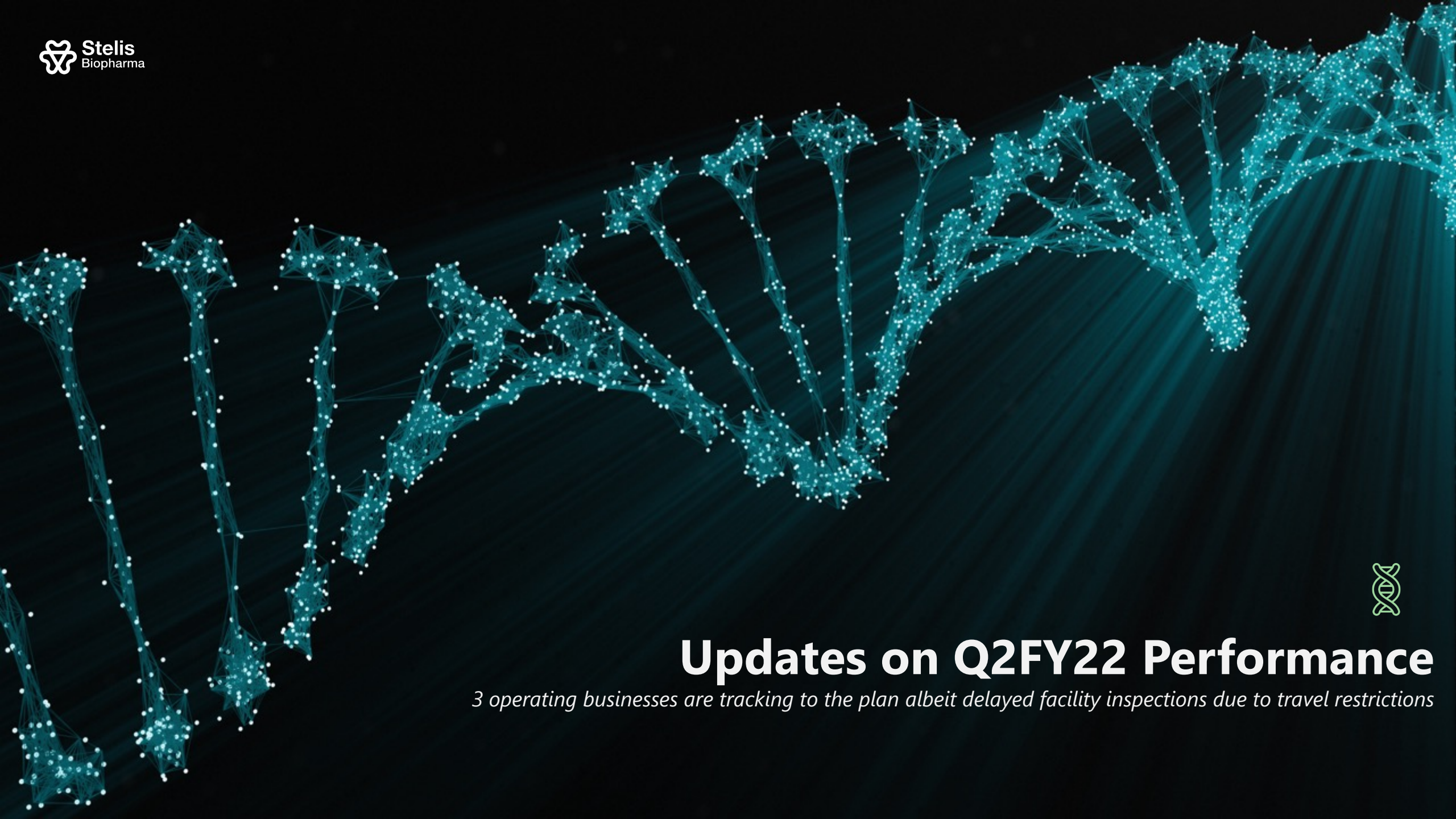
- ▶ **Dedicated vaccine facility** to cater to multiple vaccine types including viral vector, protein subunit, mRNA & DNA
- ▶ **Drug Substance Capacity** of 40,000L with integrated **drug product** manufacturing



### Embedded Compliance

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





# Updates on Q2FY22 Performance

*3 operating businesses are tracking to the plan albeit delayed facility inspections due to travel restrictions*



## The CDMO business is on track to achieve operational break even in FY22



### Current Business and Orderbook

- **New orders received for the drug product facility**, continued traction for cartridges, high speed vial fill-finish and lyophilized vials
- **Completed large scale batches(1000L)** for microbial drug substance on the site
- CDMO business on track for **achieving operational break even** in FY22



### Regulatory approval Status

- **Partnered product filings** have triggered inspections from global regulatory authorities including the EU/EMA and USFDA. However, there has been no **new development on regulatory inspections** as **Covid-19-led travel restrictions** continue to delay the facility audits



### Expanded capacity for drug substance

- **Ongoing project work** on mammalian block installation on track, block to be mechanically **completed by end FY22** (8000L Reactor capacity)



### Update on Sputnik Vaccine

- **First component** of the Sputnik vaccine has been manufactured at the **commercial scale**
- Expected to commercially launch the vaccine within **Q3FY22**



### Evaluating new vaccine partnerships

- **Ongoing discussions** to partner with other **global players for vaccines manufacturing**
- On track to on-board **at least one CDMO Contract on vaccines** by **Q4FY22**



In its **commitment to fight against Covid-19**, Stelis **rose to the challenge** and **planned its foray into vaccines in March 2021**



Stelis committed to **invest over INR 750 Crores** to **build a best-in-class** facility dedicated to produce **vaccines with integrated capabilities** within the site



Stelis facility is designed to cater to **multiple vaccine at large scale including the new platform technologies**

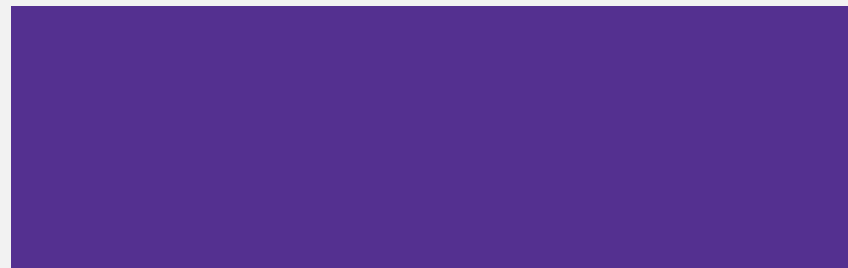
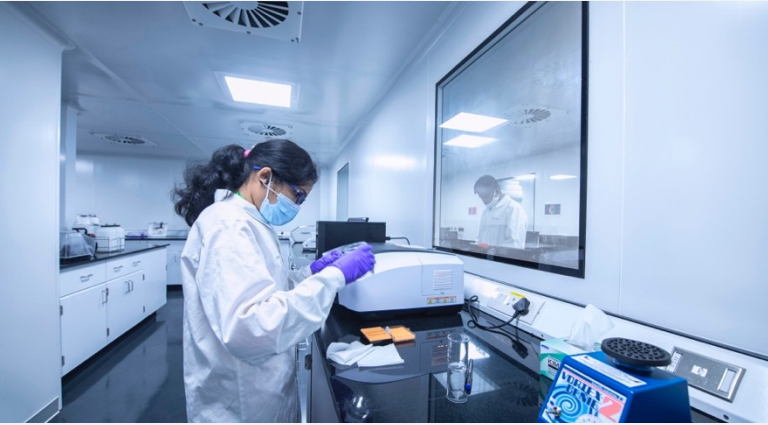


Despite the outbreak of second wave of Covid-19, Stelis vaccine facility has achieved on-time readiness to **produce over 60 million vaccine doses per month (720 million doses per year) in less than 180 days**





**IN <180 DAYS, OUR TEAM IS READY TO PRODUCE 720 MILLION VACCINE SHOTS PER YEAR AND CAN EXPAND TO 1 BILLION ANNUAL DOSES CAPACITY**





## Our biosimilar products are tracking to plan with first insulin analog completing India CT trials



Molecule	Market Size (\$b)	Indication	Development Stage	Latest Update
<b>STLP001 (Rh- Teriparatide)</b>	~2	Osteoporosis	Filed in EU/ Phase 1 ready for US	<ul style="list-style-type: none"> <li>EU file for MAA under review, on track to received approval by Q4FY22</li> </ul>
<b>STLI001 (Glargine)</b>	~13	Diabetes	Clinical	<ul style="list-style-type: none"> <li>Phase-1 clinical trial for India dosing completed, study results are encouraging. Global filings for several markets starting FY23</li> </ul>
<b>STLI002 (Aspart)</b>	~9	Diabetes	Pre-clinical	<ul style="list-style-type: none"> <li>Program on track for late FY24 filing</li> </ul>
<b>STLI003 (Lispro)</b>	~7	Diabetes	Pre-clinical	<ul style="list-style-type: none"> <li>Program initiation and scale-up ongoing</li> </ul>
<b>STLG001 (Undisclosed)</b>	~6	Diabetes	Scale-up	<ul style="list-style-type: none"> <li>On track for Q3/Q4FY22 filing via ANDA path</li> </ul>
<b>STLG002 (Undisclosed)</b>	~7	Diabetes	Scale-up	<ul style="list-style-type: none"> <li>On track for filing in FY23 via ANDA path</li> </ul>
<b>STLS001 (Undisclosed)</b>	~5	Anti- hemorrhoid	Pre-clinical	<ul style="list-style-type: none"> <li>Pre-clinical stage</li> </ul>





# Thank you

For details, please visit [www.stelisbiosource.com](http://www.stelisbiosource.com)

## **Stelis Biopharma Limited**

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