Strides

Reset.
Resurgent.

Strides Pharma Science Limited

Q2 FY20 Earnings Presentation | **October 25th, 2019**

Strides

Performance Highlights

Q2FY20 reaffirms our reset strategy to focus on regulated markets with consolidated EBITDA margins at 21% albeit a disappointing emerging market performance

Demonstrating a strong performance with consolidated EBITDA margins at 21%

		QoQ(%)	YoY(%)
REVENUES (₹M)[1]			
Q2FY20	7,180	4% ↑	37% ↑
Q1FY20	6,888		
Q2FY19	5,242		
GROSS MARGINS(%)			
Q2FY20	58.4%	430 bps ↑	800 bps ↑
Q1FY20	54.1%		
Q2FY19	50.4%		
EBITDA[2](₹M)			
Q2FY20	1,506 *(21.0%)*	22% ↑	210% ↑
Q1FY20	1,239 *(18.0%)*		
Q2FY19	486 *(9.3%)*		
ADJUSTED PAT[3] (₹M)			
Q2FY20	717	37% ↑	503% ↑
Q1FY20	523		
Q2FY19	119		
ADJUSTED EPS[3] (₹/SHARE)			
Q2FY20	8.0	37% ↑	503% ↑
Q1FY20	5.8		
Q2FY19	1.3		

This quarter's financial results validate our reset strategy, with enhanced focus on growth and margin opportunities from regulated markets. These markets now contribute to >85% of our revenues, establishing the strength of our operating model built around diversified markets and carefully selected product portfolio. In spite of an underperforming emerging markets and continued R&D spend, our group EBITDA margins exceeded 20% for the first time in many quarters.

Having said that, the challenges of institutional business & emerging markets persist, and we continue to evolve on our course-corrected strategy, which will deliver positive outcomes in the near term

Arun Kumar
Group CEO and Managing Director

1. *Numbers reported above are for the continuing business.*
2. *Percentages reflect EBITDA margins*
3. *PAT and EPS adjusted for Biotech, CHC share of loss and exceptional items*

Stellar performance driven by a resurgent regulated market strategy

All Values in ₹m

Region	Q2FY20	Q1FY20	Q2FY19	QoQ%	YoY%
Regulated Markets	**6,200**	**5,607**	**3,588**	**11%**	**73%**
US	3,980	3,902	2,200	2%	81%
Other Reg Markets[1]	2,220	1,705	1,388	30%	60%
Emerging Markets	**980**	**1,281**	**1,654**	**-23%**	**-41%**
Africa	385	401	590	-4%	-35%
Institutional	595	880	1,064	-32%	-44%
Group Revenues	**7,180**	**6,888**	**5,242**	**4%**	**37%**

KEY QUARTERLY UPDATES

US

+ The US markets delivered a **sequential growth to report $57m revenues in Q2FY20** despite temporary supply disruption of Ranitidine.
+ Our front end business reported **significant QoQ growth**. With QoQ sequential growth, the business has grown over **4x from ~$10m in Q1FY19 to ~$40m in Q2FY20**
+ US partnered business has degrown compared to Q1FY20. The business **by design is slowing down** as efforts are on track to revert more products back to in-house sales channel.

OTHER REGULATED MARKETS

+ Led by a strong **performance in UK, EU markets and scale up of supplies to Australia**, the other regulated markets delivered yet another quarter of strong sequential growth.
+ The business grew **30% QoQ and 60% YoY** to report **₹2,220m ($32m) revenues** on account of continued portfolio and footprint expansion initiatives

R&D

+ In spite of softness in filings and approvals for US, the **R&D spend** in Q2FY20 was steady at ₹255m. Continued focus on enhancing portfolio for other regulated markets with **3 new product filings** in Q2FY20. **Momentum of US filings/approvals to pick up** in H2FY20.
+ Focus on **building capabilities in sterile injectables** as we announced our foray into this space leveraging the Stelis manufacturing platform and our rich experience in aseptic fill-finish

EMERGING MARKETS

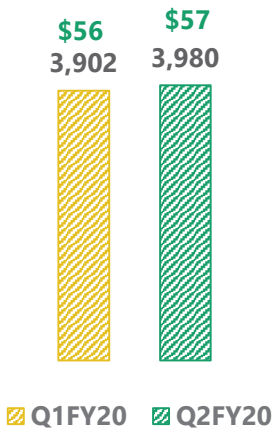
× Under performance in the **emerging markets** as the business **declined 23% QoQ and 41% YoY.**
× While we have solved for a significant part of the course correction strategy, the performance continues to remain volatile largely on account of **institutional business** which requires a **portfolio enhancement in the new ARV regimen**

1. *The revenues for other regulated markets have been recast to include supplies to Arrow which were earlier inter-company sales*

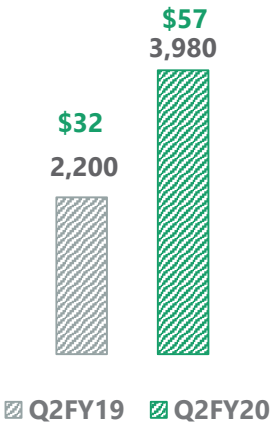
US delivered a sequential growth despite ranitidine supply disruption

FINANCIAL PERFORMANCE(₹/$m)

QUARTER ON QUARTER



YEAR ON YEAR



Quarter on Quarter Growth

2%

Year on Year Growth

81%

PERFORMANCE UPDATES

- **Reported $57m revenues in Q2FY20 demonstrating sixth consecutive quarter of** sequential growth since the strategic reset in Q4FY18
- Front end reaches **~$40m revenues in Q2FY20** , growing over **4x scale** from **~$10m revenues** in Q1FY19
- The front end business **delivered its highest ever quarterly performance with significant QoQ and YoY growth**
- Business continues to benefit from a focused product selection and launch strategies and a relentless execution by way of **supply commitments and customer advocacy.**
- Existing products and **new launch- Cinacalcet** continue to **witness traction** in the market **supporting growth** in spite of temporary supply discontinuation of Ranitidine
- **Partnered business by design** will slow down as we continue to focus on **bringing products** back to our own front end to create avenues for margin and growth expansion.
- With the acquisition of **USFDA approved** soft gel manufacturing site in Florida, our **"In market for market"** strategy has been achieved. We plan to expand additional dosage format suites at the site for select large volume products . The site will also help tap opportunities under various federal government procurement programs
- **Puducherry remediation activity on track** as we expect the facility to be ready for a re-inspection by USFDA in Q4FY20 or early Q1FY21.
- EIRs received from USFDA on continued compliance status for our manufacturing facility in **Bangalore(July 2019) and Chennai(October 2019)**
- **We continue to maintain our FY20 outlook for the US markets**

Recent developments in Ranitidine medications

Ranitidine Product Introduction

- **Ranitidine** is a prescription and OTC drug used as an H2 (histamine-2) receptor blocker, which decreases the **amount of acid** created by the stomach.
- As a **prescription drug**, it is approved for multiple indications, including treatment and prevention of ulcers of the stomach and intestines and treatment of **gastroesophageal reflux disease.**
- **OTC ranitidine** is approved to prevent and relieve heartburn associated with acid ingestion and sour stomach.
- **Strides has approval for Rx and OTC Ranitidine tablets for the US market** and has only commercialized the **Rx product in the US currently**.
- Strides, through its marketing partner, Arrow also commercialised Ranitidine for the **Australian markets.**
- Strides has **not commercialised ranitidine** in Europe

Concerns around NDMA

- Nitrosamine impurity called **N-nitrosodimethylamine (NDMA)** is present in foods such as **meats, dairy products, and vegetables and in water supplies**
- Followed by a petition filed in the US by an online pharmacy, the regulatory agencies world over including the USFDA or FDA, EMA(Europe) and TGA(Australia) learned that some ranitidine medications contain **NDMA at low levels**
- NDMA is classified as a **probable human carcinogen** (a substance that could cause cancer)
- TGA, Australia[1] has referred to **internationally agreed limit of 0.3 parts per million (ppm) of NDMA level in ranitidine**
- **No other Agencies'** have announced any limit thus far.

Timeline of events

- **September 13-** FDA and other regulators such as EMA/TGA issued a statement alerting patients of NDMA found in samples of ranitidine. The agencies , however, **did not announce any intent to recall the product**
- **September 26** - FDA asks all ranitidine manufacturers to conduct laboratory testing to examine levels of NDMA in ranitidine and to send samples of ranitidine to the agency
- **October 2-** FDA issued a statement recommending the use of a LC-HRMS testing protocol to test samples of ranitidine
- **October 22-** TGA publishes[1] test results of **135 ranitidine batches in market.** Test results from Australia confirms only **24 batches in market meeting acceptable limits of NDMA of 0.3 ppm** and below.
- **October 23-** FDA releases **additional testing methods for NDMA tests** for those companies who have difficulties in testing as per original HR-MS method

Strides Outlook

Australia

- Supplies to Australia initiated in 2017 through Arrow. To date, **23 batches of ranitidine** have been produced by Strides for Australia.
- Barring the first 3 batches which were tech transferred from a third party site, **all 20 batches of Strides produced with the API from Solara** were found acceptable in the market by TGA[1]
- **Strides , at this time, is the sole supplier for Ranitidine tablets in the market with remaining shelf life**

US

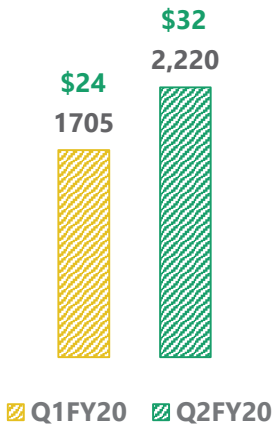
- On September 26, Strides **voluntarily suspends sale of ranitidine tablets in the US market.**
- Strides has **submitted the requested data to the FDA** in response to the Information Request. Strides is awaiting further feedback from the **FDA on the NDMA limits** and expects to receive an update soon.
- Strides is working closely with Solara & is in a strong position to consistently **meet internationally acceptable limits of NDMA in ranitidine**

1. https://www.tga.gov.au/tga-laboratories-testing-ranitidine-medicines

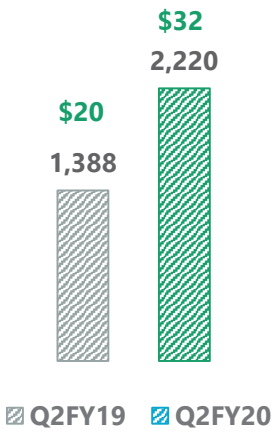
Strong other regulated performance led by UK, EU & supplies to Australia

FINANCIAL PERFORMANCE[1] (₹/$m)

QUARTER ON QUARTER



YEAR ON YEAR



Quarter on Quarter Growth

30%

Year on Year Growth

60%

PERFORMANCE UPDATES

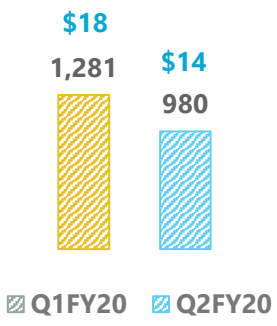
- Markets continue to benefit from the **operating leverage** and a large pipeline of **approved products with market fungibility**
- Continued gains of the market share in the front end markets of **UK and South Africa**
- Significant uptick in the **Hybrid R&D** focus for the other regulated markets. 3 Filings for the current quarter, strong visibility in filings for next 6 months
- Continued initiatives on increasing the **supply chain capabilities** to meet our growing demand and **maximize our portfolio coverage**
- **Supplies to Australia** demonstrated **2x growth** over the previous quarter as the dedicated TGA approved plant in India **stabilises operations**
- The orderbook continues to **remain healthy** for the financial year and we expect the growth to remain robust in the **H2FY20**
- **On track to deliver an industry leading growth with significant expansion in profitability led by the expansive penetration and product portfolio advantage**

1. *The revenues for other regulated markets have been recast to include supplies to Arrow which were earlier inter-company sales*

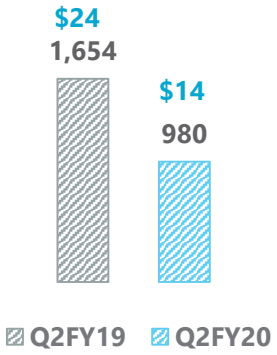
Challenges in the emerging markets and institutional business continue

FINANCIAL PERFORMANCE(₹/$m)

QUARTER ON QUARTER



YEAR ON YEAR



Quarter on Quarter Growth

-23%

Year on Year Growth

-41%

PERFORMANCE UPDATES

Our goals in the Strategic Reset

In FY19, we initiated our **course correction strategy** for emerging market & institutional business to focus on the following outcomes:

- Focus to bring out **channel hygiene** in our branded generics business in Africa with a redesigned portfolio and market selection.
- Develop a **steady portfolio** to be on the forefront of **new regimen** products in the Anti-retroviral(ARV).
- Shift our **key products** in institutional business from India to our manufacturing site in **Nairobi, Kenya for an "In Africa for Africa" market play**

What have we achieved so far?

- The **channel hygiene in Brands Africa** has now been achieved and we now continue to focus on building our people productivity and new product launches
- We continue to **retain our market share** for the **Anti-Malarial business** albeit a reduced donor commitment pool
- Our R&D pipeline for the new regimen on track with the **first key product approval due in Q4FY20/Q1FY21** which will accelerate the reset of the institutional business
- UCL , our Kenyan operations recently **completed WHO inspection** and we are in process of site transfer products to Kenya to execute on "in Africa for Africa" strategy

Near term outlook

- Near term **growth outlook remains soft** as our strategy reset plays out
- Focus only on **executing profitable business** as we achieve a critical size and deliver value

STRIDES ANNOUNCES ITS RE-ENTRY INTO STERILE INJECTABLES WITH INCREMENTAL ~$40M INVESTMENTS OVER 24 MONTHS FOR A CONTROLLING STAKE IN STELIS BIOPHARMA WHICH WILL ALSO PLAY OUT A FOLLOW ON BIOLOGICS AND HIGH-END CDMO SERVICES STRATEGY

Click here for a virtual plant tour

Stelis to break even in 18 months with 3 strategic growth engines

BIOPHARMACEUTICALS

- Stelis's portfolio includes biosimilars produced from microbial production technology.
- Its portfolio has now attained a reasonable position with significant investments already made into product development

Product	TA & Market Opportunity	Market Readiness
SBL001	Osteoporosis with ~$2b opportunity	• Successfully completed the pivotal phase 1 clinical study in Australia which meets filing requirements for EU, Australia, and Canada • Phase 3 waiver for EU received with global ex-US filings expected in the Q2 of CY20 • Significant licensing partnerships in discussion for the European markets • Incremental phase 3 studies for the US by end CY20
SBL005	Osteoarthritis with ~$2b opportunity	• Dossiers under filing in emerging and ROW market with the potential to launch this product as a device • EU/US development under progress given the recent change in regulations to classify this product as a drug • Incremental phase 3 studies for the EU & US by end CY20
Early Stage assets	• Stelis is building an integrated insulin and insulin analogue platform with proprietary technology. • Stelis believes that the platform is one of its kind and has the potential to disrupt the industry paradigm in insulin accessibility and affordability. • Stelis's R&D and clinical strategy for insulins are designed for the global markets.	

CDMO & BIOLOGICS RESEARCH SERVICES

CDMO Services

- Completed construction of **modern fully integrated state-of-the-art biopharma** manufacturing facility
- **Drug Substance(DS) block** is **under installation and validations** and **Drug product(DP)** block has been validated and now ready for commercial operations.
- **DP CDMO services** have started seeing traction from global players , recently concluded maiden CDMO contract for **fill-finish services with revenues from FY20**

Biologics Services

- Equipped to offer **biologics research services** to focus primarily on the development and commercialization of **biosimilars, bio betters and New Biological Entities.**
- In early discussions with **leading global players** for offering these services

STERILE INJECTABLES

- Received our non-compete waiver ahead of schedule in October 2019. Consequently, Strides will **re-enter sterile injectables** with envisaged incremental investments in Stelis
- Stelis to be the **manufacturing platform** for Strides' sterile injectables
- Strides will develop a basket of niche products leveraging the **group's proven experience and strong capability in the space**
- Planned **10+ filings** in the regulated markets over the **next 12-15 months**

Multiple pillars for growth and profitability for Stelis with risk mitigated cashflows

Stelis Value Chain

Insulin platform technology	• **Cost-effective process technology developed in the US with higher yield, greater recovery, and high purity vs. competition**
Follow on Biologics	• **Asset 1 -** Only known developer to provide both reusable and disposable pen device options to cater to global market demand at competitive cost. • **Asset 2** - Differentiated device for knee osteoarthritis
Sterile injectables	• **Manufacturing platform** for Strides' sterile injectables
CDMO Services for Drug Substance and high end biological services	• A healthy pipeline of contracts for the **integrated Drug Substance and Drug Product manufacturing** in mammalian and microbial opportunities
Drug Product CDMO Services	• Significant interest from pharmaceutical and biopharmaceutical companies for **fill-finish in drug products – vials, PFS and cartridges**

- **FY21-** Break even at operating level with marginal Opex under-recoveries
- **FY22-** Expected to have a positive EPS
- **FY23-** Generate positive return ratios for Strides investments

Strides

Financial Performance

Significant growth in operating PAT given the increased margins and reduced portion of term debt

Q2FY20 Financial performance

INCOME STATEMENT (₹M)

Particulars	Q2FY20	Q2FY19	YoY	Q1FY20	QoQ
Revenues	7,180	5,242	37%	6,888	4%
EBITDA	1,506	486	210%	1,239	22%
EBITDA %	*21.0%*	*9.3%*	*1,170bps*	*18.0%*	300bps
Adj PAT[1,2]	**717**			**523**	
Adj EPS[1,2]	8.0			5.8	

1. *For Q2FY20, Reported PAT at ₹1,331m which includes exceptional item gains of ₹834m resulting from the cancellation of the obligation to acquire remaining 49% stake in Universal Corporation, Kenya as the Company did not meet its intended business objectives.*
2. *For Q2FY20,adjusted for Biotech and CHC share of loss of ₹213m and exceptional gains of ₹834m as stated above.*

RECONCILIATION OF EBITDA (₹M)

As per SEBI results	Q2FY20	Q2FY19
Profit before exceptional items & tax	**782**	**57**
Less: Interest, Dividend income	*101*	*52*
Add : Depreciation and Amortization	420	309
Add : Finance costs	*404*	*172*
Consolidated EBITDA as per press release	**1,506**	**486**

CONSTANT CURRENCY NET DEBT AT END OF SEP'19 [3]

₹ **9,981** Million

Increase in net debt from ₹6,955 Mn on account of increased equity stake in Stelis, acquisition of Fairmed, US manufacturing assets and incremental working capital supporting the growth at US Front End and Other Reg markets

3, Adjusted net debt post Arrow transaction and pay out of dividend as reported in the last quarterly results.
Adjusted for QoQ currency impact on account of restatement of foreign currency debt at ₹398 Mn

Strides

Thank You