



Shilpa Medicare Limited

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CIN: L85110KA1987PLC008739

08 February 2024

Corporate Relationship Department,
BSE Limited,
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai-400 001

National Stock Exchange of India Limited,
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra Kurla Complex, Bandra (E),
Mumbai-400 051

Dear Sir/Ma'am,

Scrip Code: BSE - 530549/Stock Symbol: NSE – SHILPAMED

Sub: Investor Presentation of the Company for the Quarter ended 31 December 2023

Ref: Disclosure under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

With reference to the captioned subject, the Investor Presentation of the Company for the Quarter & Nine Months ended 31 December 2023 on Company Overview, Business highlights, financial performance and other updates is enclosed herewith for your consideration.

We request you to take the same on record.

Thanking you.

Yours faithfully,

For **Shilpa Medicare Limited**

RITU TIWARY

Digitally signed by RITU
TIWARY
Date: 2024.02.08 18:51:08
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Ritu Tiwary

Company Secretary & Compliance Officer



Shilpa Medicare Limited (SML)

Q3 & 9M FY'24 Results Presentation

Disclaimer

Certain statements in this document may be forward-looking statements. Such forward looking statements are subject to certain risks and uncertainties like regulatory changes, local political or economic developments, and many other factors that could cause our actual results to differ materially from those contemplated by the relevant forward-looking statements. Shilpa Medicare Limited (SML) will not be in any way responsible for any action taken based on such statements and undertakes no obligation to publicly update these forward-looking statements to reflect subsequent events or circumstances.



API Units, Raichur





1

Company overview

2

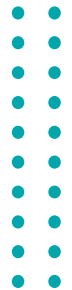
Financial performance

3

Business highlights

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Annexures



Company Overview



Established presence in Active Pharmaceutical Ingredients (APIs) and Formulations for domestic & international markets

Pursuing niche growth businesses like Biologics, Transdermal & Oral Dissolving Films Formulations



Robust research orientation resulting in innovative products

Affordable & Effective Pharmaceutical Solutions



Very strong R&D background including development, pathway engineering and characterization of biologics



Best in class manufacturing and supply of high-quality affordable drugs

Commenting on Q3 FY'24 performance, Mr. Vishnukant Bhutada, Managing Director Shilpa Medicare Limited said

"I am pleased to inform you that our consistent endeavor to improve operational efficiencies and cost rationalization with a focus on development of niche opportunities has started showing results and we have witnessed continuous improvement in our profitability quarter on quarter.

*In the US market we have filed for ANDA of Prucalopride tablets 1mg and 2mg with the reference of approved "**Competitive Generic Therapy Designation**" and also with "**Priority Review Requested**". This product has current market size of approx. \$ 120 Mn.*

For our Jadcherla facility that was audited by USFDA in November 2023 which was a for cause inspection. We have submitted all compliance of the ten observations that were received, none of which were listed as repeat observations and in relation to data integrity issues.

Our API business is on a steady growth path where we see capacity enhancement by increasing the batch sizes and improved utilization of our blocks for both oncology and non-oncology range of products. We are also adding new projects in our new sun rise divisions of Polymer and Peptide.

Our CDMO business has been receiving positive responses from customers and is experiencing consistent growth with addition of good clientele and interesting projects.

As a company, we are committed to facilitating the successful introduction of novel products within APIs and Formulations, ensuring predictable cash flows.

*On biological front, for the India market, we have launched **High concentration Adalimumab** under the brand name "**ORIADALI™**" and have also partnered with **Sun pharma**. This is a crucial step into the realm of our biological offerings, aimed at enhancing patient comfort in treating Rheumatoid Arthritis. Piggybacking on India approval and launch, our strategy extends to tapping into various international markets with this product.*

*Our large-scale fermenting facility for manufacture of **recombinant Albumin** is under erection and we expect the same to be completed before June 2024. We have already commenced phase 1 trials for this niche opportunity.*

Overall, I believe we are gradually coming out of the recent challenges and are on a robust growth trajectory with all our business units contributing towards the same."

○ About Developments

- Adding 3 molecules in the portfolio which are at validation stage and which are expected to be completed in Q4 FY24 tentatively
 - Methotrexate – Onco molecule its Validation is in progress & expected to complete by end of March its import substitute molecules
 - Liraglutide – our 3rd peptide molecule, its trial batch is successfully completed which is meeting global grade quality
 - Teriparatide – our 4th peptide molecule & its under development
- One nutraceutical product for a customer is under validation which is expected to be completed by end of Feb 24
- Tranexamic Acid capacity enhancement initiated from 15 MT – 25 MT

○ Significant Commercial Update

- Specialty polymer developed for a US based client and supplied pilot quantities
 - Commercial supplies expected in FY25
- UDCA volume is picking up
- Added 2 new customers in CDMO from Japan & Spain - CDMO segment achieved sale of Rs.12.3 cr. in Q3 FY24

○ Topical Lotion (SMLTOP09) for treatment of Androgenic Alopecia.

- Phase II trial completed
- Phase III study likely to start by March 24
- Scientific advice for EU successfully submitted and received agency feedback
- Covered by granted patents in India, USA, China, Japan, Korea till June 2038
- Patent pending in Europe
- The global alopecia market is valued at \$8.2 billion in 2022 and is expected to grow at the CAGR of 9% from 2023 to 2030
- Alopecia Disease Types:

Disease Subtype	% of Market	Value in \$billion (2022)
Alopecia Areata	34.3%	\$2.8 billion
Androgenic Alopecia	31.1%	\$2.5 billion
Cicatricial Alopecia, Traction Alopecia Alopecia Totalis, Alopecia Universalis And others	34.6%	\$2.8 billion

- Awaiting commencement of Phase III studies to initiate partnering discussion in India/EU/ROW/USA
- Significant upside possible on commencement of Phase III study in respective market

○ Grant of Code “J” for Pemetrexed Injection (NDA)

▪ About Product

- Used in the treatment of non-small cell lung cancer in combination with other chemotherapy agents
- Also indicated in the treatment of mesothelioma in combination with cisplatin
- A novel ready-to-use injection which eliminates the need for reconstitution and dilution before administration to the patient
- Ready-to-use formulation enables reduction of dosing errors, ease of administration and accurate dosing based on patient body weight

▪ About J-Code

- J-codes are permanent reimbursement codes used by healthcare providers, government payers and commercial insurers to facilitate billing of Medicare Part B treatments, which must be administered by a healthcare professional
- J-codes simplify and streamline the billing and reimbursement processes, allowing for efficient claims processing resulting in significant conveniences to the patient
- Code “J” enables marketing the product as a niche product

○ SMLNUD07

- Phase III studies have been initiated for the indication of NAFLD (Non-alcoholic fatty liver disease)
- Tentative completion of the study Q3 FY25
- About NAFLD
 - Most common liver disease and it is estimated to effect up to 25% of the population in World (approx. 1.2 billion)
 - About 188 Million people suffer from develop NAFLD in India
 - The main characteristic of NAFLD is excessive accumulation of fat in hepatocytes
 - In first stage NAFLD is characterized by simple hepatic steatosis (NAFL, Non-alcoholic fatty liver)
- Expecting additional indications approval from regulatory authorities in India
- Significant partnering opportunities in EU/ROW market for the product

- Dr. Clot Spray is a cutting-edge innovative formulation of Tranexamic Acid, designed to address the critical issue of uncontrolled bleeding during trauma, accidents, battle field, surgery, suturing and ambulance transportation of patients from the site of accidents to the hospital. Tranexamic Acid is renowned for its haemostatic properties, effectively promoting blood clotting and preventing excessive bleeding. Dr Clot globally patented formulation by Shilpa Medicare Ltd

Dr. Clot Spray: **EDGE over RUN-OFF**

Effective Action Desired Outcome Guaranteed Safety Easeful Use

- Dr Clot received approval CDSCO
- Dr Clot also endorsed by Indian Dental Association (IDA)
- Presented in various forums in India namely Trauma Society of India (AIIMS Delhi) Emergency Department Safdarjung New Delhi, RML Hospital New Delhi, EMRI – GVK (108 ambulance) Hyderabad, Indian Railway, CIDC (Construction Industry Development Council) Karnataka State GOVT, India Army Hospital. Maharashtra GOVT. and KGMC Medical college Lucknow
- Dr Clot is approved in the Project Bhishma (Arogya Maitri Cube)
- Dr Clot is being tried by Dental surgeons, Orthopedic surgeons, Trauma and Emergency

Dr Clot



○ ODF

- Betahistine ODF approved in UK market and opens up partnering opportunities
- Tadalafil ODF MA successfully filed in Europe market
- Bilastine ODF clinical study is successfully completed and expected to be filed in Q1 FY25
- Successfully launched ODF products in US market and is growing steadily

○ TDS

- Rotigotine Transdermal Patch is partnered in Europe and Emerging countries
 - Expected to be filed in Q2 FY25 in Europe
- Two new products in transdermal patches added in development portfolio

- **Launch of High Concentration Adalimumab injection in India market**
 - Launched as High Concentration 40Mg/0.4ml injection in prefilled syringe (PFS)
 - Used for the treatment of Rheumatoid Arthritis (moderate to severe active RA & severe active and progressive RA)
 - Contribute to increased patient comfort based on reduced injection volume
 - Launched under own brand name (“**ORIADALI™**”) and partnered with Sun Pharma for India market
- **Recombinant Albumin**
 - Phase I initiated for the product and expected to be completed by Q4 FY24
 - Phase III Initiation likely by June-24 & completion by Q1 FY 26
 - Product has been granted NBE(New Biological Entity) status
 - Excipient grade DMF will be filed by Q1 FY25

○ **Aflibercept**

- Phase III approval received from CDSCO and plans underway to initiate the clinical trial - a significant milestone in the development
 - Manufacturing of CT batches ongoing for phase III trial
 - Phase III will be initiated from Q1 FY 25 and completion by Q1 FY 26
- This pivotal trial is a crucial step towards advancing our commitment to delivering safe and effective solutions for various eye conditions

○ **CDMO**

- First CDMO project for microbial fermentation from a client for Korea Market

○ **Additional Three products are under development**

- Abatacept
- Etanercept
- Pembrolizumab



Financial Performance

Financial Performance – SML Standalone

(INR in Cr.)

<i>Particulars</i>	<i>Q3 FY24</i>	<i>Q2 FY24</i>	<i>% change</i>	<i>Q3 FY23</i>	<i>% change</i>
Revenues	86.3	97.4	-11%	69.2	25%
Gross Margin	67.8	78.9	-14%	54.6	24%
Gross Margin %	79%	81%	-3%	79%	0%
Employee Cost	25.3	26.2	-3%	26.6	-5%
Other Expenses	23.5	22.7	4%	20.7	13%
EBITDA	19.0	30.1	-37%	7.4	159%
EBITDA %	22%	31%		11%	
Finance Cost	2.6	5.2	-50%	6.6	-61%
Depreciation	12.4	12.7	-2%	12.3	1%
PBT	4.0	12.2	-67%	-11.6	
Execeptional Item-(Income)/Exp	0.1	0.2	-48%	0.0	
PAT	2.7	8.5	-68%	-4.8	

Balance Sheet – SML Standalone

(INR in Cr.)

Particulars	31-Dec-23	30-Sep-23	31-Dec-22
Fixed Assets	588.6	598.9	602.2
Tangible Assets	503.5	512.5	526.7
Intangible Assets	85.1	86.4	75.5
Capital WIP	235.5	227.4	246.9
Tangible Assets	24.3	27.1	49.1
Intangible Assets	211.2	200.3	197.9
Slump Sale Consideration Receivable	-	-	341.1
Other Non-current Assets	1,206.3	1,188.8	1,004.3
Net Working Capital	253.7	259.6	261.6
Current Assets	331.4	329.5	317.3
Cash and cash equivalents	4.2	6.9	5.8
Current Liabilities	-81.9	-76.8	-61.5
Total Assets (Net)	2,284.1	2,274.7	2,456.2
Equity	2,134.6	2,131.9	2,143.7
Borrowings (Current & Non current)	115.5	108.5	274.5
Other Non Current Liabilities	34.0	34.3	38.0
Total Liabilities	2,284.1	2,274.7	2,456.2

Financial Performance Consolidated

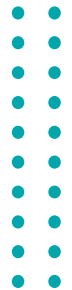
(INR in Cr.)

<i>Particulars</i>	<i>Q3 FY24</i>	<i>Q2 FY24</i>	<i>% change</i>	<i>Q3 FY23</i>	<i>% change</i>
Revenues	288.7	314.8	-8%	265.2	9%
Gross Margin	192.2	189.0	2%	159.7	20%
Gross Margin %	67%	60%		60%	
Employee Cost	69.1	73.1	-6%	68.5	1%
Other Expenses	55.0	53.8	2%	57.2	-4%
EBITDA *	68.2	62.1	10%	34.0	100.3
EBITDA %	24%	20%		13%	
Finance Cost	26.2	23.2	13%	17.9	47%
Depreciation	26.7	27.8	-4%	24.1	11%
PBT	15.2	11.1	37%	-7.9	
PAT	4.7	1.6		-6.6	

* EBITDA for Q3FY24 is after provision of certain receivables to the tune Rs. 4 cr. which are one off in nature

Balance Sheet Consolidated

Particulars	Consolidated		
	31-Dec-23	30-Sep-23	31-Dec-22
Fixed Assets	1,359.8	1,361.0	1,365.7
Tangible Assets	1,162.4	1,160.0	1190.1
Intangible Assets	197.5	201.0	175.7
Capital WIP	726.4	681.2	625.5
Tangible Assets	420.7	389.1	319.7
Intangible Assets	305.7	292.1	305.8
Other Non-current Assets	103.1	136.8	127.4
Net Working Capital	515.9	501.6	523.6
Current Assets	800.5	801.2	795.7
Cash and cash equivalents	15.4	24.0	23.3
Current Liabilities	-300.0	-323.6	-295.4
Total Assets (Net)	2,705.3	2,680.5	2,642.2
Equity	1,777.2	1,774.6	1777.6
Borrowings (Current & Non current)	889.0	863.5	798.1
Other Non Current Liabilities	39.1	42.4	66.6
Total Liabilities	2,705.3	2,680.5	2,642.2



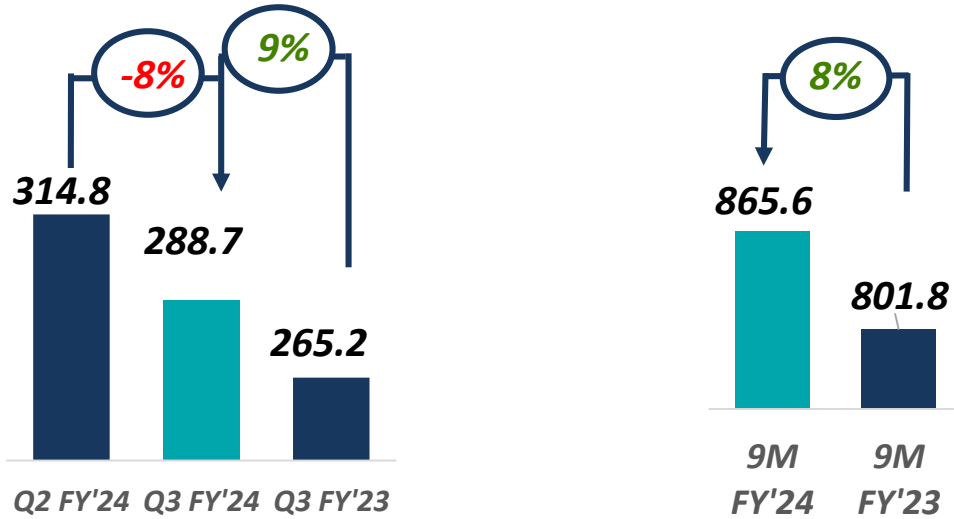
Business Highlights

9M FY'24 Consolidated Performance

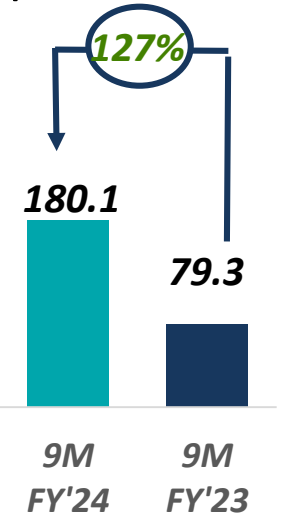
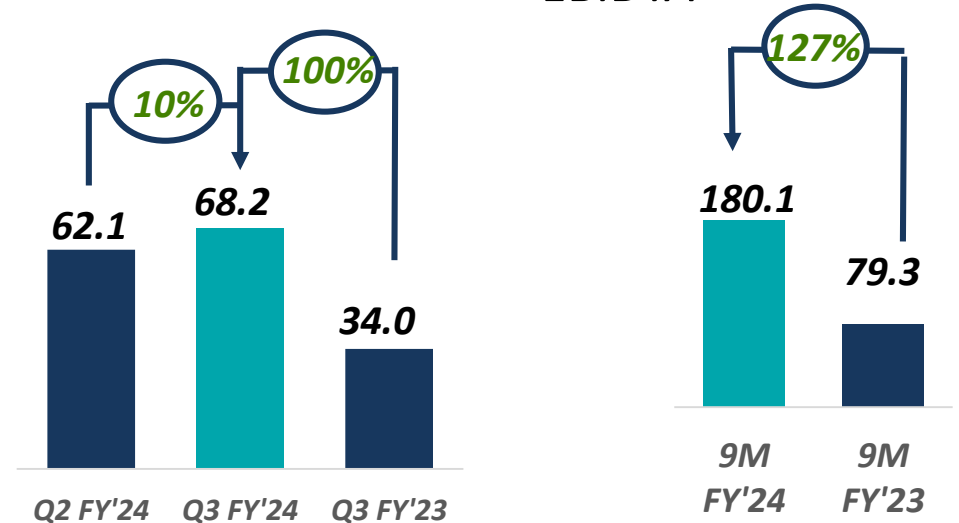
21

(INR in Cr.)

Revenue



EBIDTA



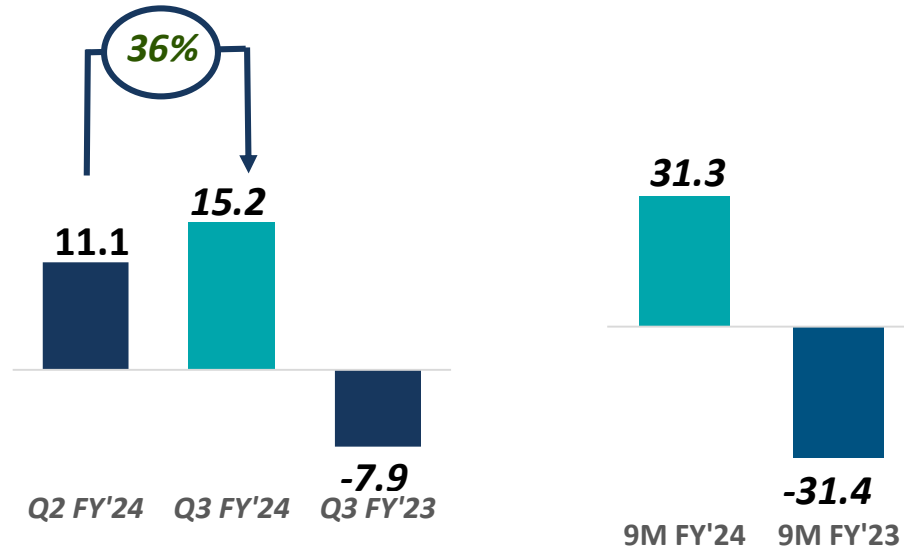
* EBITDA for Q3FY24 is after provision of certain receivables to the tune Rs. 4 cr. which are one off in nature

Q3 FY'24 Consolidated Performance

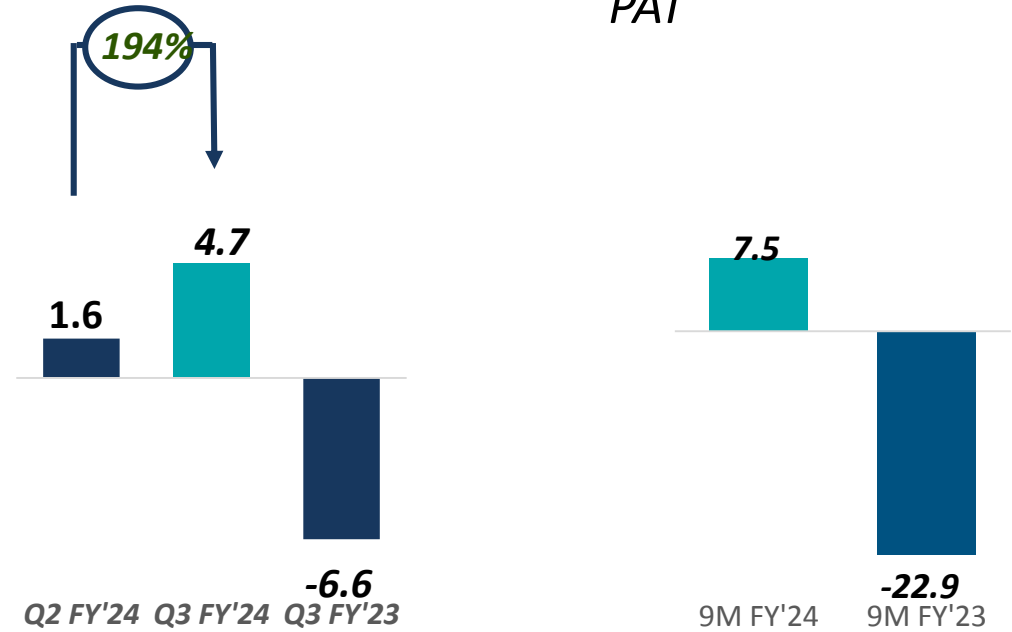
22

(INR in Cr.)

PBT



PAT



- ❖ *PBT excluding share of loss in JV/Associates*
- ❖ *Excluding exceptional items*

Consolidated Revenue Break-up – Q3 FY'24

23

(INR in Cr.)

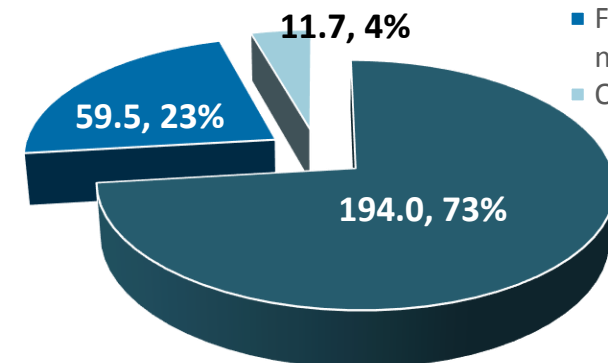
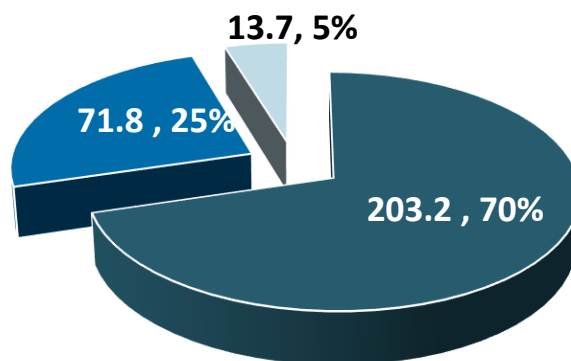
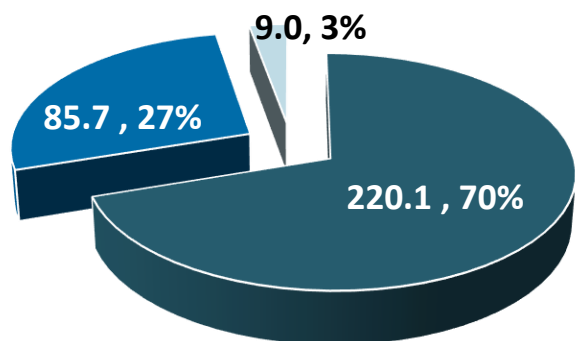
Q2 FY'24
INR 314.8 Cr.

Q3 FY'24
INR 288.7 Cr.

Q3 FY'23
INR 265.2 Cr.

Growth of 9% vs Q3 FY'23

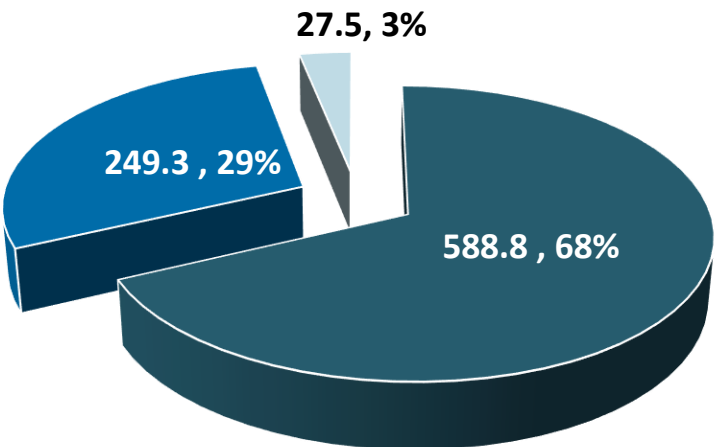
De-growth of 8% vs Q2 FY'24



- API
- Formulation
- Others

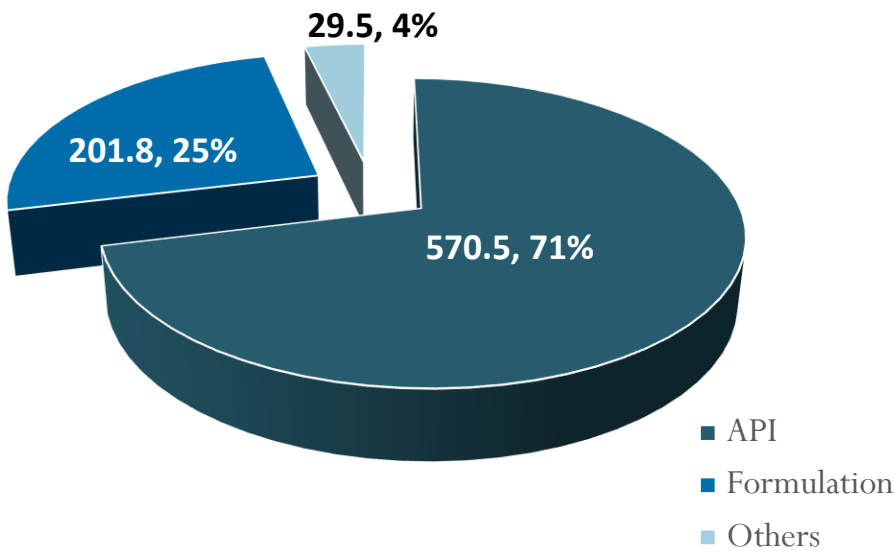
Consolidated Revenue Break-up – 9M FY'24

9M FY'24
INR 865.6 Cr.

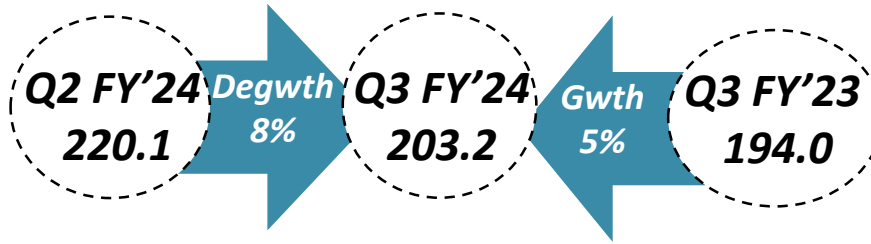
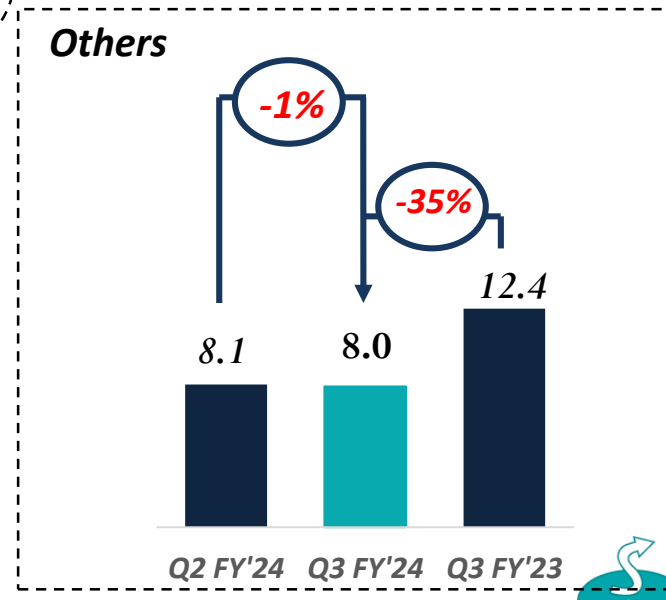
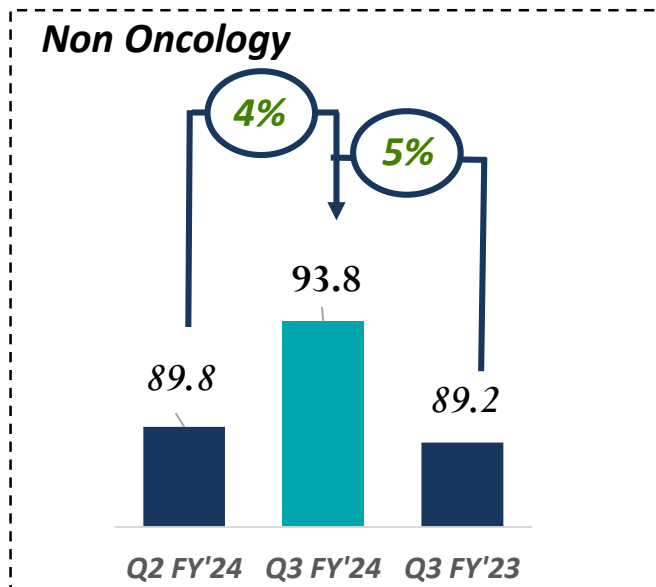
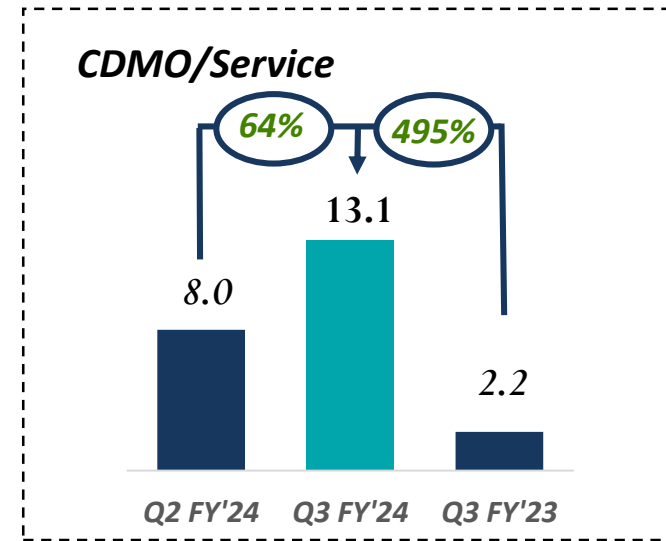
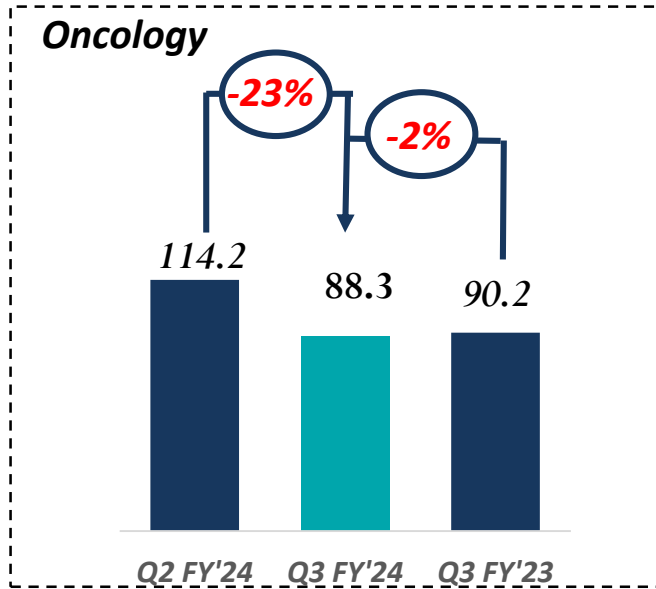


8% Growth

9M FY'23
INR 801.8 Cr.

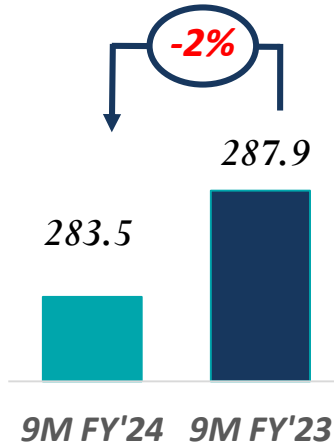


API Business

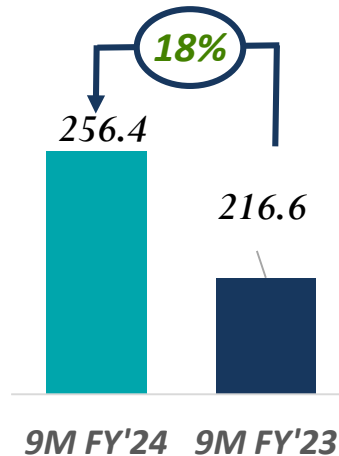


*Numbers are excluding captive consumptions

Oncology



Non Oncology

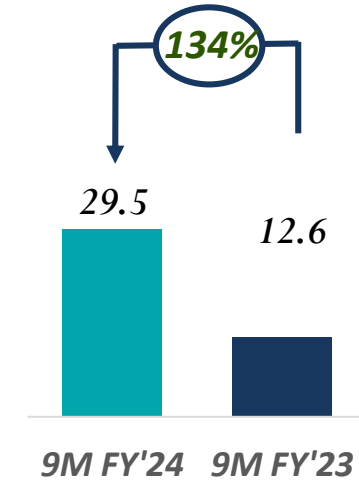


9M FY'24
588.8

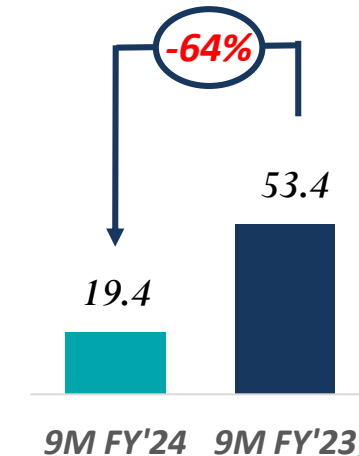
Gwth
3%

9M FY'23
570.5

CDMO/Service



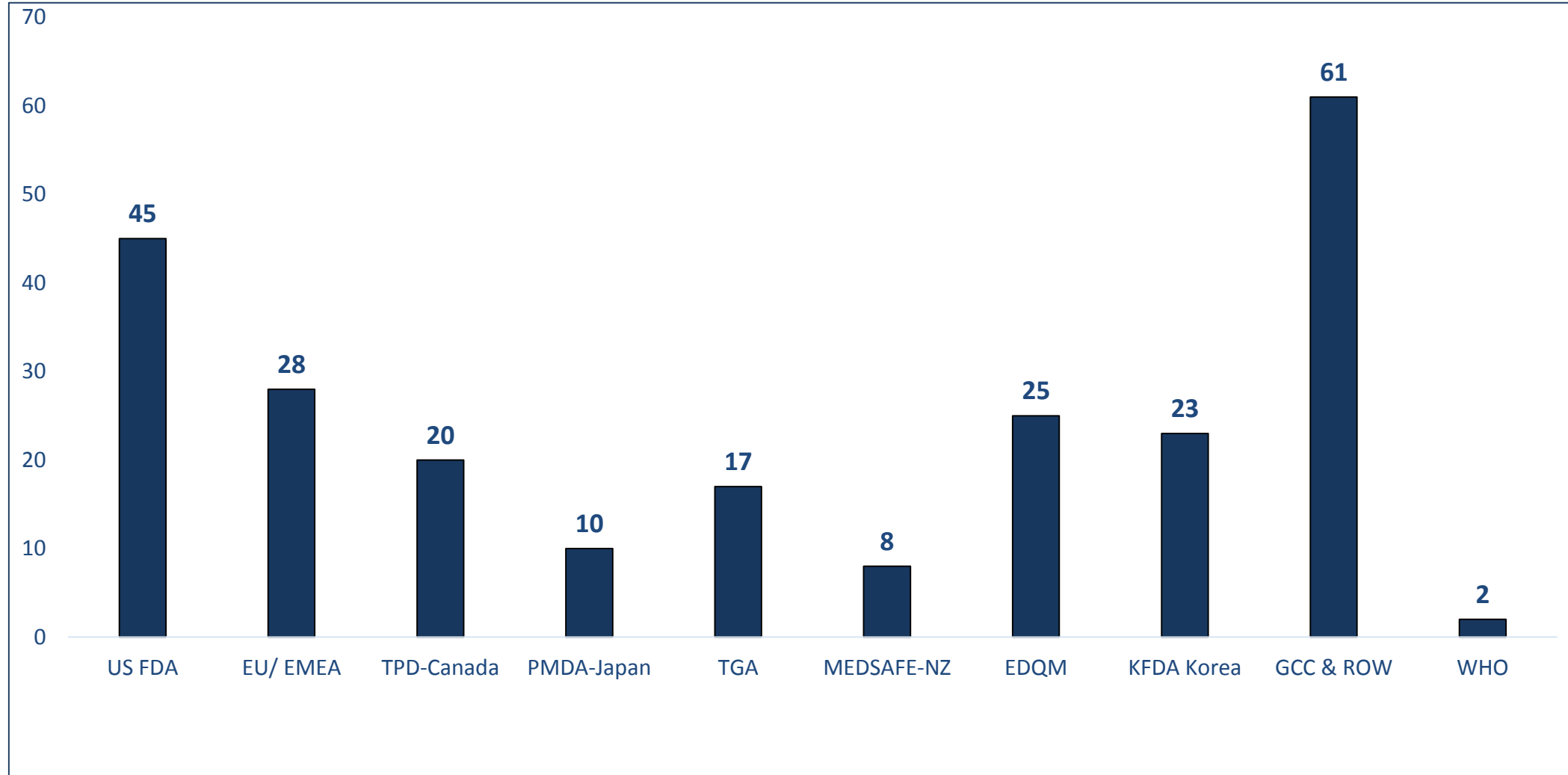
Others



*Numbers are excluding captive consumptions

DMF Filing update

*New product introduction and increase in geographical coverage replicated with **239** number of **DMF filings** done with major regulatory authorities*



As on 31st December 2023

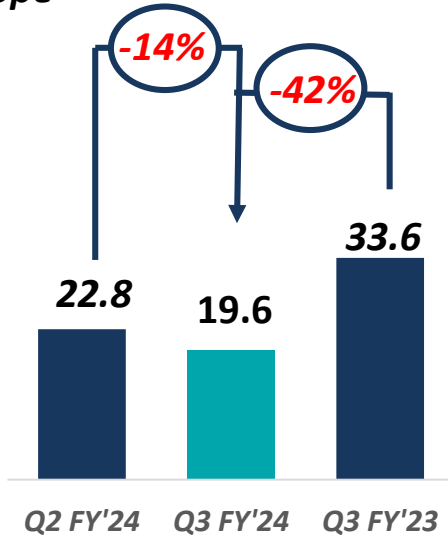
Formulation Business

Formulation Business-Highlights Q3 FY'24

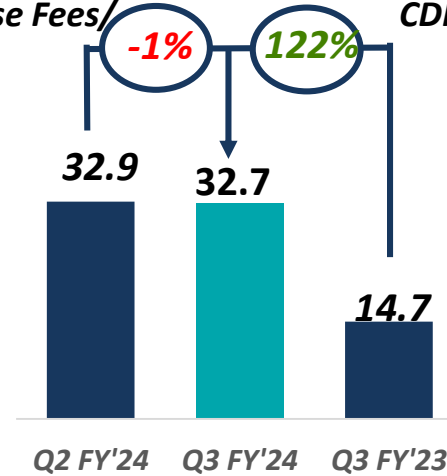
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(INR in Cr.)

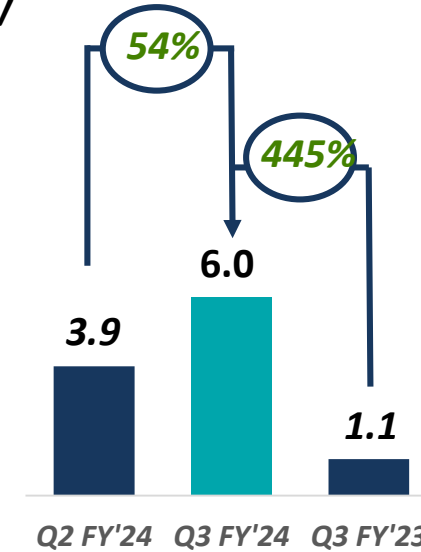
Europe



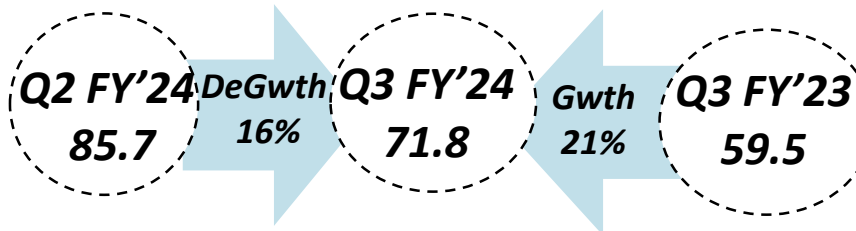
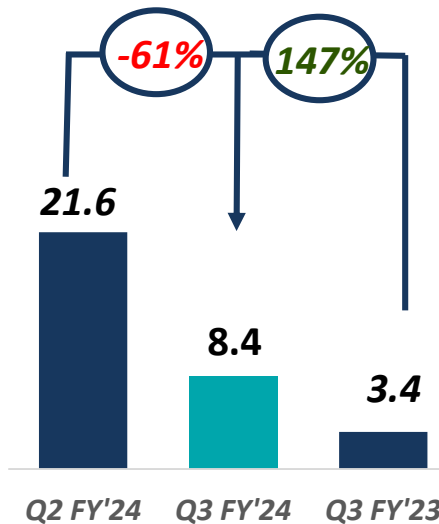
License Fees/CDMO



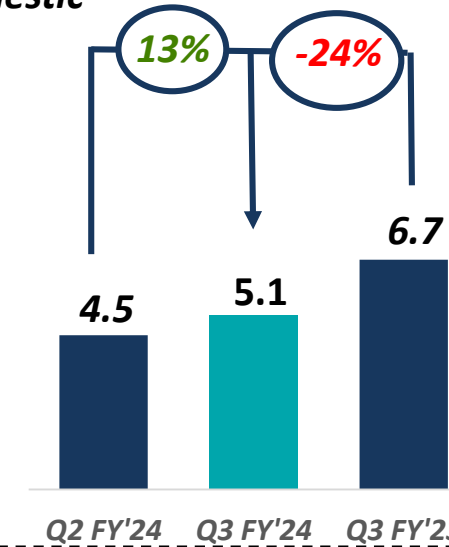
ROW



US



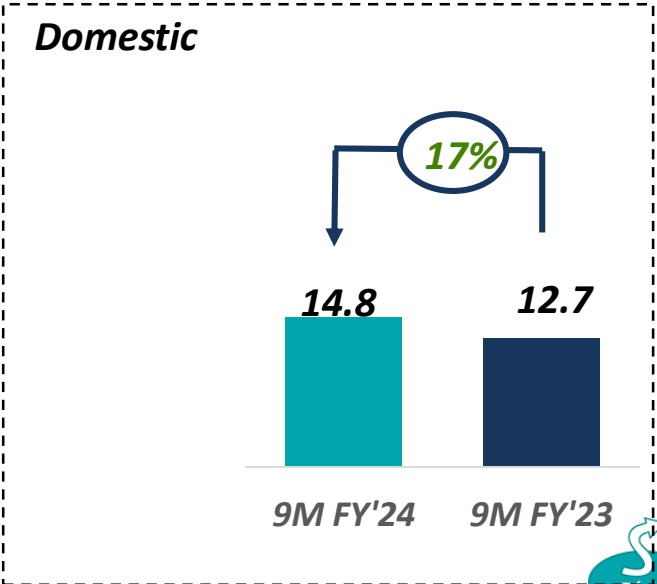
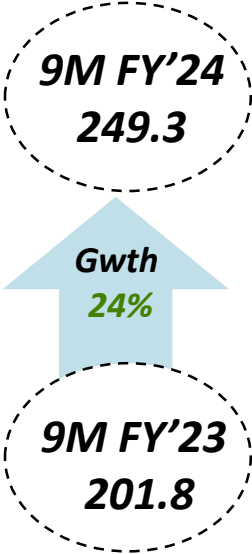
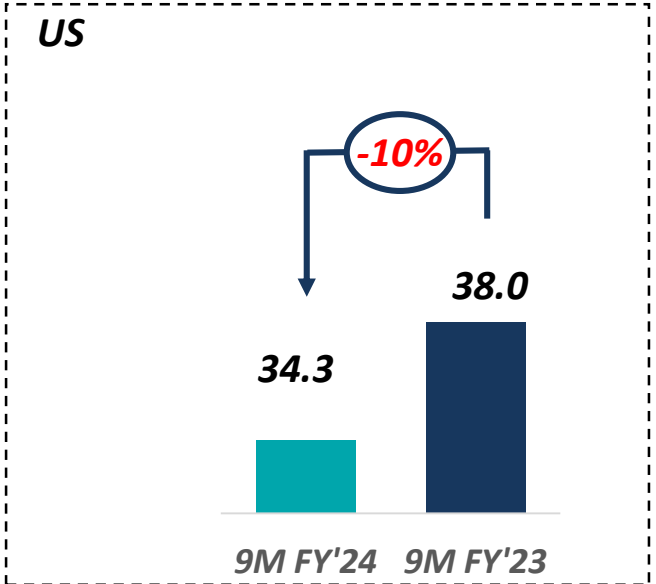
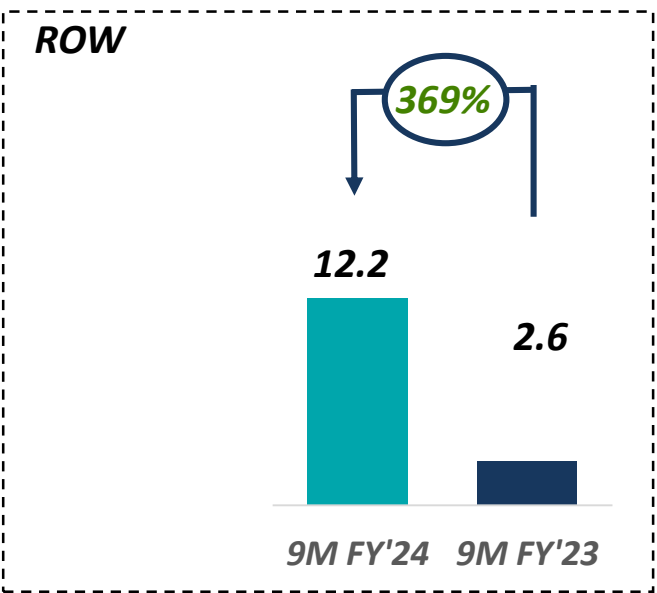
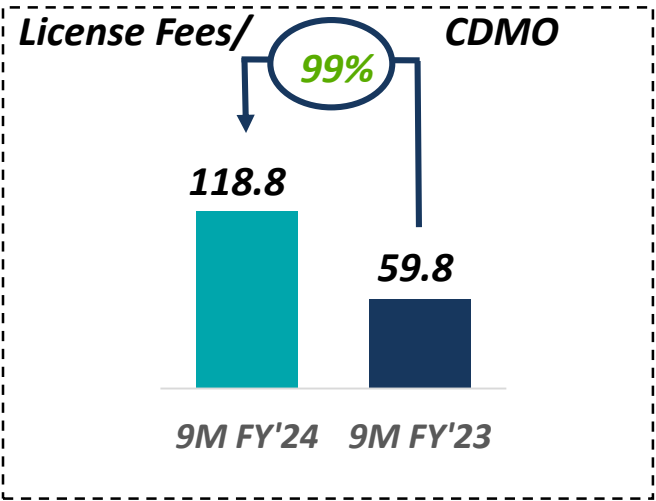
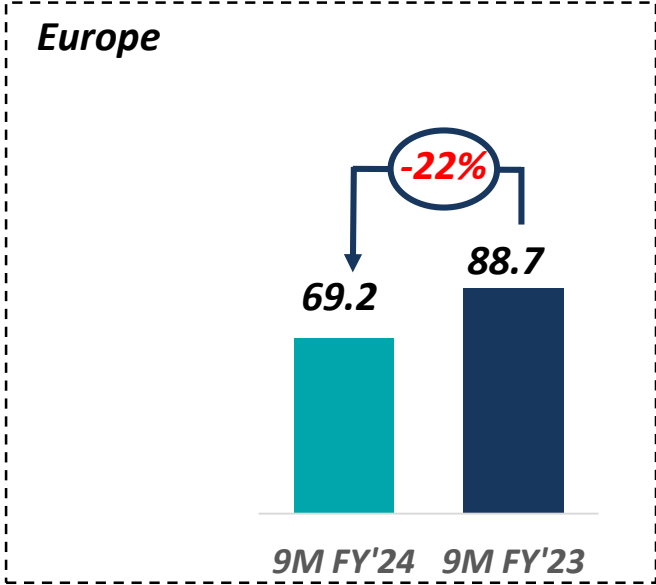
Domestic



Innovating for
affordable healthcare

Formulation Business-Highlights 9M FY'24

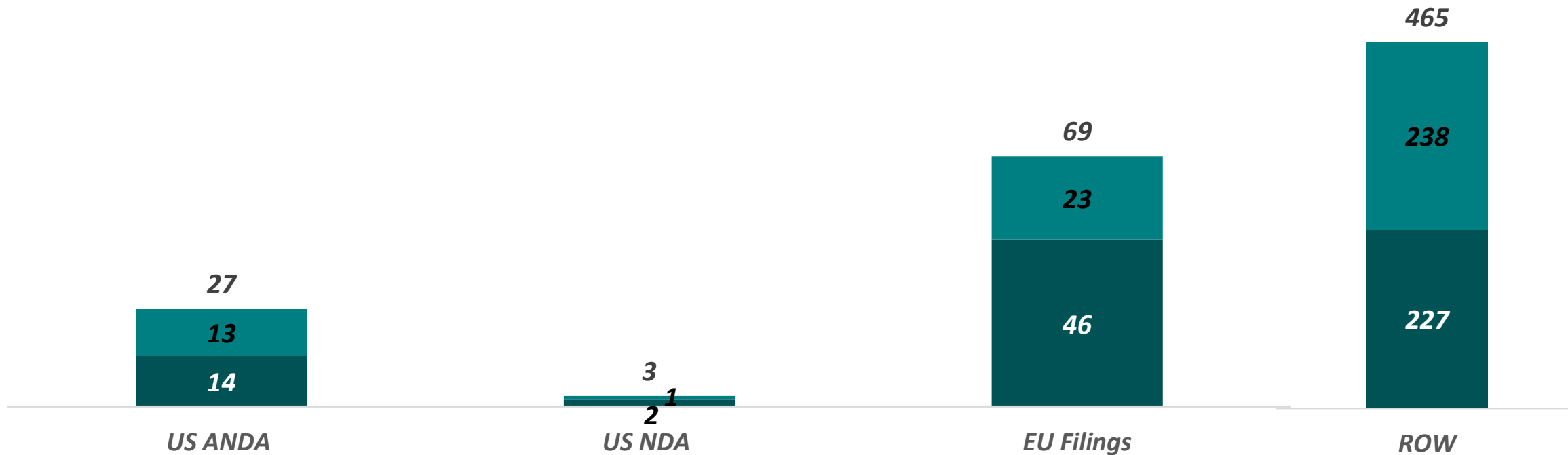
(INR in Cr.)



Regulatory Filings

Robust regulatory filings to strength the base for growth in the formulation segment

■ Approved ■ Pending



As on 31st December 2023



Annexures

Dharwad



- Biologicals Manufacturing plant & R&D Facility

Jadcherla Unit



- Formulations (Onco & Adjuvant Therapy of Onco – Injectable & Oral)

Bengaluru Unit



- TDS & ODF Manufacturing Facility & Formulation R&D

Hyderabad



- Formulations (Oral Dissolving Films)
- Bio Analytical Lab, Pharmacovigilance Lab & Quality control lab

Raichur Unit I & II



- API (Oncology – Non-Oncology)
- API (Oncology – Non-Oncology) and R&D API
- CRAMS
- Peptide
- Polymer

Ahmedabad



- CRO & CDMO
- R&D Formulation

Shilpa Medicare Limited (SML) started its operations as API manufacturer way back in 1989 at Raichur, Karnataka-India. Today Shilpa Medicare Limited is a global brand in manufacturing and supplying of affordable API and Formulation globally in different regulated markets.

Shilpa Medicare has been on path of expansion ever since its inception. With a regulatory recognized manufacturing set up and excellent scientific expert team in place, Shilpa Medicare has since been on a steady growth path. Currently they are one of the leaders in the Oncology market and offer a complete range of products in this segment spanning across APIs, formulations both in terms of R&D and manufacturing capabilities. Further to consolidate in field of Oncology, API and formulations, they are striving to put in efforts in field of novel drug delivery systems and biotech products along with widening their focus to other therapy areas. Where Shilpa Medicare Ltd is today is the result of their constant endeavors for more than three decades.



Dilip Kankani



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Thank You