

Shilpa Medicare Limited

Corporate & Admin Office:

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CIN: L85110KA1987PLC008739

11 August 2023

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: <u>Investor Presentation of the Company for the Quarter ended 30 June 2023</u>

Ref: <u>Disclosure under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements)</u>

Regulations, 2015

With reference to the captioned subject, the Investor Presentation of the Company for the Quarter ended 30 June 2023 with regard to Business highlights, financial performance and other updates is attached herewith for your consideration.

We request you to take the same on record and disseminate it to stakeholders of the Company.

Thanking you.

Yours faithfully,
For **Shilpa Medicare Limited**

Ritu Tiwary
Company Secretary & Compliance Officer



Shilpa Medicare Limited (SML)

Q1 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





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Company Overview

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

Affordable & Effective Pharmaceutical Solutions

Robust research orientation resulting in innovative products



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

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





Managing Director's Message

Commenting on Q1 FY'24 performance, Mr. Vishnukant Bhutada, Managing Director Shilpa Medicare Limited said

"I am pleased to inform you that our relentless efforts on bringing operational efficiencies and strengthening our business has resulted in us bouncing back to profitability this quarter.

On the back of the introduction of **Pemetrexed RTU** in EU market, we are preparing to launch the product in the US market in collaboration with our partner. Backed by an attractive portfolio we are gearing to scale up engagements through other notable products, which is visible in the licensing revenues that we are able to generate for our portfolio. **Complex product like Nilotinib filing** in the European market is a step in that direction.

Our CDMO business has been receiving positive responses from customers. Additionally, we are exploring the non-oncology API segment, which has high growth potential or can serve as an import substitute API. We are committed to facilitating the successful introduction of novel products within APIs and Formulations, ensuring predictable cash flows. Our new product offerings are on the brink of making tangible contributions through product commercialization; where we expect significant contribution to augment our overall margin profile. As previously mentioned, we are actively streamlining R&D expenditures and expediting the monetization process. By concentrating our efforts there, we aim to consistently lower R&D costs, resulting in substantial savings that will positively impact our cash flow. Without affecting the niche product developments"

On biological front, we have secured marketing authorization for **High concentration Adalimumab** in India which is a crucial step into the realm of our biological offerings, aimed at enhancing patient comfort in treating Rheumatoid Arthritis. Piggybacking on India approval, our strategy extends to tapping into various international markets with this product. I am happy to inform you that we have also commenced phase 1 trials for **recombinant Albumin**, which is a pivotal move for this niche opportunity. Our large-scale fermenting facility is under erection and we expect the same to be completed before march 2024."

Formulation update - Oncology

- New Drug Application for Pemetrexed Injection 1000 mg/100 ml, 500 mg/50 ml & 100 mg/10 ml, Ready to Use formulation approved by US FDA
 - First NDA product approval under 505(b)(2) application
 - Unique formulation supplied as ready to use product solution
 - Administered intravenously without any further dilution with product being stable at room temperature
 - Product approval from a third party manufacturing site
 - Commercialization arrangement in place with Amneal Pharmaceuticals LLC for the US Market
 - Plan to launch under J code program by Q4 2023
 - US market size approximately USD 735.3 million according to IQVIA MAT Q1 2023
- Filed Nilotinib Capsules 50mg, 150mg and 200mg DCP procedure from RMS Germany
 - Product filled for Europe market
 - Tentative expected launch in Q2 2024
 - Partnered with two customers for the European market
 - EU market approximately USD 418 million according to IQVIA MAT Q1 2023 data
 - US Pivotal study ongoing



Formulation update – Non Oncology

Shilpa Medicare's SMLNUD07 enters into Phase III studies

- Received approval from CDSCO for proceeding further for Phase III studies of oral product SMLNUD07
- Phase III studies have been initiated for the indication of NAFLD (Non-alcoholic fatty liver disease)
- Tentative completion of the study Q2/Q3 2024
- About NAFLD
 - Most common liver disease and it is estimated to affect up to 15% 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)



Formulation update – Oral Films and Patches

- First partnership deal inked with a Europe based company for Transdermal Patch (SMLTDP08)
 - Product Development completed and pilot studies have also been completed
 - Pivotal studies are planned in Q2/Q3 2023
 - Filed for EMA scientific advice for its skin irritation study, post approval the study shall be conducted
 - Product has been partnered with a MNC for Europe and Emerging markets
 - According to IQVIA MAT Q1 2023 data, the EU market is approximately USD 243 Million
- Launched dietary supplements/ OTC products portfolio in the USA market through a marketing partner
 - Products available in USA market on store (Walmart) as well as online shopping (Amazon)
 - Vitamin D3 Quick Dissolving Oral Strips Dietary Supplement
 - Melatonin Quick Dissolving Oral Strips . Dietary Supplement
 - Methyl Cobalamin (Vitamin B12) Quick Dissolving Oral Strips Dietary Supplement
 - Simethicone Quick Dissolving Oral Strips OTC
 - Green Tea Dissolvable Strips to Drink Dietary Supplement



Biosimilar update

Approval of High Concentration Adalimumab injection in India market

- Received the Marketing Authorization permission for Adalimumab 40 mg/0.4mL injection in prefilled syringe (PFS), a biosimilar of Adalimumab higher concentration formulation (100mg/mL) in India
- Used for the treatment of Rheumatoid Arthritis (moderate to severe active RA & severe active and progressive RA) for which the phase 3 clinical trial have been successfully completed in Q3 2022
- Results in increased patient comfort based on reduced injection volume
- Planned launch in Q2 2023
- Signed licence agreement with one big Indian company for commercialization in India along with own brand

Recombinant Albumin

- Phase I initiated for the product
- Product has been granted NBE (New Biological Entity) status

Aflibercept

- Phase III approval received from CDSCO and plan to initiate a Phase 3 clinical trial, marking a significant milestone in the development
- Pivotal trial is a crucial step towards advancing our commitment to delivering safe and effective solutions for various eye conditions



Financial Performance

Financial Performance – SML Standalone

Particulars	Q1 FY24	Q4 FY23	% change	Q1 FY23	% change
Revenues	104.5	86.8	20%	73.5	42%
Gross Margin	85.1	61.5	38%	63.9	33%
Gross Margin %	81%	71%		87%	
Employee Cost	27.8	26.3	6%	27.9	-1%
Other Expenses	21.2	28.7	-26%	18.9	12%
EBITDA	36.1	6.6		17.1	
EBITDA %	35%	8%		23%	
Finance Cost	6.7	6.6	2%	2.7	154%
Depreciation	12.3	12.0	2%	10.4	18%
PBT	17.1	-12.0		4.1	
Execeptional Item-(Income)/Exp	6.3	15.0		0.0	
PAT	7.9	-28.9		3.9	105%



Balance Sheet — SML Standalone

Particulars	30-Jun-23	31-Mar-23	30-Jun-22
Fixed Assets	598.3	608.9	613.1
Tangible Assets	509.1	517.0	541.2
Intangible Assets	89.2	92.0	71.9
Capital WIP	230.5	226.4	242.9
Tangible Assets	38.7	41.8	53.0
Intangible Assets	191.8	184.6	189.8
Slump Sale Consideration Receivable	249.0	316.0	486.3
Other Non-current Assets	1122.8	1047.0	900.7
Net Working Capital	233.8	242.1	244.8
Current Assets	300.7	314.4	315.1
Cash and cash equivalents	11.8	4.5	23.8
Current Liabilities	-78.7	-76.8	-94.1
Total Assets (Net)	2434.3	2440.5	2487.7
Equity	2125.3	2117.5	2175.0
Borrowings (Current & Non current)	271.8	287.4	260.3
Other Non Current Liabilities	37.2	35.6	52.3
Total Liabilities	2434.3	2440.5	2487.7



Financial Performance Consolidated

Particulars	Q1 FY24	Q4 FY23	% change	Q1 FY23	% change
Revenues	262.1	265.7	-1%	269.3	-3%
Gross Margin	174.2	176.3	-1%	165.3	5%
Gross Margin %	66%	66%		61%	
Employee Cost	72.9	72.4	1%	72.9	
Other Expenses	51.5	63.5	-19%	63.8	-19%
EBITDA	49.9	40.4	23%	28.6	74%
EBITDA %	19%	15%		11%	
Finance Cost	18.2	17.7	2%	9.6	89%
Depreciation	26.7	25.7	4%	22.4	19%
PBT	5.0	-3.0		-3.4	
PAT	1.2	-8.1		2.3	-49%



Balance Sheet Consolidated

	Consolidated			
Particulars	30-Jun-23	31-Mar-23	30-Jun-22	
Fixed Assets	1,371.6	1,368.3	1,372.9	
Tangible Assets	1,163.7	1,179.5	1,201.2	
Intangible Assets	208.0	188.9	171.6	
Capital WIP	657.0	655.3	515.3	
Tangible Assets	374.9	358.0	231.0	
Intangible Assets	282.2	297.3	284.3	
Other Non-current Assets	123.8	110.7	144.1	
Net Working Capital	459.6	492.0	614.7	
Current Assets	733.3	746.7	851.2	
Cash and cash equivalents	32.8	21.3	48.9	
Current Liabilities	-306.4	-276.0	-285.4	
Total Assets (Net)	2,612.0	2,626.6	2,646.9	
Equity	1,772.7	1,774.4	1,815.1	
Borrowings (Current & Non current)	789.0	795.7	755.0	
Other Non Current Liabilities	50.3	56.3	76.8	
Total Liabilities	2,612.0	2,626.6	2,646.9	



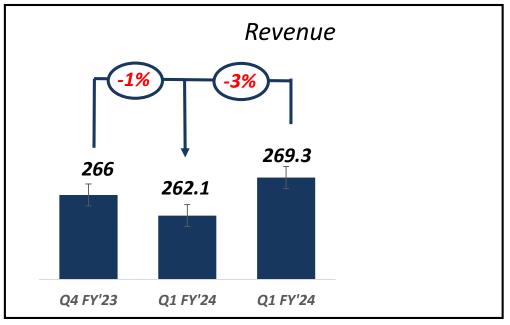
Business Highlights

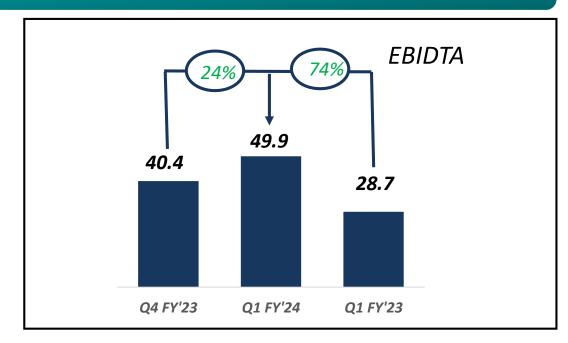
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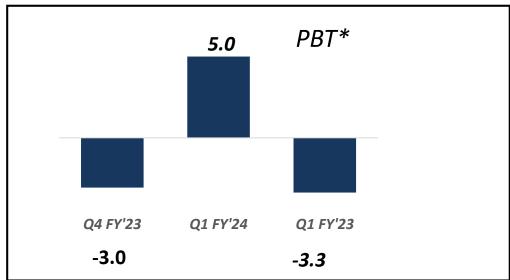
Q1 FY'24 Consolidated Performance

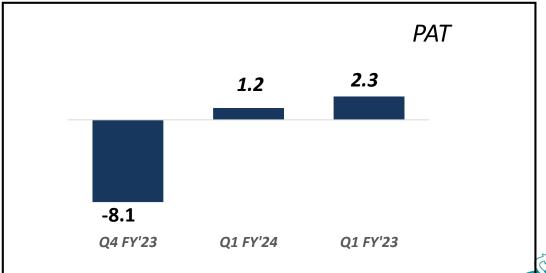


Innovating for affordable healthcare





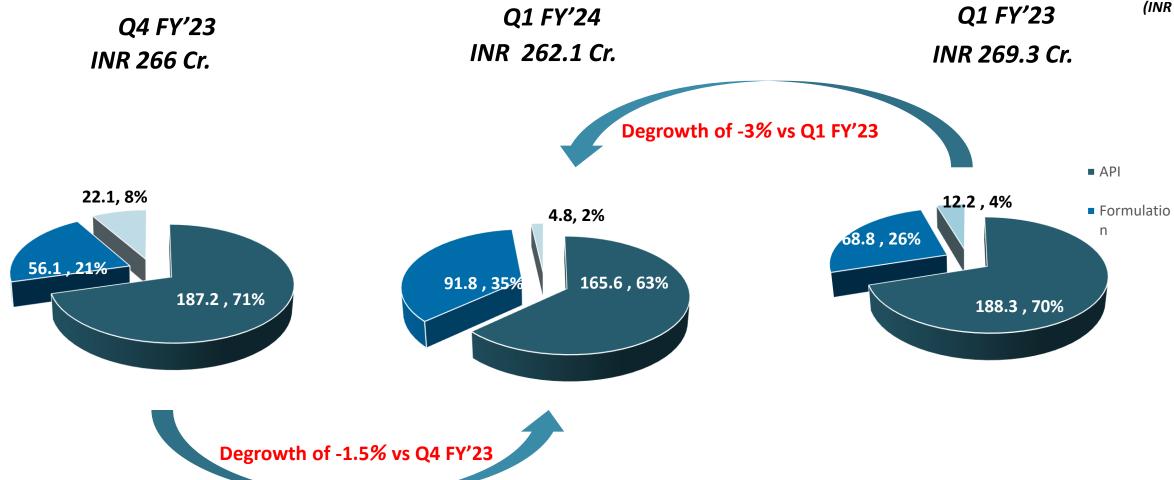




^{*}Before share of loss in associates/JV's

Consolidated Revenue Break-up – Q1 FY'24







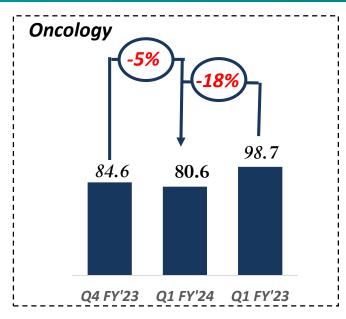
API Business

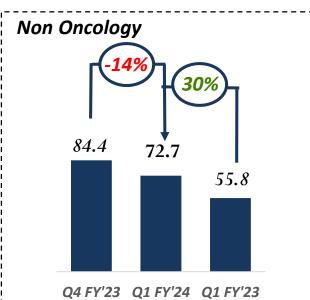


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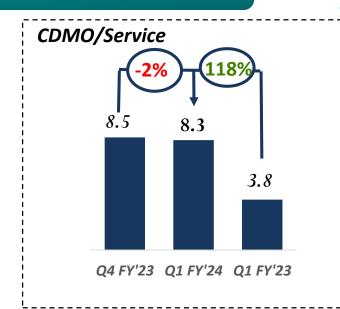
API Business-Highlights Q1 FY'24

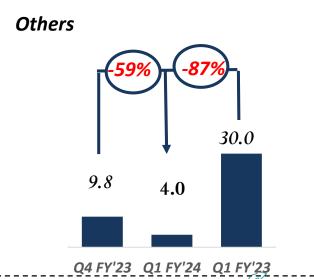










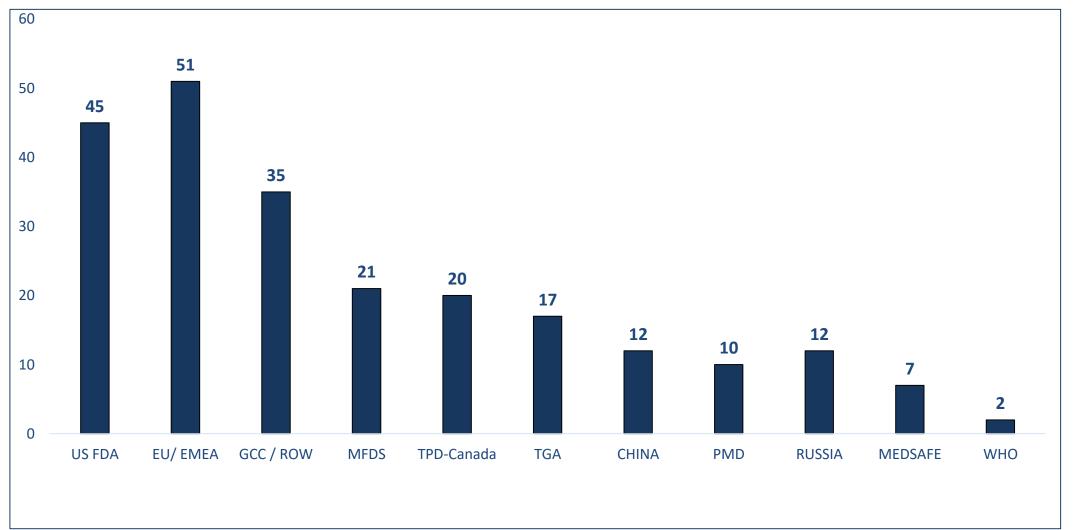


*Numbers are excluding captive consumptions



DMF Filing update

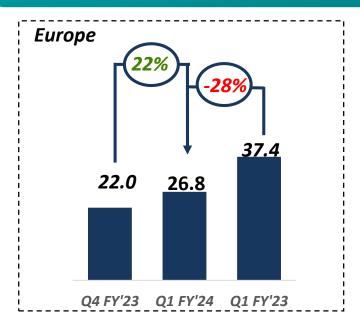
New product introduction and increase in geographical coverage replicated with **232** number of **DMF filings** done with major regulatory authorities

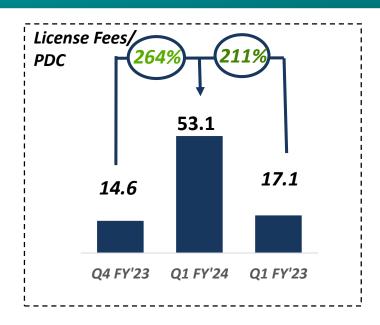


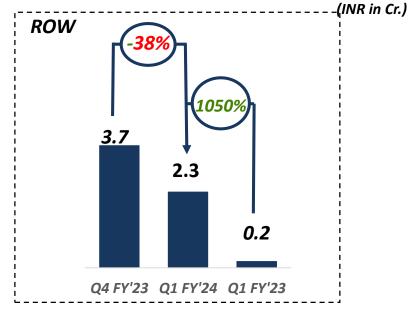
Formulation Business

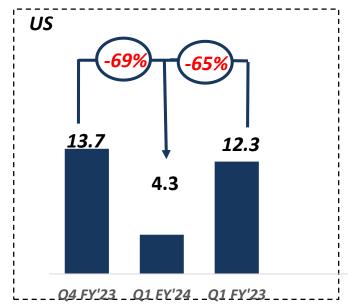


Formulation Business-Highlights Q1 FY'24

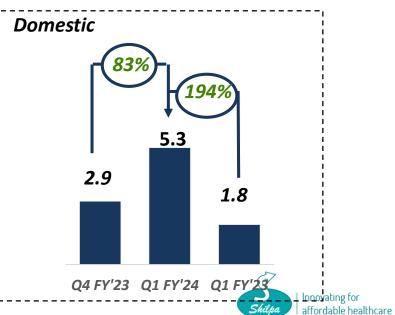








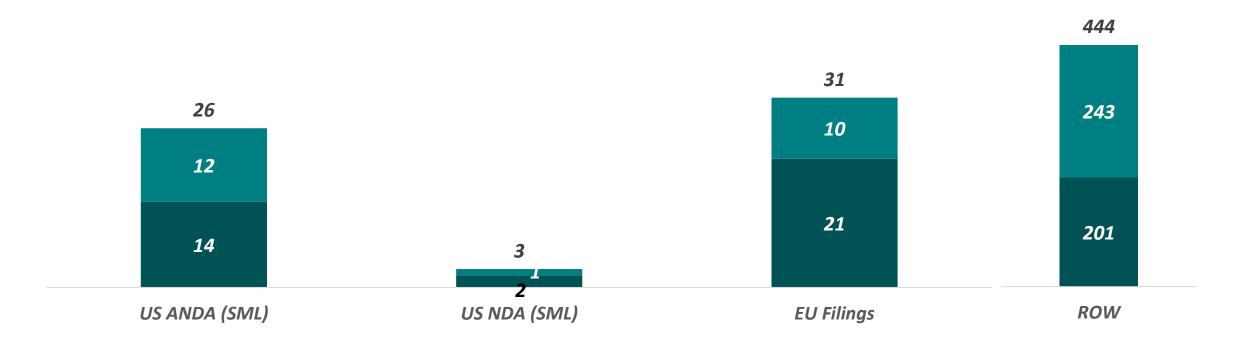




Regulatory Filings

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

■ Approved ■ Pending





Annexures

Manufacturing Excellence

Dharwad



 Biologicals Manufacturing plant & R&D Facility

Bengaluru Unit



 TDS & ODF Manufacturing Facility & Formulation R&D

Raichur Unit I & II



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

Jadcherla Unit



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

Hyderabad



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

Ahmedabad



- CRO & CDMO
- R&D Formulation



About Shilpa Medicare Ltd.

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.



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Thank You

